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Dear Colleagues:

At Pfizer, we are committed to upholding the highest standards when we interact with physicians, healthcare organizations, patients and other stakeholders. The [Orange Guide](#) (also known as the **Field Guide**) provides an overview of the laws, regulations, Pfizer policies and guidelines that govern our U.S. field colleagues in the human biopharmaceutical business. A revised edition of the Orange Guide is now available on PfieldNet. It is essential that you familiarize yourself with the Orange Guide.

Every colleague is accountable for understanding and meeting our company's compliance requirements. Do not hesitate to consult with your team attorney or the Orange Guide team at OrangeGuide@pfizer.com if you have any questions.

Thank you for your commitment to doing business with integrity and helping to build the trust and respect that are so critical to Pfizer's success.

A handwritten signature in blue ink, appearing to read "D. Lankler".

Douglas M. Lankler

A handwritten signature in black ink, appearing to read "Amy W. Schulman".

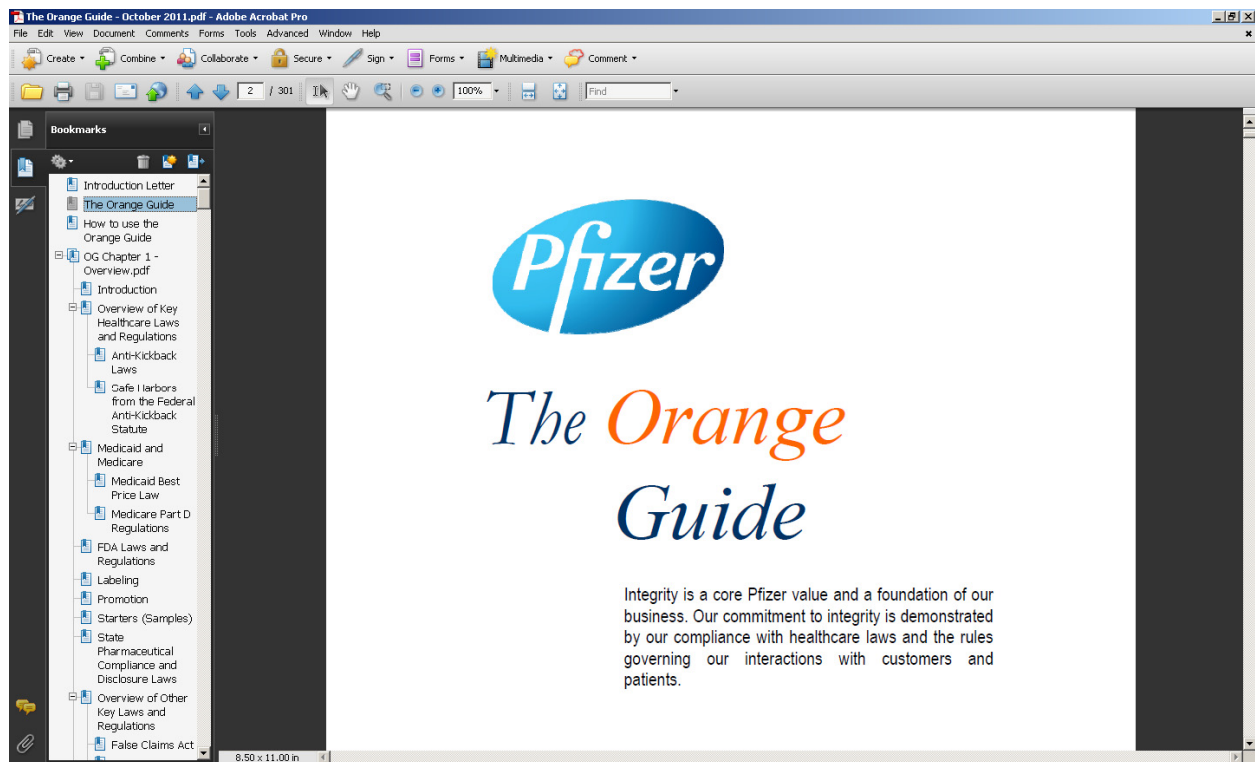
Amy W. Schulman



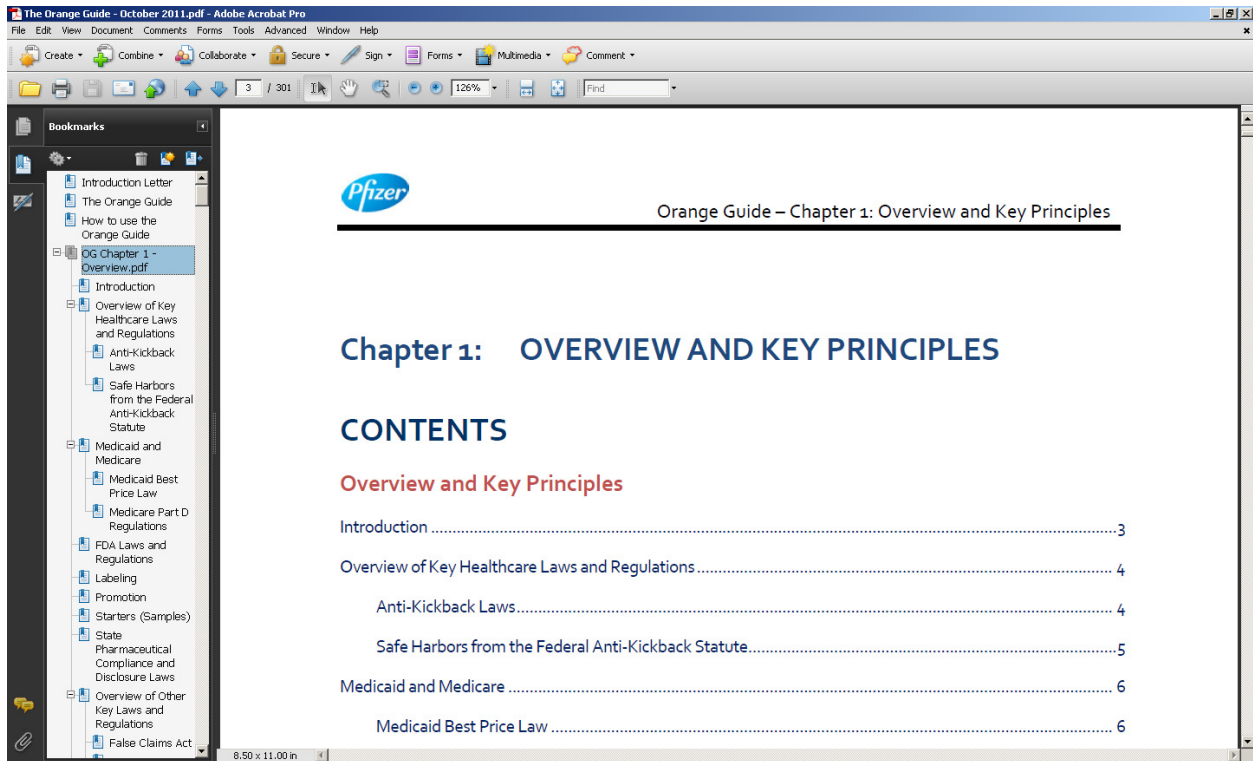
HOW TO USE THE ORANGE GUIDE

The **Orange Guide** is intended to serve as the main compliance resource for US-based Sales colleagues supporting Pfizer's biopharmaceutical business. In addition to stating the compliance rules on each covered **Orange Guide** topic, relevant Pfizer policies, Standard Operating Procedures (SOPs), as well as external laws, regulations, and guidances are cited and/or hyperlinked in the **Orange Guide**. You should consult the **Orange Guide** as your "one-stop shop" to stay knowledgeable about compliance rules pertinent to your day-to-day activities.

For ease of navigation, the Orange Guide is embedded with "bookmarks" for each chapter topic and subheading. When you are reviewing the Orange Guide, make sure you keep the "Bookmark" pane on the left side of the page open and accessible as shown below:



To expand the bookmarks for a chapter, simply click on the  and you will see the topics covered listed and accessible by hyperlinks as shown below.



If you have any questions, comments or feedback, please email OrangeGuide@pfizer.com. This will help us continuously improve the **Orange Guide** to help meet your needs!

Sincerely,

The Orange Guide Team



The Orange Guide

Integrity is a core Pfizer value and a foundation of our business. Our commitment to integrity is demonstrated by our compliance with healthcare laws and the rules governing our interactions with customers and patients.



Chapter 1: OVERVIEW AND KEY PRINCIPLES

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Chapter 1: OVERVIEW AND KEY PRINCIPLES

Introduction

Integrity is a core Pfizer value and a foundation of our business. Our commitment to integrity is demonstrated by our compliance with laws and the rules governing our business. Compliance with these laws builds trust with patients, healthcare professionals (HCPs), institutions, purchasers, and the government.

All Pfizer employees must have a general understanding of the laws, regulations, guidance, and industry codes that apply to our business, including:

Key Healthcare Laws	Other Key Laws	Industry Codes, Guidance and Our CIA
Anti-Kickback Laws (state and federal)	False Claims Act	PhRMA Code on Interactions with Healthcare Professionals
Medicaid Best Price Law & Medicare Part D Regulations	Privacy Laws	PhRMA Guiding Principles on Direct to Consumer Advertising
FDA Laws & Regulations	State Consumer Protection Laws	OIG Compliance Program Guidance for Pharmaceutical Manufacturers
State Pharmaceutical Compliance and Disclosure Laws	Foreign Corrupt Practices Act	Pfizer's Corporate Integrity Agreement



Anti-Kickback Laws: Prohibit improper influence on healthcare decisions by making it a crime to knowingly and willfully give or receive anything of value in order to influence or obtain government healthcare business.

Best Price Law: Prohibits charging Medicaid more than the lowest price (i.e., “best price”) at which Pfizer offers a product to any other customer. Pfizer must calculate and report to the federal government our “best price” for each product.

False Claims Act: Prohibits making or inducing someone else to make a false claim for reimbursement from the federal government.

This Chapter provides an overview of some of the key laws, regulations, guidance, and industry codes that apply to our business. The policies contained in this Guide are designed to ensure that your activities comply with these laws, regulations, guidance, industry codes, and our CIA.

Non-compliance with these policies can subject Pfizer colleagues to disciplinary action up to and including termination. Further, improper activities that violate one or more of these laws and regulations could result in civil and criminal penalties for you and the Company.

If the application of any policy is unclear to you, discuss the issue with your manager or team attorney.

Overview of Key Healthcare Laws and Regulations

Anti-Kickback Laws

An HCP’s treatment decision should not be tainted by motives of personal gain or enrichment. The anti-kickback laws seek to prohibit improper influences on healthcare decisions by making it a criminal and/or civil offense to knowingly and willfully give or receive anything of value in order to influence or obtain government healthcare business. These laws prohibit payments intended to induce someone to purchase, prescribe, endorse or recommend a product that is reimbursed under federal or state healthcare programs. For example, the anti-kickback laws prohibit such activities as:

- Providing a gift to an HCP (including a pharmacist) to influence the prescribing, dispensing, or recommending of pharmaceutical products;
- Providing a gift to a retail or wholesale customer to influence the purchase of pharmaceutical products;



- Providing an educational or research grant to a managed care organization to influence the formulary position of a product; and
- Paying for the services (e.g., consulting services) of an HCP or other customer at a fee above the reasonable, **fair market value** for such services.

Fair Market Value: Price at which an asset or service passes from a willing seller to a willing buyer based on market demand and supply. Pfizer is required to pay HCPs fair market value compensation for speaking and consulting services.

Pfizer treats all HCPs and other customers as if they are subject to the anti-kickback laws, even though they may not participate in government programs.

Safe Harbors from the Federal Anti-Kickback Statute

The federal anti-kickback statute is so broad that, if read literally, it could restrict many otherwise legitimate marketing activities and even some non-promotional activities. Recognizing this, the U.S. Department of Health and Human Services (**HHS**), Office of Inspector General (**OIG**) has defined certain “safe harbors.” Activities that fall entirely within a safe harbor, such as legitimate service arrangements, do not violate the anti-kickback statute.

HHS: Federal administrative agency that oversees Medicaid, Medicare and other federally funded healthcare programs.

OIG: A legal department within HHS charged with enforcing federal healthcare laws and regulations and negotiating and overseeing Corporate Integrity Agreements.

A number of safe harbors are relevant to our business activities, but three are especially important:

- **Discount safe harbor:** allows Pfizer to discount the price of a product to make it competitive with other products, provided that the discount is properly reported to the government and complies with other safe harbor requirements.
- **Managed Care safe harbor:** permits Pfizer to provide a wide array of discounted items or services to certain eligible managed care organizations under specified circumstances.
- **Personal Services safe harbor:** protects legitimate service arrangements with healthcare professionals, such as consulting or speaking agreements. Compliance with this safe harbor

requires, among other things, a written agreement and compensation determined in advance and on a fair market value basis.

Medicaid and Medicare

Federal healthcare programs, such as Medicaid and Medicare, are large purchasers of prescription drug products. Under Medicaid, the government has traditionally covered the cost of prescription medicines for low income and disabled patients. In contrast, Medicare historically only covered the cost of prescription medicines that were dispensed to eligible senior citizens in a doctor's office or institutional setting. In 2006, Medicare coverage was expanded to include prescription medicines purchased by eligible senior citizens through a pharmacy. The government's increased role as a purchaser of pharmaceuticals has heightened its attention to certain federal laws, including the False Claims Act (further described below), to ensure that entities are not submitting false claims to the government for reimbursement.

Medicaid Best Price Law

Under federal law, Medicaid is entitled to quarterly rebates based on the lowest price a pharmaceutical company offers on a product to any customer. This is generally referred to as the "best price" for the product. Pfizer is responsible for calculating and reporting to the federal government the metrics that are utilized to calculate these rebates.

A failure to accurately account for discounts or other price concessions could result in inaccurate price reporting to the federal government. This could occur if, for example, Pfizer improperly provides money to a managed care or retail customer, such as through an educational grant that was structured outside of a safe harbor or by paying more than fair market value at a pharmacy trade show, in order to reduce the net cost of the Pfizer products that organization purchases. If this occurs, Medicaid could end up paying more for the Pfizer products than the managed care or retail customer, which could violate the Medicaid Best Price Law. Violating this law could result in a company having to pay significant penalties and being subjected to operating restrictions. For more information on issues pertaining to discounting and price reporting, see Orange Guide Chapter 12: Contracting and White Guide Chapter 6: Government Health Care Programs.

Medicare Part D Regulations

The Medicare program provides a drug benefit to Medicare beneficiaries through Medicare “Part D.” There are two types of Medicare health plans. “Medicare Advantage Prescription Drug” plans (also called “MA-PD” plans) provide both medical coverage (for hospital and physician charges) as well as drug coverage. Alternatively, stand-alone “Prescription Drug Plans” (also called “PDPs”) only provide drug coverage. Beneficiaries who enroll in PDPs can still receive broader medical coverage through Medicare.

MA-PDs and PDPs are private health plans which contract with the Centers for Medicare and Medicaid Services (CMS), the federal agency that administers Medicare and Medicaid. CMS regulates these health plans closely and has become increasingly vigilant in monitoring their interactions with manufacturers. In particular, CMS has expressed concern that Medicare health plans not be overcharged for prescription drugs, and that all formulary placement and prescribing decisions be made based on appropriate considerations. As a result, MA-PDs and PDPs are required to report their costs to the government, and in so doing, must disclose any “direct or indirect remuneration” which they receive from pharmaceutical companies. Accordingly, Pfizer should be vigilant in monitoring the payments that it makes to MA-PDs and PDPs, as well as in its general relationship with these plans.

FDA Laws and Regulations

The Food and Drug Administration (**FDA**) regulates almost every aspect of our business, from research and development to sales and marketing. FDA regulation of product advertising and promotion directly affects our customer relationships. Therefore, all colleagues must understand the basic rules we must follow to ensure compliance with FDA laws and regulations.

FDA: A federal agency responsible for the safety regulation of most foods, dietary supplements, drugs, vaccines, biological medical products, blood products, medical devices, radiation-emitting devices, veterinary products, and cosmetics.

Labeling

The FDA strictly regulates the **labeling** of all prescription drug products that Pfizer markets in the United States.

Labeling: Includes all information on a drug's package or label, prescribing information contained in the package insert, and any other written, printed or graphic material provided about a drug.

Promotion

Any materials (whether in print or electronic form) used to promote our products – including all visual aids, brochures, journal advertising, promotional programs and other sales aids – may include only those claims about the product that are consistent with that product's labeling. In addition, these materials must contain balanced statements about the product's benefits and safety risks. All promotional materials must also include the product's package insert or, for certain advertisements, a brief summary relating to side effects, contraindications, and effectiveness.

With respect to interactions involving the promotion of Pfizer products, Sales Colleagues must adhere to the policies set forth in the Orange Guide Chapter 2: Detailing to HCPs, and all other colleagues must adhere to the policies set forth in White Guide Chapter 2: Advertising and Promotional Materials and White Guide Chapter 3: Promotional Interactions with Healthcare Professionals.

Starters (Samples)

The Prescription Drug Marketing Act of 1987 (PDMA) prohibits the sale, purchase or trade of drug samples (called "starters" at Pfizer). It is illegal for a physician to sell (or seek reimbursement for) a free sample. Individuals who engage in or encourage such conduct are subject to criminal prosecution. Drug samples could be considered "remuneration" under the anti-kickback laws if given to an HCP for the wrong reason. Starters should never be distributed to personally benefit an HCP or to induce an HCP to prescribe our products, as prescription decisions should be based solely on patient need.

In addition, several states have laws that affect whether and to whom starters may be distributed. For example, some states have particular limitations on distributing starters for controlled substances and some have requirements on when starters that were lost or stolen must be reported. Moreover, states

have various approaches to which HCPs (e.g., nurse practitioners, physician assistants) may prescribe drugs and therefore are authorized to accept starters. For more information on how to develop a compliant starter strategy, see the Starters Chapter.

State Pharmaceutical Compliance and Disclosure Laws

In addition to the federal government, a growing number of states are regulating pharmaceutical companies' interactions with HCPs. These regulations include restrictions and sometimes prohibitions on gifts and meals, disclosure of payments made to HCPs, and reporting of data such as Average Manufacturing Price and "best price." Some of these restrictions may even extend to interactions that occur outside of the geographic boundaries of the state that enacted the regulation.

For more information on whether your activities are implicated by state pharmaceutical compliance and disclosure laws, see the Chapter on State Laws: HCP and State Employee Restrictions and the Chapter on Meals, Educational Items, and HCP Payment Disclosure.

Overview of Other Key Laws and Regulations

False Claims Act

The False Claims Act (FCA) prohibits entities and individuals from submitting, or inducing another to submit, a false claim for reimbursement from the federal government. For example, the federal government has used the FCA to investigate and prosecute pharmaceutical companies for falsely reporting best price, paying kickbacks to healthcare providers, and encouraging physicians to seek reimbursement from the government for free samples of prescription drug products.

The government also has utilized the FCA to combat instances of off-label promotion. Under this reasoning, when a pharmaceutical company engages in off-label marketing, the company puts into motion a series of events in which a prescription will be reimbursed by a government program even though it was not eligible for reimbursement (e.g., physician writes a prescription for an off-label use, pharmacist fills the prescription, pharmacist then seeks reimbursement for the off-label prescription). In so doing, it has been argued by the government that the pharmaceutical company has "induced" another party to submit a false claim, resulting in a violation by the pharmaceutical company. Sales

Colleagues must ensure that all HCP interactions comply with Orange Guide Chapter 2: Detailing to HCPs. All other colleagues must ensure that marketing materials and other commercial activities comply with White Guide Chapter 2: Advertising and Promotional Materials and White Guide Chapter 3: Promotional Interactions with Healthcare Professionals.

Privacy Laws

Pfizer and firms engaged by us to perform various services (e.g., advertising and promotion agencies and other vendors) might collect and process various types of personal healthcare data, and colleagues may encounter sensitive personal information in the course of their visits to meet with HCPs. Colleagues are responsible for ensuring that the data is handled carefully and in compliance with Pfizer’s policies and applicable federal and state privacy laws and regulations.

For more information about your obligations to maintain patient privacy, see the Privacy: Protecting Personal Information Chapter.

State Consumer Protection Laws

Many states have laws that seek to protect consumers from inappropriate marketing and sales practices. For example, virtually all states have broad laws prohibiting “unfair” or “deceptive” trade practices. Some state Attorneys General contend that state consumer protection laws encompass off-label promotion. You should direct any questions regarding state consumer protection laws and their impact on your activities to your team attorney.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act (FCPA) is a federal law that prohibits corrupt or improper payments to government officials outside the U.S. The FCPA consists of two primary sections: (1) the anti-bribery provision; and (2) the record keeping provision. Violations of the FCPA may subject Pfizer and its individual employees to criminal and civil penalties. The anti-bribery section of the FCPA prohibits U.S.-based companies from offering, paying, promising to pay or authorizing payment of anything of value to a foreign official with the intent of influencing the official or gaining improper advantage. The statute broadly includes “anything of value,” which consists of cash payments, gifts, meals or any other

item that may have value to the recipient. Further, the definition of foreign official includes any officer or employee of a foreign government (any department, agency or instrumentality) or public international organization. HCPs at government-owned hospitals, for example, may qualify as foreign officials under the FCPA. Under the record keeping requirements of the FCPA, Pfizer and its employees must “keep books, records and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets... and maintain a system of internal accounting controls...”

Pfizer colleagues that are permitted to engage a non-U.S. HCP as a consultant (or enter into any other interaction in which a payment or other benefit may be given to the individual), must follow the Pfizer FCPA procedures applicable to their Division. For more information, see White Guide Chapter 5: HCP and Government Official Consulting Engagements.

Industry Codes, Guidance and Our CIA

PhRMA Code

The Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals (PhRMA Code) was developed and adopted by many of the country’s leading research-based pharmaceutical and biotechnology companies. It applies to relationships with physicians and other HCPs. Pfizer is committed to following its principles.

The PhRMA Code is intended to protect patients from undue influences on healthcare decision-making and reaffirms that interactions between company representatives and HCPs should be focused on informing HCPs about the benefits and risks of medicines to help enhance patient care. The PhRMA Code principles are embedded in the policies throughout this Guide.

The PhRMA Code, as well as updated Frequently Asked Questions, can be viewed by Sales Colleagues on PfieldNet at <http://pfieldnet.pfizer.com/Pages/Welcome.aspx> under the Compliance Tab and by other colleagues on OpSource at <http://opsource.pfizer.com/Pages/PhRMAHCPHome.aspx>.

PhRMA Guiding Principles – Direct To Consumer Advertisements About Prescription Medicines

In 2009, PhRMA adopted its updated [Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines](#). These Principles guide the industry's use of Direct to Consumer (DTC) advertising to communicate information about disease states and potential treatments so that patients can make informed choices. PhRMA's Guiding DTC Principles go beyond legal obligations to set forth a method of communicating that will enable DTC communications to serve to educate patients and consumers and encourage them to seek guidance from their healthcare professionals. Pfizer has adopted its [Guidance for the Implementation of the Updated PhRMA DTC Principles](#). When developing DTC advertising, Marketing Colleagues must adhere to the policies set forth in White Guide Chapter 2: Advertising and Promotional Materials.

OIG Compliance Program Guidance for Pharmaceutical Manufacturers

In 2003, the OIG issued its [Compliance Program Guidance for Pharmaceutical Manufacturers](#), which sets forth its general views on the value and fundamental principles of compliance programs for pharmaceutical companies and the specific elements that pharmaceutical companies should consider when developing and implementing an effective compliance program. The Guidance states the following seven elements are recognized as fundamental to an effective compliance program: (1) Implementing written policies and procedures; (2) Designating a compliance officer and compliance committee; (3) Conducting effective training and education; (4) Developing effective lines of communication; (5) Conducting internal monitoring and auditing; (6) Enforcing standards through well-publicized disciplinary guidelines; and (7) Responding promptly to detected problems and undertaking corrective action. All seven elements are embedded in Pfizer's compliance program.

Pfizer's Corporate Integrity Agreements

A **Corporate Integrity Agreement (CIA)** is a written agreement with the OIG that typically imposes upon a company certain integrity obligations (e.g., training, reporting or audits) for a specified period of time, generally five years from the date the CIA is executed.



Pfizer has entered into three CIAs as part of three settlements for alleged violations of federal healthcare program requirements.

- **Lipitor CIA (2002):** In 2002, Pfizer paid a \$49 million fine and entered into a CIA for a term of five years. The case involved a *qui tam* (whistleblower) suit filed by a Warner-Lambert employee alleging that Pfizer provided \$250,000 in undisclosed cash discounts (concealed as “unrestricted educational grants”) to a managed care customer to get Lipitor on the plan’s formulary. The government alleged that Pfizer underpaid Medicaid rebates as a result of failing to properly calculate the “best price” for Lipitor.
- **Neurontin CIA (2004):** In 2004, Pfizer paid a \$429 million fine and entered into its second five-year CIA. The case was also based upon a whistleblower suit filed by a former Warner-Lambert employee alleging that Pfizer had engaged in off-label marketing to promote Neurontin.
- **Bextra CIA (2009):** In 2009, Pfizer entered into a five-year CIA as part of its settlement for alleged violations of federal health care program requirements. As part of the settlement, Pfizer paid \$2.3 billion in fines. The case originated with eleven separate whistleblower lawsuits that included allegations that Pfizer promoted Bextra for uses and in dosages that the FDA did not approve. The CIA also settled alleged off-label promotional activities concerning several other Pfizer products.

Under the 2009 CIA, Pfizer must annually report specific information to the OIG through December 31, 2014. Some of the CIA requirements are new, while others reflect policies that Pfizer already had in place. Our obligations under the CIA include: (i) providing annual compliance training to most U.S. personnel; (ii) disclosing activities by colleagues that are non-compliant with healthcare laws; (iii) hiring an Independent Review Organization (IRO) to conduct annual reviews of certain Pfizer systems, policies and processes; (iv) expanding certain transparency initiatives (such as posting payments to HCPs); and (v) certain Field Force and Headquarters monitoring activities.

Violations and Penalties

The OIG, the U.S. Department of Justice, the FDA, and state Attorneys General aggressively enforce the anti-kickback and other laws and regulations discussed in this Overview. In addition to violating our



obligations under the existing CIA, any violation of law is subject to prosecution and potentially punishable by a fine and/or imprisonment, as well as civil monetary penalties. Conviction under these laws can also result in Pfizer’s exclusion from participation in federal and state healthcare programs, as well as imprisonment of officers and/or employees responsible for each violation.

Failure to adhere to FDA advertising and promotion regulation, in particular, can result in a requirement to run corrective advertising or “pre-clear” future promotional materials. Violations of the PDMA, which can include failing to follow starter management requirements, may result in criminal sanctions, including imprisonment.

Pfizer Compliance Program

Pfizer takes compliance with these laws and regulations very seriously and expects every colleague to do the same. Taking compliance seriously includes taking prompt action to disclose potential violations and cooperating with investigations of possible violations. Each colleague has a **Duty to Act** by reporting suspected compliance violations to Pfizer Human Resources, Legal, or to the **Compliance Division via the Compliance Helpline (1-866-866-7349) or via e-mail at corporate.compliance@pfizer.com**. In addition, Pfizer prohibits colleagues participating in compliance investigations from discussing the investigation with anyone other than Human Resources or Pfizer legal representatives. This maintains the integrity of the process and assures fairness to all colleagues. Failure to maintain confidentiality and/or failure to act may result in disciplinary action up to and including termination.

Duty to Act: If you reasonably believe that an employee has violated the law or Pfizer policy, you have a duty to report that information immediately to your supervisor, Human Resources, Legal, or the Compliance Division. Pfizer has open door, anti-retaliation and confidentiality policies to encourage and protect all Pfizer colleagues who raise valid concerns.

FOR MORE INFORMATION

- Colleagues must be familiar with and abide by all of the policies and guidance in this Guide.
- Questions may be referred to your manager or team attorney.

Chapter 2: DETAILING TO HCPs

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Chapter 2: DETAILING TO HCPs

Introduction

Your promotional interactions with healthcare professionals (HCPs) are essential to Pfizer's success. Therefore, your interactions with HCPs (aka "customers") must always focus on providing accurate, on-label, balanced information about our products.

For purposes of this Chapter, HCP is defined broadly as any individual who directly interacts with patients or has a role in patient diagnosis or treatment. It includes nurses, nurse practitioners, physicians, and pharmacists. It also may include individuals who do not work directly with patients but have influence over the recommendation, purchase, or prescribing of Pfizer products, such as health plan administrators, organized customer administrators (i.e., "C-suite" administrators), Pharmacy & Therapeutics Committee members, and Formulary Committee members who do not see patients. However, note that the definition of an HCP may differ in certain contexts, including, for example, how states define HCPs in the context of applicable state laws.

For information on interactions with consumers and employees, please see Orange Guide Chapter 16: Consumer and Employee Interactions. Also, please see Orange Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure for information on providing meals to HCPs. For guidance specific to interactions involving Greenstone and Pfizer Injectables Colleagues, see Orange Guide Chapter 19: Sales Activities: Greenstone and Pfizer Injectables.

Non-compliance with these policies can subject Pfizer colleagues to disciplinary actions up to and including termination. Further, improper activities that violate one or more of these laws and regulations could result in criminal and civil penalties for you and the company.

If the application of any policy is unclear to you discuss the issue with your manager or your team attorney.

Key Points to Ensure Compliance

- Use only RC-approved materials. Do not use materials that you have created or altered in any way.
- All statements must be on-label (consistent with the product's package insert) and truthful and not misleading. Only use selling statements that are consistent with RC-approved materials and guidance (including any product Implementation Guide(s)).
- All items provided to HCPs must be RC-approved.
- Always give a fair and balanced presentation of the benefits and risks of a product.
- All inquiries about off-label information or unapproved clinical data must be unsolicited and referred to Pfizer Medical Information using the iCUE tablet.
- Colleagues on iCUE are expected to utilize materials on the tablet whenever possible when engaging in detailing.
- Only discuss approved products and indications. Do not discuss new products or indications until you have received RC-approved promotional materials and messaging.
- Do not detail, provide a meal or starter, invite to a speaker program or otherwise promote a product to an HCP that belongs to an excluded specialty for the specified product. Consult PfieldNet or the iCUE Product Exclusion Guide for additional guidance.
- Never engage in any actual or perceived quid pro quo.
- Follow the provisions set forth in Orange Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure when providing meals or other food or beverage items to HCPs.
- Remember to comply with all applicable State Laws when providing meals or educational items to HCPs as discussed in Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions.
- Treat employer representatives and administrators at organized customers as if they are HCPs when engaging in promotion and detailing activities.

Core Compliance Principles for Successful Product Promotion

Your interactions with HCPs must always be based on providing accurate information. Pfizer has four Core Compliance Principles that protect you and the Company when you are promoting products to HCPs:

- Use Only RC-Approved Materials and Selling Statements
- Stay On-Label and Discuss Only Approved Products and Indications
- Provide an Accurate and Balanced Presentation
- Never Engage in Actual or Perceived Quid Pro Quo

Use Only RC-Approved Materials and Selling Statements

Using RC-Approved Materials in Details

Pfizer is generally responsible for anything that you say or show to customers. Federal law requires that Pfizer file all promotional materials with the FDA prior to use with any customer. The guidance below must be followed when presenting information to customers and/or engaging in detailing:

- Show only materials that have been approved for detailing by the Review Committee. Colleagues are prohibited from altering these materials in any way.
- If promotional material is not available for ordering through Pfizer's on-line ordering system (PROMOS) or not available on iCUE, it is not approved for use with customers.
- Colleagues on iCUE are expected to utilize materials on the tablet whenever possible when engaging in detailing. When using materials on iCUE, you are using materials that are up to date, compliant and RC-approved.
- "Do Not Detail" pieces or background materials must not be disclosed to customers.

Each Pfizer product has an Asset Team which creates promotional materials and messaging for that product. These materials and messaging are reviewed and approved by a Review Committee (RC) that includes a cross-disciplinary group of colleagues from Marketing, Medical, Regulatory Affairs and Legal.

Key Points: Permitted vs. Prohibited Activities	
Permitted	Prohibited
Using promotional materials that have been approved by the relevant RC	Showing a chart that you put together based on two RC-approved pieces Using any unapproved item as a visual aid to illustrate a point or concept (e.g., pill bottles, money, food, candy)
Marking a training copy of your clinical reprint (that you don't show to HCPs) to help you learn key points Using the highlighting function in iCUE as appropriate	Showing an HCP any promotional material that has been marked or altered in any way (e.g., no highlighting outside of the iCUE functionality, and no sticky notes, handwritten notes, check marks, arrows, etc.)
Leaving a handwritten thank you note that includes the name of the product but does not make any direct or indirect product claim	Leaving a thank you note that contains more than the name of a product, including any direct or indirect product claim (e.g., mentioning indications or disease state information)
Using Pfizer training materials and other "Do Not Detail" pieces for your education only	Showing Pfizer training materials or other "Do Not Detail" pieces to customers

Key Points: Permitted vs. Prohibited Activities	
Permitted	Prohibited
Sending a very brief e-mail/text to a customer (using your Pfizer device) asking if you can schedule an appointment to discuss a specific product (e.g., “Dr., I’d like to set up an appointment to discuss Lyrica with you.”)	Sending an e-mail/text to a customer asking if you can schedule an appointment to discuss a product and including anything at all in the e-mail/text that makes a claim about the product, including mentioning indications or therapeutic areas (e.g., “Dr., I’d like to set up an appointment to discuss Lyrica and fibromyalgia with you.”)

Use of Unapproved Studies



Q. Am I allowed to discuss unapproved studies with specialist HCPs whom I call on if I do not show or leave a copy of the study?

A. No. You may only use or discuss RC-approved materials. You are prohibited from discussing any unapproved studies with HCPs.

Modifying a Pfizer Approved Patient Survey



Q. A medical practice that I am working with wants to modify one of Pfizer's approved patient surveys to better meet the needs of its practice. The change does not alter the substance of the survey in any way. Can I make the change and return it to the practice?

A. No. Any alteration to RC-approved materials changes the material and results in the creation of a homemade promotional piece, which is not allowed.

Communicating Formulary Status



- Q. Can I discuss with physicians the formulary status of Pfizer products as compared with competitor products? If so, can I create a chart showing the different formulary status by health plan?
- A. In some circumstances, it might be appropriate to discuss the formulary status of Pfizer and competitor products with HCPs provided that all statements you make are accurate and do not make any non RC-approved direct or indirect comparative claims. For example, you can point out when a Pfizer product has a favorable formulary status, but you may not state or imply that the formulary status makes the Pfizer product more effective or safer than a competitor product. You are not permitted to create a formulary status chart because this would be considered a homemade promotional piece, which is not allowed.
- Q. What materials are available to me to help discuss formulary status?
- A. The Corporate and Government Customers (CGC) group provides RC-approved access grids (generated in the Fingertip Formulary System) which depict the formulary status of Pfizer products. Contact the relevant CGC Account Manager if information is not available in the Fingertip Formulary System or if you need to request a copy of up-to-date formulary access grids.

Mailing Clinical Studies to HCPs



- Q. Am I permitted to mail an RC-approved clinical study (“reprint”) to an HCP?
- A. Generally, no, unless there is explicit guidance and permission in iCUE to do so.

Discussing Prior Authorizations



- Q. Can I engage in discussions with HCPs about Prior Authorizations?
- A. You should follow any applicable RC-approved guidance when engaging in a discussion about specific prior authorization (PA) criteria or forms. In order for you to give or show a specific PA form, it must be RC-approved or you must first obtain written approval from an appropriate CGC representative. If a PA form has been approved for distribution, you may discuss the relevant factual prior authorization criteria with an HCP. If the form contains a Pfizer product name, the applicable package insert must be left behind with any approved PA form.
- You should never assist HCPs or staff in filling out any prior authorization form and you may not coach anyone on fulfilling or evading a prior authorization form’s requirements in order to obtain approval for either a specific patient or a type of patient.

Selling Statements

It is critical that you only make selling statements that are consistent with RC-approved materials and follow all guidance and direction contained in any relevant product Implementation Guide(s) or other RC-approved guidance. These materials are prepared in accordance with FDA-approved product labeling and are designed to minimize execution risk.

Sometimes colleagues share suggested selling statements internally, often by e-mail or before or after internal meetings. Although sharing recommended selling statements can sometimes help improve selling skills, it is critical that these statements be consistent with RC-approved selling messages.

Suggesting inappropriate selling statements or statements that are not consistent with claims contained in RC-approved materials can carry significant legal risks for Pfizer. Thus, if you determine that it might be beneficial to discuss a proposed selling statement, either by preparing a document or sending an e-mail about it, you must carefully review the statements to make sure they are consistent with RC-approved materials, including the relevant product Implementation Guide(s). If you make a change to an approved selling statement (even if minimal), you must obtain your manager's approval prior to disseminating any document containing such selling statements (including, for example, e-mails, play cards, PowerPoint presentations, and summaries of district meetings or workshops).

Each colleague is responsible for the appropriate promotion of products in a manner consistent with RC-approved materials and FDA-approved labeling. Suggesting or utilizing inappropriate selling statements, whether intentional or not, can have far-reaching consequences for Pfizer, and may result in disciplinary action.

Selling Statements: Key Points to Ensure Compliance

- Do not make selling statements that are inconsistent with RC-approved materials, including the product Implementation Guide.
- Before you make any change to an approved selling statement, even if minimal, you must carefully review the statement to ensure it is consistent with RC-approved materials (including relevant Implementation Guides) and consult with your manager to ensure it is compliant.
- Making changes to approved selling statements is discouraged and should be the exception – not the rule.
- Do not disseminate suggested selling statements that differ from RC-approved selling statements, internally or externally, without obtaining your manager’s approval.
- Do not make or imply comparative claims of any kind, especially superiority claims, unless the claim is specifically made in RC-approved promotional materials.

E-mailing/Texting HCPs



- Q. Am I permitted to e-mail/text a customer to schedule an appointment about one of my products? Is it OK if I write a product name in my e-mail/text?
- A. Generally, yes, but only in the limited circumstances set forth here. You may use e-mail/texting to communicate logistical and non-substantive information (e.g., time, date, place of appointment). You may not utilize e-mail or texts to discuss substantive business matters.

You may use a product name in these e-mails/texts only if necessary to give the recipient context for why you would like to meet. However, you may not make any claims about a product in any e-mail/text—this includes mentioning indications or therapeutic areas. E-mails/texts that do not follow this strict rule are considered “homemade” and are prohibited.

- Permissible: “Doctor, I'd like to make an appointment with you to discuss Lyrica's new indication.”
- Prohibited: “Doctor, I'd like to make an appointment with you to discuss Lyrica's new indication for fibromyalgia.”



- Q. Am I permitted to use a non-Pfizer e-mail account, or a non-Pfizer device with texting capabilities or other social networking tool (e.g., Google®, Yahoo® or Facebook®), to interact with HCPs or other customers regarding Pfizer business?
- A. No. You may only use your Pfizer e-mail account or a Pfizer-issued device to communicate with customers regarding Pfizer business.

Stay On-Label and Discuss Only Approved Products and Indications

Pfizer may only promote FDA-approved products and FDA-approved uses and dosing of its products. All promotional statements made about a drug must be consistent with the product's labeling and must be based on the information contained in RC-approved materials. Off-label promotion is taken very seriously by Pfizer and the government. In fact, Pfizer is obligated under a Corporate Integrity Agreement (CIA) to proactively report instances of off-label promotion to the U.S. Department of Health and Human Services, Office of Inspector General (OIG).

Uses or indications that have not been approved, that remain under investigation, or that are under FDA review are considered off-label and may not be discussed. Pre-approval promotion can jeopardize the approval of a new product or indication and may result in severe penalties. Therefore, Pfizer policy mandates that you discuss only approved products, indications and dosing in accordance with RC-approved promotional materials, including any applicable product Implementation Guides. No matter how appealing or robust the scientific evidence, you cannot discuss any product or indication with customers until it is approved by the FDA.

If an HCP asks an unsolicited question about a new product or unapproved indication, you must refer the question to Pfizer's Medical Information Department. Colleagues using an iCUE tablet must submit any such questions using the iCUE system. You may also provide the HCP with USMI's phone number and website address to enable the HCP to contact USMI directly. You may not otherwise facilitate any USMI request.

Critical to staying on-label is making sure that the right discussions and activities are taking place with the right HCPs. Therefore, you must make a good faith effort to avoid presenting product information to, or otherwise engaging in promotion with, HCPs who are excluded for the product you are promoting. This means you must not detail, provide starters, vouchers, co-pay cards, educational



materials or meals, or invite to speaker programs HCPs who practice in a specialty that is excluded for a specific product (e.g., a pulmonologist for Viagra). The specialty exclusion lists by product are available on PfieldNet. Although iCUE will not allow you to record a detail with an HCP that is excluded for the specified product, you should be cautious not to promote a product to any such HCP inadvertently (for example, in an unexpected situation where an HCP joins a group conversation about a certain product). If you inadvertently detail or leave starters with an excluded HCP, in accordance with the Product Exclusion Guide on PfieldNet, you must complete the Exceptions Process form to document the situation that occurred with the excluded HCP. The functionality on your iCUE tablet supports compliant detailing and starter distribution activities by indicating when an HCP belongs to an included specialty for a product and ensuring that a call cannot be closed when an excluded specialty for a product is involved. Careful iCUE pre-call planning will help ensure your interactions regarding a product will be conducted with specialists who are appropriate to be detailed on that product. Please consult the iCUE Product Exclusion Guide on PfieldNet for additional guidance on iCUE functionality.

In certain situations, an HCP may still be an inappropriate recipient of a product detail even if he or she does not belong to a specific excluded specialty where iCUE would otherwise permit you to detail the HCP. For example, it is typically inappropriate to promote a product to a mid-level HCP (e.g., a nurse practitioner or physician’s assistant) if he or she practices exclusively with a physician who is excluded for that product. If you believe that a particular HCP is unlikely to prescribe that product on-label, do not detail that HCP or leave starters, vouchers, co-pay cards, educational materials, or invite the HCP to a speaker program for the specific product. If you think that a certain customer should not be detailed on a specific product or included in your Target Call List (TCL), or you are unsure, you should discuss with your Manager.

Detailing and Sales Materials: On-Label vs. Off-Label Claims	
On-Label Claims (Appropriate)	Off-Label Claims (Inappropriate)
Statements about a product's efficacy for the approved indication, supported by an approved promotional piece	Statements about a product's efficacy for an unapproved use e.g.: Lyrica can help your patients with insomnia to sleep better



Detailing and Sales Materials: On-Label vs. Off-Label Claims	
On-Label Claims (Appropriate)	Off-Label Claims (Inappropriate)
Statements about a product's efficacy within a population of patients specifically identified in the package insert	Statements about a product's efficacy within a population of patients who are not included in the product labeling e.g.: Pristiq can be used in pediatric patients
Statements about the safety of a product that are consistent with the information in the package insert	Statements about the safety of a product that are overly broad or minimize risk e.g.: Toviaz is well tolerated and patients do not really experience side effects
Statements that accurately reflect an approved indication	Statements that inappropriately broaden an indication e.g.: Lyrica is effective therapy across the full spectrum of painful neuropathic conditions

Hospital Protocols



- Q. May I detail an HCP who is involved in the development of a hospital clinical protocol or who is in a position to influence which products are included in a hospital clinical protocol?
- A. Yes. You may detail any such HCP if your detailing is otherwise done in accordance with all applicable Orange Guide principles, including the four Core Compliance Principles discussed in this Chapter.
- Q. May I detail an HCP in order to ask the HCP to consider inclusion of a Pfizer product in a hospital's clinical protocol?
- A. Yes. Pfizer colleagues may encourage an HCP to consider including a Pfizer product in a hospital protocol or standing order provided that such promotion is strictly limited to approved, on-label messaging of the Pfizer product and all Orange Guide principles are followed.
- Q. May I participate in the development of a hospital clinical protocol?
- A. No. Pfizer Sales Colleagues are not permitted to assist hospitals with drafting or otherwise developing hospital clinical protocols or treatment standing orders.
- Q. May I use a hospital protocol in detailing sessions?
- A. Only if the Review Committee has approved the use of such hospital protocol. You may not distribute the protocol and it may not be used outside of the originating institution.

Comparative Claims

You can only make comparative claims when there are Pfizer RC-approved promotional materials (including iCUE slides and any applicable product Implementation Guides) that expressly make such claims. The FDA considers promotional materials or claims to be false and misleading if they state or suggest that a drug's safety or efficacy is comparable or superior to that of another drug's without "substantial evidence" to support such statements or suggestions. It is not appropriate to make comparative claims based on the data in products' respective package inserts. Similarly, because of the differences in clinical trial designs, inclusion criteria, and other factors, it is not permissible to compare results from two non-comparative trials.

Comparative Claim: Comparing any attribute of a Pfizer product to an attribute of another product. The FDA requires “substantial evidence” to make these claims, which generally means two adequate, well-controlled studies comparing the two drugs head to head using comparable dosage regimens or a single, large, well-controlled study.

Superlative Claims



- Q. Is it ever appropriate to use superlatives like “best” or “safest” in discussing a Pfizer product?
- A. No. It is almost never appropriate to use such unqualified superlatives in making claims about our products because they are rarely supported by substantial evidence.

Comparing Product Package Inserts



- Q. Can I compare information contained in the package insert of a Pfizer product with the information in the package insert of a competitor's product?
- A. No, you may never make package insert comparisons unless such comparisons are expressly made in RC-approved materials.

Provide an Accurate and Balanced Presentation

All promotional materials and selling statements must be truthful and not misleading, supported by substantial scientific evidence, and must appropriately “balance” product safety risks. Promotion is false and misleading if it does not include relevant risk and safety information or if it is not supported by appropriate scientific evidence.

The FDA requires that product presentations include a “**fair balance**” of a product’s benefits and risks. Thus, relevant safety information must be presented to “balance” any statements on the product’s efficacy. This is necessary for HCPs to make informed treatment decisions. The more robust the efficacy statements, the more risk information needs to be provided. This means providing the relevant warnings, precautions, side effects or other material information that is necessary for an HCP to make an informed decision. Balanced presentations demonstrate Pfizer’s commitment to improving patient care and are required by law.

Although HCP interactions may be limited in duration, you are still required to provide a balanced presentation that includes relevant safety information.

Fair Balance: statements made about the efficacy of a product must be balanced with relevant statements about the risks of the product, i.e., relevant contraindications, warnings, precautions, side effects or other material information.

Fair Balance and Accurate and Not Misleading Claims



- Q. Can a promotional presentation include a claim that a product is “safe” if the product has a strong and established safety profile?
- A. No. The word “safe” should never be used without qualification because all products have benefits and risks. RC-approved materials may include safety-based claims (e.g., an “established safety profile”), and you should only make safety claims that appear in RC-approved materials and should not elaborate or rephrase such statements.

Never Engage in Actual or Perceived Quid Pro Quo

Quid pro quo is Latin for “this for that.” You must never offer or appear to offer any remuneration or item of value in exchange for inducing an HCP to prescribe a product or put a product on a formulary. An HCP’s decision to prescribe or recommend a Pfizer product must be based on the best interests of the patient and not on any item of value offered to the HCP.

You should never tie giving something of value—even something of nominal value—to induce, directly or indirectly, an HCP’s prescribing or recommendation of a product.

Interacting with Employer Representatives and C-Suite Administrators

Employers are increasingly making decisions regarding the access their employees have to medicine. Similarly, C-Suite Administrators at practice groups and other organized customers may also have a role in influencing access to medicine. Therefore, you may have an interest in calling on employers and C-Suite Administrators. It is important to understand that working with these customers has both

business and legal risks if not done in the appropriate manner. Further, when working with employers, you should treat their employees as consumers, and your discussions should follow Pfizer's guidance on interactions with consumers. See Orange Guide Chapter 16: Consumer and Employee Interactions for guidance on interactions with consumers and employees.

In working with employers, you may interact with medical personnel such as on-site HCPs, and non-medical personnel such as CEOs, CFOs, CMDs, benefit managers, and brokers/consultants. These employer representatives often have influence over the products to which employees have access and over the coverage levels provided by their health benefit plans. When communicating with individuals such as employer representatives or benefits brokers, you must speak with them as you would speak with HCPs (as opposed to consumers). As with other HCPs, you must always give a fair and balanced presentation that includes both the benefits and risks of the product. You should treat all employer representatives and benefits professionals as if they are subject to federal and state healthcare laws, including anti-kickback laws, even if they may not participate in government programs.

When interacting with employer representatives and benefits professionals, you should tailor any product discussion carefully to their background, especially if they do not have a medical background. Use appropriate, RC-approved, employer market specific tools since resources that are designed for other audiences may not resonate with or be appropriate for these customers.

Benefits professionals may want to discuss the coverage offerings and access opportunities for Pfizer products. You may engage in discussions about access for Pfizer products, provided that your statements are truthful, accurate, not misleading, and provided that you only use RC-approved materials, such as approved access grids. You may not direct employers to a specific PBM/HMO or encourage an employer to switch to a different PBM/HMO. The rebate agreement terms we have with customers (including PBMs and HMOs) are confidential (as is the existence of the rebate agreement itself) and must never be discussed with employers, even when the terms are related to the PBM/HMO of that employer. Directing or influencing employers to work with a specific broker or consultant is also prohibited.

To best leverage existing relationships and avoid providing inconsistent messages, you must inform the National Director Employer (NDE) or other appropriate CGC representative in your region about your activities with employers and coordinate with such persons as needed. NDEs are colleagues who are dedicated to working with employer groups and benefits professionals. NDEs collaborate directly with

regional leadership to understand the regional employer market, develop clear plans, and coordinate implementation of those plans with regional colleagues. In many cases, NDEs may already have established relationships with employers or unions in your area and may have clear guidance on areas to avoid.

Keep the following points in mind when interacting with employer representatives:

- NDEs and Account Managers have received training on the appropriate use of health screenings and quality programs such as Quality Forums™ and the guidelines preventing misuse. As a result, only CGC Colleagues should engage in discussions regarding health screenings, quality programs and other CGC tools.
- Certain interactions with unions are subject to federal reporting obligations and possibly other limitations. Check with your NDE or Legal Counsel before interacting with any union.

Other Things You Need to Know

Educational Items to HCPs

The PhRMA Code prohibits Pfizer from offering non-educational items to HCPs or members of their staff, even if the items are practice related and of minimal value (such as pens, pads, mugs, etc). RC-approved educational items generally may be provided to HCPs and their staff as long as they are not otherwise prohibited under applicable state laws or applicable VA/DoD restrictions. For more information about state laws, see the State Laws: HCP and State Employee Restrictions Chapter, and for more information about interactions with the VA and DoD, see the Federal Employee Interactions and Lobbying Chapter. Additionally, a detailed and updated Q&A on the PhRMA Code is available on PfieldNet under the Compliance tab. If you have any questions about the PhRMA Code, you can send your question to PhrmaCode@pfizer.com. Remember that the value of most educational items provided to HCPs is subject to public disclosure under our HCP disclosure policy as discussed in Orange Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure.

Out-of-Pocket Gifts for HCPs

- Q. Can I pay for a gift for an HCP out of my own pocket if I do not expense it?
- A. It is not appropriate to purchase personal gifts of any kind for HCPs in the course of doing business, even if you pay out of pocket and do not seek reimbursement from Pfizer. The gesture can too easily appear to be an attempt to illegally influence prescribing in violation of the anti-kickback laws. Remember that Pfizer Policies on Business Conduct require you to avoid even the appearance of a conflict of interest.

Interacting with MOS Colleagues

Medical Outcomes Specialists (MOS) are field-based medical colleagues within the U.S. Medical Affairs function. The role of the MOS is that of a medical generalist across Pfizer in-line medicines. MOS Colleagues have expertise in pharmacoeconomics and serve the medical needs of managed care and other organized customers across Primary Care, Specialty and Oncology Business Units. MOS activities may include responding to certain types of unsolicited medical requests or pharmacoeconomic information from organized customers. The policies applicable to most MOS activities are contained in the Governance of Medical Outcomes Specialists' Activities (the "Purple Guide").

MOS Colleagues may participate in internal meetings with commercial colleagues to ensure medical understanding of the business goals and objectives in order to appropriately align medical strategies. Medical Colleagues, including MOS Colleagues, should not attend commercial meetings when the focus is contracting, rebating, or other issues relating to pricing.

MOS engagement in medical activities with organized customers should be executed independent of their respective commercial counterparts. However, certain joint meetings with MOS and commercial colleagues may be appropriate in certain limited circumstances. MOS Colleagues have been provided with specific guidance on when joint meetings might be appropriate in the Purple Guide.

All unsolicited medical requests for off-label information must be sent to Medical Information. You may not forward such inquiries directly to MOS.

Interacting with RMRS Colleagues

Regional Medical Research Specialists (RMRS) are field-based Medical Colleagues with expertise in the Medical Affairs functions. Their responsibilities are generally focused on medicine development and include: (a) contributing to the design and support of Pfizer's clinical research and activities; (b) developing and maintaining relationships with key clinical and research leaders; (c) responding to unsolicited medical requests; and (d) communicating scientific and medical information through scientific exchange.

RMRS Colleagues engage almost exclusively in nonpromotional activities and thus are generally subject to compliance principles that differ from the promotional principles applicable to commercial colleagues. However, in very limited circumstances, RMRS Colleagues may engage in activities that are governed by promotional standards. These limited circumstances include helping to train commercial colleagues and presenting to managed care formulary decision-makers as requested by commercial colleagues. In both of these cases, RMRS Colleagues must use only RC-approved materials. The decision to involve a RMRS Colleague in promotional activities can be made only by the senior leadership of the RMRS and Medical Affairs groups. For similar reasons, external interactions or meetings among RMRS Colleagues, commercial colleagues, and HCPs or other customers must also be limited. Commercial colleagues must speak with their manager and RMRS Colleagues in advance of any such proposed meetings with HCPs or other customers to evaluate whether such meetings are appropriate.

RMRS Colleagues may attend internal quarterly (or less frequent) regional meetings with senior Sales Colleagues to provide an update on RMRS activities in a region or with a particular customer, or to provide product medical content training (using RC-approved materials). It is not appropriate for colleagues who directly call upon HCPs or other customers (or their direct managers) to have regular, scheduled internal interactions or meetings with RMRS Colleagues.

All unsolicited medical requests for off-label information must be sent to Medical Information. You may not forward such inquiries directly to RMRS Colleagues. If an HCP indicates that the information received from Medical Information is not sufficient, you may give the HCP the appropriate RMRS contact information for the HCP to follow up directly with the RMRS.

You may refer general requests from HCPs or other customers to discuss current or future research-related activities (e.g., clinical trials, IIRs) to the RMRS directly or provide contact information for the customer to follow-up directly with the RMRS. You may also refer P&T formulary requests from organized customers to a MOS Colleague who will coordinate any appropriate follow-up with the RMRS. You may also suggest local or regional thought leaders for the RMRS to consider for specific Pfizer medical needs; however, the decision to engage with that customer rests solely with the RMRS.

For more information on appropriate interactions with RMRS Colleagues, see the RMRS Guide: Governance for Field Based Medical Activities (the “Green Guide”).

Communicating Clinical Trial Results



- Q. If I suspect that an HCP would be interested in learning about results from a clinical trial looking at a new use for one of Pfizer's products, am I allowed to ask a RMRS Colleague to speak to that physician about the trial results?
- A. No. No colleague, including RMRS and MOS Colleagues, can promote the results of an unapproved or off-label study to an HCP at the request of a commercial colleague, nor may they encourage the HCP to ask about new off-label uses. The only time that a Pfizer Medical Colleague can provide off-label information to a customer is in response to a specific unsolicited question seeking such information as set forth in the Green Guide or Purple Guide. Any unsolicited request for off-label information must be referred to USMI.

Exhibits and Displays

Pfizer is often given the opportunity to promote Pfizer products and RC-provide approved information and materials to customers by paying for an exhibit or display table at an organization's event. An exhibit or display opportunity can occur at a variety of venues and programs, but the key principle for you to remember is that Pfizer is paying solely for the space to promote our products and must not pay more than fair market value for the display opportunity. Money that we allocate to fund an exhibit or display at independent educational programs should not be used to fund other aspects of the program (e.g., speaker honoraria, rental fees, or food). The location of the display should also be separate and apart from any independent educational activity.

All exhibit and display requests must be reviewed and approved by your Manager and submitted to your designated Program Activity Coordinator (PAC) for processing and approval. You should submit requests to the PAC at least 21 days prior to the date of the event. It is not permissible to participate in an exhibit or display if you have not received prior approval. Exhibit and display requests from Managed Care Customers over \$3,500 must be reviewed and approved through the Managed Care Review Committee (MCRC) before the date of the event and before any payment can be made or activities associated with the payment can be undertaken. For more information on the MCRC, see Orange Guide Chapter 5: Payments to Managed Care Customers.

In evaluating an exhibit or display request, Pfizer will ensure it is paying fair market value for the opportunity. If other companies are displaying their products, you should confirm whether such other exhibitors are being charged comparable amounts for the same type of space (it is also acceptable if all exhibitors are being charged the same fee but Pfizer has negotiated to pay a discounted rate). Often the event brochure will list the levels of exhibit and display opportunities and describe the space and services that are being purchased at each level. This type of brochure should accompany your exhibit or display request because it helps to validate the fair market value of the exhibit opportunity. Some factors to consider when evaluating whether there is fair market value for an exhibit or display opportunity include the following:

- The number of people the display opportunity will reach (i.e., the size of the audience);
- Whether the intended audience is generally difficult to access outside of the display opportunity;
- The size of the table/booth and number of colleagues who can work the table or booth;
- The length of time given to Pfizer to engage in promotional discussions with event attendees;
- The physical location of the table or booth in relation to those attending an event;
- Availability of electricity or internet/computer connections; and
- Whether setup and cleanup are included with the exhibit and display fee.

Paying for Display Space at a Private Practice Event

- Q. I received an invitation from one of my specialty practice groups to pay a display fee to set up an exhibit at the practice's business meeting. Can we pay for the display?
- A. Generally, no. Payments to private practice groups are subject to increased scrutiny and are generally impermissible, particularly at events exclusively for members of the practice or events which are aimed at benefiting the practice's business. However, there may be exceptions to this rule that you should discuss with your manager or Regional Attorney. For example, payment might be permissible in a situation where a private practice group is relatively large and other pharmaceutical companies will be providing an exhibit. Similarly, payment might be permissible if an event involves the participation of a larger community of physicians (such as one providing continuing education credit).

Call Notes

Sales representatives are permitted, but not required, to keep “call notes” documenting their details with HCPs, provided that such call notes are kept solely in iCUE. Any call notes documented in iCUE should be written in such a way that the context is clear and not misleading to an outside reader.

Preceptorships and Other Training for Sales Colleagues

In limited circumstances, HCPs may be hired to train colleagues where there is a legitimate and unmet educational need. The need must have a purpose not already met by training provided by Pfizer Learning & Development and relate to the improvement of sales performance.

You must never pay an HCP to speak to colleagues for the purpose of giving the HCP practice making presentations or as a way to ensure that the HCP reads certain information. Similarly, you must never pay an HCP to train colleagues for the purpose of building a relationship with the HCP, gaining or improving access to the HCP, rewarding past prescribing, or inducing future prescribing.

A “preceptorship” refers to a group learning situation where a group of colleagues meet at a local or national Center of Excellence to hear presentations from one or more HCPs or observe patient care situations over the course of a day. The need for these events should be limited, and you should conduct these events infrequently.

Colleagues must be aware that patient privacy issues are often implicated when Pfizer employees are permitted to observe treatment or consultation sessions with patients and HCPs. Pfizer's policies for protecting patient privacy in these circumstances are discussed in Orange Guide Chapter 8: Privacy: Protecting Personal Information. Colleagues must obtain all required permissions and fully comply with Pfizer policies and the rules of any institution where a program occurs.

Preceptorships may only be organized by colleagues who are District Manager level and above ("Project Managers"). Project Managers must complete the appropriate documentation located under the "HCP Engagements" tab at <http://OpSource.Pfizer.com>. Project Managers are required to obtain Legal approval for preceptorship engagements and must document the key learnings from the engagement and how the learnings will be incorporated into future business activities.

Occasionally, Sales Colleagues (Regional Manager level and higher) may engage HCPs to provide educational presentations at Pfizer meetings for the purpose of training colleagues. These training sessions should not be product-specific but rather should focus on the treatment of disease states in patient populations relevant to Pfizer.

The following conditions must be met when any HCP is engaged to train colleagues:

- The education must be provided only to relevant colleagues and should be provided at a widely attended Pfizer meeting (e.g., District or Regional POA/IEM);
- The training must address a legitimate and unmet training need;
- The training must never be used as a guide for training colleagues on promotional messages that are inconsistent with RC-approved promotional materials and in-context training;
- The colleague organizing this training must receive confirmation by e-mail from their liaison in the training department that the proposed training is not otherwise available through Pfizer Learning & Development;
- The presenting HCPs must not be paid more than fair market value; and
- The content should be "unbranded" and not product specific. If there is any mention of any Pfizer product, whether direct or implied, RC-approval is required.

The organizer of the training must review the content of the presentation in advance to make sure that it is appropriate, addresses an unmet training need, and is not product specific. The organizer must also remind all colleagues in attendance that the training is being provided for internal educational purposes only and that any information inconsistent with RC-approved promotional materials and in-context training cannot be used in detailing.

Refer to the One Process/HCP Engagement tab on <http://PfieldNet.pfizer.com/Pages/Welcome.aspx> for the procedures and policies that apply to these types of arrangements. You should always consult with your manager and obtain the approval of the Regional Attorney before engaging in these activities.

Detailing Activities in Connection with Customer and Other Third Party Meetings

Third party meetings, including those held by local medical associations or residents at institutions (e.g., a journal club or residents' meeting) may provide you with an excellent opportunity to promote Pfizer products to HCPs who are gathering together for another purpose.

Conducting a promotional presentation in this circumstance must, as always, be based on a legitimate business purpose and must target appropriate HCPs who have a specialty related to the information presented. These promotional presentations cannot be based on a desire to support or otherwise fund an independent meeting.

Follow these key principles to ensure that any promotional activities conducted in conjunction with third party meetings are appropriate:

- A representative may only provide a meal at an in-office or in-hospital setting,* unless a legitimate speaker program is being conducted, in which case the program must comply with the rules set forth in Orange Guide Chapter 9: Speaker Programs for HCPs.
- All Pfizer policies and processes regarding detailing must be adhered to—for example, you should use iCUE to record all attendees at a product detail (regardless of whether a meal was provided).
- You must make a good faith effort to avoid presenting product information to HCPs who are excluded for the product you are promoting.

- You must make it clear to the customer or organization that Pfizer is not a “sponsor” of its business meeting. Explain that Pfizer is engaging in a separate promotional activity with attendees of the meeting. Identify to the audience a clear start and end to the Pfizer promotional activities to avoid the misperception that Pfizer is supporting any part of the meeting itself.
- You must not distribute invitations or any other written material created by the host organization unless the material has been RC-approved.
- If you provide a meal, * it must be offered as part of the detail and incidental to the program. It is improper to provide frequent, regular and recurring meals. For additional information on appropriate provision of meals, see Orange Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure.
- Pfizer cannot split the cost of a meal with the host of a third party meeting. However, you may engage in promotion during a meal that is provided and paid for entirely by a third party, as long as you make clear that Pfizer is not responsible for providing the meal. Meals provided by third parties will not be reported as part of Pfizer’s payment disclosure policy.
- You must avoid being present during any discussion of any Pfizer product that you anticipate will be inconsistent with that product's labeling.

If a colleague participates in any way in the content of the non-Pfizer meeting, the entire meeting may be considered a promotional event and is then governed by the same rules that apply to all Pfizer promotional activities.

***Remember that you cannot provide any food or other support in connection with an accredited continuing medical education activity (ACCME, ACPE, or ANCC).** Even if you are offered time to promote while providing a meal to attendees at an accredited medical education conference, you must decline that opportunity since any type of financial support for accredited continuing education, including payment for event expenses or meals, can only be funded through an independent professional education grant. Requests for these grants should be sent by the requestor through Pfizer's Medical Education Grants website. For more information, see the Support of External Organizations chapter.

Attendance at Continuing Medical Education Events

Continuing medical education lectures (CME) often take place during conventions or Congresses at which Sales Colleagues may be present. Sales Colleagues' attendance at CME-accredited programs can present legal, perception and other risks. Therefore, in the case of widely attended medical congresses or conventions, Sales Colleagues may attend CME-accredited lectures, provided that the following guidance is followed.

- Attendance must be occasional
- You must not engage in promotional activity at the CME event
- You must avoid initiating conversations with prescribers and you should not discuss Pfizer products if you are approached by an HCP while at the CME event

However, you should not attend CME events that are likely to involve substantial discussion of investigational Pfizer compounds or issues that are inconsistent with labeling for an approved Pfizer product.

Except where approved in writing by Legal, or otherwise permitted by any applicable BU policy exception, you should not attend any other CME events. If you are uncertain if it is permissible for you to attend a CME event, please contact your Regional Attorney.

Detailing at Journal Club Meetings



Q. I've been invited to make a promotional presentation at a journal club meeting held at a local hospital. Is it permissible for me to make a promotional presentation? And if so, can I provide a modest meal?

A. You may provide a promotional presentation. However, you should not attend or provide content or logistical support for any portions of a third-party meeting that are accredited for CME. Additional information about Pfizer's policies for attending CME-accredited events is located on the PfieldNet Compliance page.

You may provide a meal as part of the presentation only if the meeting does not involve CME and you comply with all applicable Pfizer policies, including:

1. Ensuring that the audience is appropriate and does not contain HCPs who practice in excluded specialties;
2. Ensuring that you have a legitimate opportunity to present information about Pfizer products;
3. Appropriately recording all attendees in iCUE and all expenditures in GCE;
4. Segregating the Pfizer promotional presentation from the rest of the meeting; and
5. Ensuring that all relevant state restrictions on provision of meals and other items are followed (see the State Laws: HCP and State Employee Restrictions Chapter).

If you are unsure whether the promotional opportunity is appropriate, contact your manager or Regional Attorney.

FOR MORE INFORMATION

- For more information on interacting with consumers and employees, see Orange Guide Chapter 16: Consumer and Employee Interactions.
- For more information on providing meals to HCPs and for information on Pfizer's HCP Disclosure Policy, see Orange Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure.
- For more information on interactions related to Greenstone and Pfizer Injectables, see Orange Guide Chapter 19: Sales Activities: Greenstone and Pfizer Injectables.

- For Q&A on the PhRMA Code, see the Compliance Tab on PfieldNet at <http://PfieldNet.pfizer.com/Pages/Welcome.aspx>.
- For more information on interacting with MOS Colleagues, see the MOS Guide: Governance of Medical Outcomes Specialists' Activities (the "Purple Guide") at <http://corporatecompliance.Pfizer.com/Pages/Home.aspx>.
- For more information on interacting with RMRS, see the RMRS Guide: Governance for Field Based Medical Activities (the "Green Guide") at <http://corporatecompliance.pfizer.com/Pages/Home.aspx>.
- For more information on exhibit and display requests from managed care customers, see Orange Guide Chapter 5: Payments to Managed Care Customers.
- For more information on Pfizer's policies for protecting patient privacy, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.
- For more information on documentation to be completed for preceptorships, see the HCP Engagements Tab at <http://OpSource.Pfizer.com/Pages/Home.aspx>.
- For information on relevant state law restrictions, see Chapter 17: State Laws: HCP and State Employee Restrictions.
- For information on the Product Exclusions Guide see <http://Pfieldnet.pfizer.com/workspace/CUEApplicationSupport/Documents/Product%20Exclusion%20guide%20Final%20with%20branding.pdf>.
- Refer any questions to your manager or Regional Attorney.

Chapter 3: SUPPORT OF EXTERNAL ORGANIZATIONS

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Chapter 3: SUPPORT OF EXTERNAL ORGANIZATIONS

Introduction

Pfizer is often asked to provide funding or other support to external organizations, including for-profit and not-for-profit entities. Pfizer provides external funding through medical education grants, sponsorships, and charitable contributions. Pfizer also supports or joins collaborations and coalitions with external organizations to advance shared objectives. Pfizer additionally sponsors awards, scholarships, fellowships and similar funding in support or recognition of the education and professional accomplishments of healthcare professionals and students. Such Pfizer funding and support is a demonstration of the commitment to fund programs and initiatives that have broad public benefit, advance medical care and improve patient outcomes.

As with any other interactions between Pfizer and entities involved in healthcare-related industries, providing funding or other support to external organizations can present legal risks if applicable laws, regulations and Pfizer policies are not followed. All such interactions and the provision of financial support must be conducted appropriately to ensure that payments will not be perceived as an attempt to inappropriately influence the prescribing or recommendation of Pfizer products and to ensure the preservation of external organizations' independence. In addition, Pfizer's policy requires that promotional materials, and certain other materials funded by commercial colleagues through collaborations with external organizations, be reviewed and approved by the applicable Review Committee.

This Chapter summarizes key Pfizer policies regarding specified types of funding and support of external organizations. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination.



Key Points to Ensure Compliance

Understand the Policies that Apply to Your Group

- Funding to not-for-profit organizations by colleagues within the U.S. biopharmaceutical business (including Sales), Pfizer Medical and Pfizer Policy, External Affairs and Communications (PEAC) groups must follow the policy and procedures outlined in the [SOP on Funding Requests for Not-for-Profit Organizations](#). For questions relating to this SOP, e-mail USFundingRequest@Pfizer.com. For specific questions relating to funding by PEAC, e-mail PolicyFRC@Pfizer.com.
- Funding to external organizations by colleagues in R&D must follow [Worldwide R&D SOP 201](#).
- Pfizer colleagues in other divisions must follow Corporate Procedure 801 and also the review, approval and documentation requirements applicable to their division.

Understand the Types of Activities Your Group Is Permitted to Fund

- For colleagues in the US biopharmaceutical business, Pfizer Medical and PEAC Groups, the following table summarizes permitted funding by group:

Type of Funding	Sales	Non-Sales BU Colleagues (including CGC)	PEAC	Pfizer Medical and BU Medical	Medical Education Group
Non-Healthcare Charitable Contribution		Yes	Yes	Yes	
Healthcare Charitable Contribution			External Medical Affairs only		Yes



Key Points to Ensure Compliance

Type of Funding	Sales	Non-Sales BU Colleagues (including CGC)	PEAC	Pfizer Medical and BU Medical	Medical Education Group
Policy Focused Healthcare Charitable Contribution			Yes		
Special Event			Yes		
Sponsorship	Yes, but DBM and above only	Yes	Yes	Yes	
Collaboration	Yes, but DBM and above only	Yes	Yes	Yes	
Coalition		Yes	Yes	Yes	
Fellowship			External Medical Affairs only	Yes	
Medical Education Grant					Yes

Key Points to Ensure Compliance

- Sales Colleagues and other colleagues in the US biopharmaceutical business, Medical and PEAC groups may fund sponsorships that provide an appropriate “tangible benefit” (as defined later in this Chapter) to Pfizer.
- Any funding request that does not include a “tangible benefit” will not be treated as a sponsorship but rather as a charitable contribution. Charitable contributions are not eligible for funding by Sales Colleagues. Select non-Sales Colleagues are permitted to make certain narrowly defined charitable contributions in accordance with the policies outlined in this Chapter.
- External organizations will often submit funding requests using key terms (e.g., “charitable contribution”, “grant” and “sponsorship”) interchangeably and inconsistently. Pfizer colleagues must identify the substantive nature of each request based on Pfizer definitions to ensure that it is a type of request they are permitted to fund.
- Only provide funding based on the merits of the request and never: (i) as a “quid pro quo” to inappropriately influence the formulary positioning, recommendation or increased prescribing of a Pfizer product; or (ii) to gain improper favor with a healthcare professional, government official or any other individual or organization.
- Never provide individual HCPs or group practices with non-research grant funding or donations unless approved in advance by the relevant Chief Counsel or Compliance Counsel.
- Never link charitable funding to a commercial transaction or interaction.
- Never provide funding to an organization in a manner that undermines the organization’s independence or mission, or for capital support or “start up” costs.
- Never provide funding for any activity that may result in off-label promotion of Pfizer products or where there is a likelihood that treatment options will not be presented in a fair and balanced manner.

Medical Education Grants

Overview

Pfizer provides non-promotional funding to third party organizations in the form of **independent medical education grants**. An independent medical education grant refers to funding given to a third-party entity to support a specific educational or professional development activity directed at healthcare professionals (HCPs) that will benefit the public and improve patient health.

Legitimate professional and educational initiatives that can be supported with medical education grants include activities like continuing medical education for HCPs. Medical education grants are permissible only if they are “independent”, which means that colleagues may not influence the content of the supported activity or how it is conducted. For example, colleagues cannot choose or have any input on the topic of the activity, food served at the activity, or the speakers who participate in the activity.

The review and approval of education grants in the U.S. (and Puerto Rico) is conducted by Pfizer’s Medical Education Group (MEG). MEG, a part of Pfizer Medical, works in collaboration with therapeutic area representatives from Medical, Regulatory Affairs and Legal to develop medical educational goals for all clinical areas of interest. To be considered for funding, a grant request must align with one of these pre-determined medical educational goals and must meet all of the criteria of an appropriate educational activity, including that it is independent and information provided is balanced, accurate and not misleading, delivered to a broad audience and reasonable in cost.

Under no circumstances does Pfizer condition grant funding upon past, present or future prescribing, purchasing or recommending of Pfizer products, nor will Pfizer accept any benefits in return for providing a medical education grant. MEG also does not provide medical education grants in support of an individual’s career advancement or development. (The review and approval process for these activities is covered below in the section titled “Awards, Scholarships and Fellowships”.) By requiring the review and approval of these requests by MEG, Pfizer seeks to minimize the risk that a medical education grant could be approved, or perceived to have been approved, for an improper purpose.

Commercial support of medical education grants has been under increasing scrutiny by Congress and the U.S. Department of Health and Human Services, Office of Inspector General (OIG). In an effort to be more transparent, Pfizer publicly reports grants and charitable contributions provided to medical, scientific and patient organizations in the United States, on the [Pfizer website](#).

Registration and Application Submission

All requests for U.S. medical education grants must be submitted by the external organization directly to MEG via Pfizer’s online **Grant Management System (GMS)**. All submissions, required documentation and internal determinations are recorded and archived in GMS.

Organizations must first be evaluated for eligibility criteria such as accreditation and independence in order to register in GMS. Once qualified for registration, eligible organizations may submit a request at www.pfizermededgrants.com. MEG accepts applications for all independent accredited and non-accredited professional educational programs and activities. Requests for accredited independent professional education must originate from accredited organizations. Examples of accreditations include ACCME, ACPE, ANCC and AOA. Organizations with healthcare accreditation, such as JCAHO accredited hospitals, are eligible to submit grant applications. Providers must be in compliance with Pfizer standards as well as the guidelines of the OIG, ACCME and other relevant bodies. Pfizer does not support requests from individual physicians, private practice groups, or institutions that appear to have significant conflicts of interest. For example, organizations where practicing healthcare providers have a proprietary or ownership interest in the organization will not be eligible to apply for medical education grants from Pfizer.

International Grant Activity



- Q. May Pfizer Country Offices outside the U.S. fund independent medical education programs occurring in the U.S.?
- A. No. All such requests must be submitted by the external organization directly to MEG via GMS. Under strictly limited conditions, exceptions may be permitted with approval from MEG and Legal.

Application Review, Notification and Payment

MEG will review application submissions for completeness, alignment with pre-determined medical educational goals, compliance with Pfizer policies, and other legal and regulatory requirements. Due to limited funding, not all grant requests will be approved. Requestors will receive an e-mail notification when a grant is approved or denied. All approved grants will be funded through the MEG budget. Checks are sent directly to the requesting organization.

Colleague Roles in Grant Process



- Q. May a Sales, Marketing or PEAC Colleague communicate with grant requestors regarding the status of grant requests?
- A. No. These colleagues must not be part of the submission, review or approval process. Requestors must communicate only with members of the MEG team regarding grant requests, funding, or denials. These colleagues must direct requestors to the MEG website at www.pfizermededgrants.com, the dedicated e-mail address mededgrants@pfizer.com, or the toll-free number 1-866-MEG-4647.

Pfizer May Not Influence Grant-Funded Events

Colleagues may not offer suggestions regarding topics, content or speakers to a continuing medical education (CME)/continuing education (CE) provider, program sponsor or speaker at a CME/CE medical education event. Even if you are asked to provide input on topics or speakers, you must decline. If a provider or speaker were to implement Pfizer suggestions, the independence of that medical education program could be compromised. Similarly, a grant request for an independent medical education event that includes faculty who have spoken on similar topics in a promotional capacity for Pfizer in the 12 months prior to the date of submission will be declined. Additionally, colleagues must not provide logistical support at an independent medical education event.

On occasion, Pfizer may be offered promotional opportunities in connection with an independent medical education event, such as exhibit space or time to conduct a speaker program. Such opportunities may be accepted only under strictly limited conditions. For information on promotional opportunities at CME/CE events, see the section below.

Colleagues' Role in Grant Process

- Q. Can a colleague provide input on the content of a CME/CE activity in order to inform the accredited provider that the information is inaccurate or unreasonably favors Pfizer products?
- A. No. Colleagues must not be part of the submission, review or approval process. This means that requestors must communicate only with the MEG team regarding grant activities.
- Q. Can a colleague provide input on the content of a non-CME/CE activity funded through MEG? Similarly, can a colleague provide logistical assistance for a non-CE event funded through MEG?
- A. No. Pfizer considers all grant-funded events, even non-CME/CE events, to be independent. Colleagues should not influence any grant-funded event in any way.

Promotional Opportunities at Medical Education Conferences

From time to time you may be asked to pay for or provide a meal at a medical education conference held by a third party organization where CME/CE credit is being offered. You should not under any circumstances fund a meal or any other type of expense associated with a third party's medical education conference or activity where CE credit is being offered.

On occasion, Pfizer may be offered the opportunity to conduct a speaker program in connection with an accredited medical education activity (ACCME, ACPE, or ANCC). This may be done *only* under the following conditions:

- The Pfizer program must be conducted in a room physically separated from the space where CE content is being provided.
- At the start of the program, the speaker must clearly communicate to attendees that it is a separate Pfizer promotional presentation not accredited for CME/CE credit.
- Pfizer cannot provide meals or beverages in connection with the Pfizer program. Any meals provided by a CME/CE provider must be made available to all CME/CE event attendees, including those not attending the Pfizer presentation.
- No advice or guidance may be provided regarding the content of the medical education activity.

- No financial or other support, including payment for event expenses or meals, setting up logistics or handling non-Pfizer speaker arrangements, may be provided in connection with the Pfizer program (subject to vary narrow exceptions for logistical expenses discussed in Orange Guide Chapter 9: Speaker Programs for HCP). As discussed above, financial support may only be funded by an independent medical education grant approved by MEG.

If colleagues are offered an opportunity to conduct a speaker program at an event where CME/CE is not being provided, the above restrictions do not apply, however they must still follow all applicable Pfizer policies for promotional speaker programs (including the policies outlined in Orange Guide Chapter 9: Speaker Programs for HCPs).

Complimentary Exhibit or Display Space

If exhibit opportunities are available at an event—whether or not CME/CE credit is being offered – Pfizer may pay for placement of an exhibit or display at fair market value. From time to time event organizers may offer Pfizer complimentary exhibit and display space. If such complimentary offerings are tied to a MEG-approved grant, then Pfizer will only accept complimentary exhibit space when it is offered to all potential exhibitors equally.

Sponsorships and Charitable Contributions: All Divisions

General

Not-for-profit organizations, including but not limited to qualified 501(c)(3) charitable organizations, may offer Pfizer the opportunity to provide funding for sponsorships or charitable contributions. Colleagues must follow the review, approval and documentation requirements applicable to their division.

Sponsorships and Charitable Contributions: R&D

Funding to external organizations by Worldwide R&D Colleagues must follow [Worldwide R&D SOP 201](#). Any charitable contributions initiated by Worldwide R&D Colleagues must be submitted using the Charitable Contributions Request Form located on the R&D Compliance website. A letter of request from the organization on its letterhead, or alternative documentation that is approved in advance by



the R&D HCP and FCPA Program Office, is also required. Charitable contributions less than \$10,000 are subject to relevant Authorized Signatory List (ASL) and R&D HCP and FCPA Program Office approval. Charitable contributions of \$10,000 or more are further subject to R&D Legal approval. R&D Colleagues should consult [Worldwide R&D SOP 201](#) for additional guidelines and requirements.

Sponsorships and Charitable Contributions: the US Biopharmaceutical business, Pfizer Medical and Policy, External Affairs and Communications Groups

The remainder of this section describes the policy that applies to the U.S. Biopharmaceutical Business (including Sales), Pfizer Medical (formerly called the CMO division) and Policy, External Affairs and Communications (PEAC) Groups. Colleagues in these divisions should refer to the [SOP on Funding Requests for Not-for-Profit Organizations](#) (“Funding SOP”) to determine whether a funding opportunity is a sponsorship or a charitable contribution. This Chapter does not comprehensively address the activities that may be funded by the External Medical Affairs group and the General Manager and Medical Lead for each BU. Those activities are addressed in the Funding SOP.

Determining the appropriate funding type will determine which colleague groups are permitted to fund them. How a third party defines or describes the funding request does not determine Pfizer’s classification. In fact, external organizations will often submit funding requests using key terms interchangeably and inconsistently (e.g., “charitable contributions”, “grants” and “sponsorships”). Each colleague must identify the substantive nature of each request, based on Pfizer’s standard definitions summarized below, to ensure that a request presents the type of opportunity that they can appropriately fund.

“Not-for-Profit” Defined

A “not-for-profit” (also referred to as a “non-profit”) organization is an organization that does not distribute its profits to its owners and is typically organized for educational, charitable, or scientific purposes. The Funding SOP applies to entities that have been designated as not-for-profit by appropriate state and federal agencies, including but not limited to: 1) certain charities and patient advocacy groups designated by a 501(c)(3) status, 2) professional medical associations or chambers of commerce (501(c)(6) status and 3) cultural and civic organizations (501(c)(4) status).



Sponsorships

Sponsorships are funding opportunities provided by either for-profit or not-for-profit organizations that present a “tangible benefit” to Pfizer. They can be funded by all Pfizer groups in accordance with the processes and requirements described in this Chapter. A **tangible benefit** is any legitimate, appropriate and business-oriented benefit to the proprietary interests, business, or public policy goals of Pfizer or its products, services or programs. The receipt of general recognition or incidental goods or services that do not directly promote Pfizer business goals in and of itself does not constitute a tangible benefit. A tangible benefit must provide the opportunity to truly advertise or advance Pfizer business interests, e.g., to educate customers and/or prescribers about the specific attributes of our products and/or services.

Any funding request that does not include a tangible benefit in return for funding will not be treated as a sponsorship but rather as a charitable contribution. As discussed in the next section, Sales Colleagues are not permitted to make any charitable contributions. All other colleagues (including CGC) are not permitted to make healthcare charitable contributions but are permitted to make appropriate non-healthcare charitable contributions. Colleagues may not ask a requesting organization to change the associated benefits being offered for funding in order to impact the classification or source of funding within Pfizer.



Tangible Benefit Examples*	Fair Recognition Examples (Not Considered A Tangible Benefit)
<p>Opportunity to promote Pfizer and its products or brands (such as via branded materials or a booth at an exhibition).</p> <p>Opportunity to promote Pfizer programs or services, such as Pfizer Helpful Answers (PHA) or programs like Connection to Care, Pfizer Pfriends, FirstResource RSVP, Sharing the Care, Pfizer Hospital Partnership Program and MAINTAIN. (Approval from PHA is required.)</p> <p>Speaking opportunities that directly promote or raise awareness of Pfizer marketed products and/or commercial activities (including policy and disease state related topics).</p> <p>Input into the execution or content of an activity (e.g., providing strategic direction or message development).</p> <p>Directly receiving funded activity output (e.g., funding the development of literature that will be used by Pfizer).</p> <p>Placement of product logos on a podium or in literature aimed at HCPs or patients.</p>	<p>Placement of a Pfizer corporate logo on podium or brochure.</p> <p>Honorable mentions and announcement of thanks, written or verbal.</p> <p>Placement of a Pfizer corporate logo on a purchased table at an event.</p> <p>Tickets to an event.</p>

* Subject to meeting all relevant review committee approval requirements.

If a not-for-profit sponsorship opportunity satisfies the above key characteristics, U.S. biopharmaceutical, Medical and PEAC Colleagues may submit a funding request using the Funding Request Form (FRF) available at <http://InterAct.Pfizer.com>. Sponsorship opportunities involving

for-profit organizations are evaluated under similar rules but must be submitted for Legal approval directly and not through the InterAct/FRF system.

Submission of Funding Requests by Sales Colleagues

Sponsorships may be funded only by colleagues at the District Business Manager (DBM) level or higher. The purchase of exhibit and display space by U.S. Sales Colleagues is covered by the [Exhibit and Displays SOP \(ED SOP2-01\)](#) and is processed through the BETSY system. However, if a U.S. Sales Colleague funds a sponsorship that provides for a package of benefits (i.e., in addition to the exhibit and display space) then the [SOP on Funding Requests for Not-for-Profit Organizations](#) should be followed.

Before submitting any requests using the FRF (including applicable charitable contributions described below), colleagues should review the training materials located under the Funding Request tab at <http://OpSource.Pfizer.com>. Completion of the Funding Request training module is a prerequisite for having access to the FRF. All such funding requests are subject to review and approval by the appropriate Legal Division Colleague, unless otherwise noted. Contact USFundingRequest@Pfizer.com to gain access to the training module.

Charitable Contributions

Generally, charitable contributions are expenditures that are intended to fund a qualified 501(c)(3) (or other valid not-for-profit) organization's broad charitable purpose or mission. As described above, any funding opportunity that does not include a direct tangible benefit to Pfizer will be treated as a charitable contribution (for purposes of determining whether specified colleagues can fund it). When permitted, charitable contributions must be made for a bona fide charitable purpose and without any ulterior commercial motive. Charitable contributions may include some benefit to Pfizer, but any benefit given to Pfizer must be incidental to the donation itself. Pfizer may not provide input into the content or strategic direction of the activity being funded, nor receive rights to use the results of the activity being funded. Due to limited funding, not all charitable contribution requests will be approved.

Pfizer broadly distinguishes between four categories of charitable contributions: non-healthcare, healthcare, policy-focused healthcare, and Special Events. This section contains definitions and examples of each type of charitable contribution, a description of the groups that may provide funding and an overview of the relevant approval process.

Non-healthcare charitable contributions are the donation of money, goods or services to organizations or programs that exist for broad public benefit not related to products or healthcare topics.

- **Examples:** Contribution for disaster relief; contribution for a school fundraiser.
- **Colleagues that May Provide Funding:** U.S.-based colleagues in the following Pfizer divisions: U.S. biopharmaceutical business (except for Sales Colleagues), PEAC, and Pfizer Medical.
- **Approval Process:** Requests for non-healthcare charitable contributions may be submitted using the Funding Request Form at
- <http://InterAct.Pfizer.com>.

Healthcare charitable contributions are charitable contributions to healthcare-related organizations or to non-healthcare related organizations for healthcare-related programs. The MEG group funds charitable contributions related to the following: disease state focused patient or community education or advocacy; health screening and surveying; improved patient access to care (e.g., affordability, transportation costs); and/or organizations whose general mission is to benefit specific patient groups.

- **Examples:** Contribution to the American Heart Association for patient education on cholesterol management; contribution to the Filipino Heritage society for patient education on heart-healthy eating.
- **Colleagues that May Provide Funding:** MEG only.
- **Approval Process:** Similar to medical education grant submissions, requests for (non-policy-related) healthcare charitable contributions that meet the criteria above must be submitted directly by the not-for-profit organization to MEG via the charitables website at www.pfizerhealthcharitables.com. Colleagues should not submit requests to MEG on an organization's behalf. This website includes a list of criteria that any request must meet to be eligible for MEG charitable funding. MEG will review submissions for completeness, compliance with Pfizer policies, and other legal and regulatory requirements. Requestors will receive an e-mail notification when the request is approved or denied. Approved healthcare-related charitable contributions will be funded through the MEG budget.

Policy-focused healthcare charitable contributions are contributions to third-party not-for-profit organizations where the funds are to be used for the organization’s specific mission-related activities that align with Pfizer’s public policy goals. This includes, but is not limited to, patient education on public policy issues, policy-related access to healthcare issues, and support of charities whose general mission is to further healthcare policy (and does not include healthcare professionals’ continuing medical education or disease state, medical or clinically-focused activities).

- **Example:** Charitable contribution to the Georgia Medical Society for education of members on healthcare reform.
- **Colleagues that May Provide Funding:** PEAC only.
- **Approval Process:** Requests must be submitted by appropriate colleagues using the Funding Request Form at <http://InterAct.Pfizer.com>. All such requests are subject to review and approval by Legal.

“**Special Events**” are contributions to third party not-for-profit organizations whose goals align with Pfizer’s public policy goals to help fund their fundraising dinners, walks, biking and golf events, galas, awards ceremonies, and other similar events. Special Events are activities that do not present tangible benefits to Pfizer (and are therefore ineligible for sponsorship funding).

- **Examples:** Financial support of a Multiple Sclerosis Society walkathon.
- **Colleagues that May Provide Funding:** PEAC only.
- **Approval Process:** All requests must be submitted by appropriate colleagues using the Funding Request Form at <http://InterAct.Pfizer.com>. All such requests are subject to review and approval by Legal.

Colleagues in the U.S. biopharmaceutical business and Medical are prohibited from providing funding for Special Events but may refer organizations to the Special Events page on Pfizer’s website(www.pfizer.com/grantsandcontributions/specialevents/).

- **Internal Coordination:** Involvement of Business Unit Colleagues in policy-focused healthcare charitable contributions and Special Events must be strictly limited. Certain designated Business Unit Colleagues are permitted to present therapeutic area strategies and priorities to Public Affairs so that the Public Affairs group has access to the most



comprehensive information in determining how best to work with requesting organizations. These presentations may not focus on specific events or funding opportunities and may occur only during development of operating plans and strategic planning discussions.

- **Additional Assistance:** If a Special Event includes or requires Pfizer participation, such as volunteers to hand out materials or seats at a gala table, Public Affairs may invite colleagues to participate only if there is no branded or promotional interaction with the organization, and discussions with attendees must not involve Pfizer brands or products. Colleagues are not permitted to invite HCPs to these events.

Key Characteristics: Sponsorships vs. Charitable Contributions		
Characteristic	Sponsorship	Charitable Contributions
Promotional in nature	Yes	No
Payee must be a not-for-profit organization (501(c)(3) or similar designation)	No	Yes
Pfizer must receive a “tangible benefit”	Yes	No
Payment can be made to an individual HCP or private practice group	No	No
Tickets or invitations received as a result can be offered to Healthcare Professionals	No	No
Agreement documenting terms and conditions of Pfizer funding	Yes (agreement must clearly indicate the “tangible benefit”)	Yes

Information on Pfizer’s External Funding Policy



- Q. Where can Pfizer colleagues in the BUs, Medical and PEAC get help and information on Pfizer’s policy regarding funding to not-for-profit organizations?
- A. Funding requests must be initiated online using the Funding Request Form at <http://InterAct.Pfizer.com> under the “BU/Pfizer Medical/Policy FRF” tab. Additional resources are also available at <http://OpSource.pfizer.com> under the “US Funding Request” tab. The OpSource site also includes a funding request “wizard” and other tools that can help you determine whether a proposed funding activity is permissible for you to undertake. You can direct any questions about the process to USFundingRequest@Pfizer.com.

Purchase of a single ticket to a Gala/Fundraiser



- Q. The External Funding Policy prohibits Sales, Marketing and Medical Colleagues from funding a table at a gala or fundraiser for a not-for-profit organization. But can these colleagues purchase a single ticket to this type of event?
- A. Yes. The Policy permits these colleagues to purchase single tickets to fundraising events for legitimate business purposes. The ticket fee may be submitted as an invoice and charged to your department’s payment process. However, remember that colleagues in these groups are not permitted to purchase entire tables at such events. Colleagues should operate within the spirit of these guidelines and not purchase individual tickets in a manner that results in the purchase of a whole table in order to circumvent the Policy.

Sponsorship Request related to For-Profit Organizations

- Q. Does the External Funding Policy apply to sponsorship and funding requests from for-profit organizations?
- A. No. These requests are evaluated under similar standards but are not covered by the Funding SOP and should not be processed using the Funding Request Form (FRF). Sales Colleagues can continue to process these requests through their Program Activities Coordinator and non-Sales Colleagues must submit these requests to their Legal counsel.

Sales Funded Exhibit and Display Requests

- Q. Are Exhibit and Display Fees made payable to not-for-profit organizations covered by the External Funding Policy?
- A. No. Exhibit and Display requests received by Sales are excluded from the External Funding Policy. You should continue to send Exhibit and Display requests to your Program Activity Coordinator and follow applicable policies (available in BETSY under the "Forms" tab). However, if an Exhibit and Display request is part of a package that includes other benefits (in addition to exhibit and display space), then the External Funding Policy should be followed.

Appropriate Pfizer Foundation Referrals

- Q. Can a customer's request for a charitable contribution be forwarded to the Pfizer Foundation for consideration?
- A. No. The Pfizer Foundation is an independent, tax exempt organization established by Pfizer Inc. The Pfizer Foundation provides funding through targeted initiatives focused primarily on health care and science education such as the Pfizer Foundation Matching Gifts Program or the Pfizer Foundation Southern HIV/AIDS Prevention Initiative.

Collaborations and Coalitions

Another way that Pfizer supports external organizations is by participating in collaborations or joining coalitions to advance shared objectives. Colleagues must follow the review, approval and documentation requirements applicable to their division. The requirements for WBB, Pfizer Medical and PEAC groups are described below.

Overview

A **collaboration** is an activity or project undertaken by Pfizer with one or more external organizations (either for-profit or not-for-profit) to advance specific and discrete shared policy or disease awareness objectives. Pfizer may provide funds, resources or expertise to the collaboration. Pfizer is involved to some extent in the creation of the materials or other activities (e.g., providing suggestions or feedback) and may receive the right to use the materials or other output created pursuant to the collaboration. The external organization(s), however, retains ultimate control of the goals, activities and messaging, subject to Pfizer's limited right to review (via Review Committee, where applicable) for accuracy and compliance with relevant laws and regulations, industry codes, external standards and internal Pfizer policies and procedures.

- **Examples:** A brand team may collaborate with cancer survivor organizations on a pamphlet about effective patient–physician dialogue; “Campaign to Quit” conducted jointly with the American Lung Association.
- **Colleagues That May Provide Funding:** Colleagues in the US biopharmaceutical business, Pfizer Medical and PEAC groups.
- **Approval Process:** All requests to participate in a collaboration must be submitted by appropriate colleagues using the Funding Request Form at <http://InterAct.Pfizer.com>. All such requests are subject to review and approval by Legal. Colleagues should discuss all pertinent facts about a collaboration with Legal prior to submitting the Funding Request Form for approval.

A **coalition** is an activity or project where Pfizer and two or more other organizations (either for-profit or not-for-profit) formally and publicly join forces over a period of time that is expected to be not less than a year to advance a common policy or disease awareness objective. Pfizer is involved in advancing the goals of the coalition in addition to Pfizer being a member of the coalition. With respect to healthcare-related coalitions, the majority of coalition members must be non-commercial, non-manufacturer organizations and they should have ultimate control over the coalition and its message. Pfizer may provide funds, resources or expertise to the coalition. The coalition controls the goals, activities and messaging, subject to Pfizer’s limited right to review for accuracy and compliance with relevant laws and regulations, industry codes, external standards and internal Pfizer policies and procedures.

- **Examples:** U.S. Public Affairs participates in a coalition with national and state-based cancer advocacy groups to work together on reimbursement and coverage challenges; funding of a coalition to organize a series of events and develop white papers on relevant public policy topics.
- **Colleagues That May Provide Funding:** Coalitions can be funded by colleagues in the U.S. biopharmaceutical business (except Sales Colleagues), Pfizer Medical and PEAC groups.
- **Approval Process:** All requests to participate in a coalition must be submitted by appropriate colleagues using the Funding Request Form at <http://InterAct.Pfizer.com>. All such requests are subject to review and approval by Legal. Colleagues should discuss all pertinent facts about a coalition with Legal prior to submitting the Funding Request Form for approval.

Collaborations and Coalitions – Tangible Benefit and Disclosure of Pfizer Involvement

Given the nature of Pfizer’s involvement in collaborations and coalitions, including the provision of strategic input and often the rights to use the output of the activities, **these categories provide Pfizer with a tangible benefit and should not be considered a charitable contribution even if the receiving organization is a not-for-profit entity.**

Pfizer’s participation in collaborations and coalitions must also be appropriately disclosed in all resulting materials in a manner that does not imply that funding was provided via an independent grant (e.g. “Developed in collaboration with Pfizer” versus “Funding Support Provided by Pfizer”).

Awards, Scholarships and Fellowships

Overview

Pfizer sponsors awards, scholarships, fellowships and similar funding in support or recognition of HCPs and students. Only Pfizer Medical (formerly the CMO division) and BU Medical Colleagues are permitted to fund awards, fellowships and scholarships.

Awards are programs developed with an independent professional group to provide funds or other recognition to an individual demonstrating professional excellence or an outstanding commitment to public health or patient care. **Fellowships** are funds paid to U.S. medical schools, academic medical centers, teaching hospitals, schools of nursing, pharmacy or public health, and other healthcare-related organizations to support junior faculty or emerging leaders in medical science for one or more years of study. **Scholarships** are funds awarded to students engaged in a full-time academic activity (normally a medical degree) to aid with education costs. Pfizer also sponsors awards, scholarships, fellowships and similar funding that: (1) permit medical students, residents, fellows and other healthcare professionals in training to attend conferences; or (2) support clinical or research fellowships.

- **Colleagues That May Provide Funding:** Awards, scholarships and fellowships are permitted to be funded only by **Pfizer Medical** and **BU Medical** Colleagues.
- **Approval Process:** All such funding requests are subject to review and approval by the Legal representative on the Policy Funding Review Committee, a review committee comprised of Legal and Public Affairs and Policy Colleagues.
- **Requirements:** Pfizer funding of awards, scholarships and fellowships is permissible only under the following circumstances:
 - The selection of recipients is completely independent of direct or indirect Pfizer influence, which includes direct selection of awardees as well as paying or choosing the selection committee that makes the ultimate decision about individual awardees;
 - The application is competitive and open to all relevant institutions and candidates in a given geographic area or therapeutic area;
 - Resulting programs are not related to any Pfizer product; and

- Such award complies with applicable state laws and regulations.

In addition, awards, scholarship and fellowships must be provided directly to third-party organizations (e.g., academic medical center; professional association; Centers for Disease Control; National Institutes of Health) that independently select final awardees. It is permissible to assemble and retain a selection committee to evaluate third-party organization applicants; provided that such third-party organization awardees independently select the individual student or HCP ultimately to receive the award, fellowship or scholarship. Whenever possible, programs should be co-sponsored with non-profit medical societies, professional groups or similar organizations.

Awarded funds must be used only for the direct expenses of the program, and may not be used to subsidize the recipient's existing, routine or ordinary business expenses. Fellowships must be paid directly to the successful applicant's institution and cannot be paid directly to the successful applicant. In addition, Pfizer can provide fellowships only to support the research activities of applicants who already have positions at academic institutions. Fellowship funds cannot be used to cover a salary for a position that bills services, or for that portion of a position that bills services. If a position includes both billable services and research or teaching, the award must be pro-rated based on the amount of time the fellow will devote to non-billable teaching and research.

Non-Financial Support

Personal Volunteering

With the exception of approved team building activities, personal volunteering activities by Pfizer colleagues must be a personal activity done during a colleague's personal time and not a Pfizer effort. Volunteering must be an individual choice and no managerial pressure or direction can be exerted to influence a colleague to volunteer their time. Personal volunteering must therefore not be linked to commercial goals or objectives or otherwise be part of promotional activities or business plans. An exception to this is that at certain Special Events (as described above), the Public Affairs group may seek assistance from colleagues to attend or help at the event.

This prohibition, however, does not apply to activities approved by the relevant BU or division that are undertaken with organizations to appropriately promote Pfizer's products or advance Pfizer's business

interests. For example, an Account Manager can join employer coalition for the purpose of advocating for Pfizer's position on formulary benefit design (assuming necessary approvals are obtained).

Regular Membership and Board Membership

Colleagues should exercise caution when participating as a regular member, officer or board member of an external organization, particularly if the organization is likely to request funding from Pfizer. Colleagues must always ensure that their participation in external organizations is consistent with this Chapter, the Summary of Pfizer Policies on Business Conduct (the "Blue Book") and other applicable Pfizer policies that address conflicts of interest. **Pfizer colleagues participating as officers or board members must recuse themselves from joining in any decisions or activities relating to Pfizer, Pfizer products or competitor products.**

The fact that a Pfizer colleague participates as a regular member, officer or board member of an external organization does not necessarily preclude the organization from receiving funding from Pfizer. However, a colleague's participation in any such organization must not affect Pfizer's decision to approve or reject the funding request.

Accordingly, every colleague who participates as a regular member, officer or board member of an external organization that requests funding from Pfizer (in the form of a sponsorship, charitable contribution, Special Event or otherwise) must:

1. Make appropriate disclosures to the Legal reviewer responsible for reviewing the funding request. These disclosures must identify the colleague's role in the organization and his/her involvement in the activity for which funding is being solicited (for example, participation on an event planning committee); and
2. Disclose to the organization, prior to the submission of a funding request, that he/she is not participating in Pfizer's review or approval of the request.

FOR MORE INFORMATION

- Sales Colleagues who need information about policies for funding Exhibit and Display opportunities can review Orange Guide Chapter 2: Detailing to HCPs and ED SOP2-01 –

Exhibits and Displays Standard Operating Procedure (available in BETSY under the “Forms” tab).

- SOP on [Funding Requests for Not-for-Profit Organizations](#) (applies to the U.S.-biopharmaceutical business, Pfizer Medical, and PEAC groups). For questions relating to this SOP, e-mail USFundingRequest@Pfizer.com. For specific questions relating to funding by PEAC groups, e-mail PolicyFRC@Pfizer.com.
- For other general information and training materials regarding Funding Requests, consult the Funding Requests tab on <http://OpSource.Pfizer.com>.
- For questions regarding medical education grants, e-mail mededgrants@Pfizer.com.
- For questions regarding (non-policy-focused) healthcare charitable contributions, e-mail healthcharitables@Pfizer.com or visit www.pfizerhealthcharitables.com.
- For questions regarding policy-focused healthcare charitable contributions, e-mail PolicyFRC@pfizer.com.
- For questions regarding “Special Events” funding (e.g., walk-a-thons, bike-a-thons, golf events, fundraising dinners, award ceremonies), e-mail publicaffairssupport@pfizer.com.
- For questions regarding awards, scholarships or fellowships, e-mail PolicyFRC@Pfizer.com.
- For more information on the Pfizer Foundation, refer to www.pfizer.com/responsibility.
- Refer other questions to your team attorney.



Chapter 4: FEDERAL EMPLOYEE INTERACTIONS AND LOBBYING

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Chapter 4: FEDERAL EMPLOYEE INTERACTIONS AND LOBBYING

Introduction

This Chapter focuses on: (a) the important rules you must understand and follow when engaging in promotional and non-promotional activities with the Department of Veterans Affairs (VA), Department of Defense (DoD) and other federal employees; and (b) summarizes certain key Pfizer policies regarding lobbying registration and disclosure. This Chapter is relevant to any colleague who interacts with healthcare (HCP) professionals employed by the federal government (including interactions with any HCP employed by the VA or DoD) or engages in lobbying activities with any elected or appointed state or federal government official or public employee (including state Medicaid agency employees and public hospital and government HCPs).

Each Colleague is responsible for adhering to Pfizer's policies regarding interactions with federal employees and lobbying activities involving government officials and public employees. Non-compliance with these policies puts the Company at risk and can subject Colleagues to disciplinary action up to and including termination.

Federal Employee Interactions

As Pfizer's sales to the federal government continue to increase, interactions with government officials (e.g., Director of Medicaid) and government employees (e.g., a physician at a federal institution or at a federal prison) are becoming common. Pfizer's customers include federal government agencies and institutions, including the **Department of Veterans Affairs (VA)** and its hospitals, and the **Department of Defense (DoD)** and its medical facilities. Pfizer colleagues may interact with HCPs who work for these government agencies and institutions and who are employees of the federal government.

Interactions with federal employees are governed by the Standards of Ethical Conduct established by the Office of Government Ethics ("Standards of Ethical Conduct") as well as the local site policies of each institution. In the case of VA employees, your activities are even further restricted by the more specific rules contained in Veterans Health Administration Handbook 1004.07 ("Financial Relationships



Between VHA Healthcare Professionals and Industry”). As a result, promotional activities that are permissible when conducted with HCPs who do not work for the federal government may be prohibited when these same activities are conducted with HCPs who work for the federal government.

Department of Veterans Affairs (VA): Federal agency that provides patient care, services and benefits to U.S. veterans.

Department of Defense (DoD): Federal agency that oversees the four branches of the U.S. military (Army, Navy, Marine Corps. and Air Force).

Key Points to Ensure Compliance

- Always check local VA or DoD site rules, which may be more restrictive than the guidelines set forth in this Chapter.
- If local site rules permit providing meals, then the following conditions must also be met:
 - Meals may not be offered on a regular, repeated or routine basis to an HCP or group of HCPs;
 - The total value of a single meal cannot exceed \$20 per HCP;
 - The total value of all meals and educational items during a calendar year cannot exceed \$50 per HCP; and
 - VA and DoD employees must confirm in advance that they are permitted to accept an in-office or in-hospital meal under the Standards of Ethical Conduct and the local site rules.
- Speaker program meals may only be provided to an HCP employed by a federal institution in connection with a “widely attended gathering” as described in this Chapter.
- Modest refreshments can be offered to federally-employed HCPs (including VA employees) when incidental to a scheduled meeting or legitimate educational interchange not otherwise prohibited by the facility or local rules. Modest refreshments are not considered “gifts” and do not count toward the \$50 annual cap for each government HCP. However, if you offer them as part of a meal, then they will count towards the \$50 annual cap and will be considered a “gift.”

Key Points to Ensure Compliance

- Only Review Committee approved (“RC-approved”) nominally priced educational materials may be provided to a government HCP. It is your responsibility to ensure that the annual aggregate value of all meals and educational items to a government HCP from Pfizer does not exceed \$50 annually.
- You must learn the sample policies of any institution that you call on and follow those rules, unless they conflict with Pfizer policy or the Prescription Drug Marketing Act (PDMA).
- Federally-employed HCPs may be hired to speak on Pfizer’s behalf only if they receive prior approval by their agency before accepting such an outside engagement and if the HCP:
 - Determines that the speaking engagement does not conflict with his or her official duties;
 - Is speaking in his or her individual capacity and not as an employee of the government;
 - Is not using his or her government position or title to identify himself or herself at the speaker program;
 - Is speaking because he or she is a subject matter expert on a topic;
 - Is not speaking on a matter pending before his/her government agency or institution, or any matter which the employee was assigned during the previous one year period;
 - Is taking personal time to speak rather than speaking during government time; and
 - Is not disclosing any non-public or government confidential information.



Promotional Activities

Impact of Formulary Status on Ability to Promote

Sales Colleagues must comply with any federal institution’s local requirement that only products on formulary be discussed with its HCPs. In some cases, local regulations will prohibit any discussion of products that are either not on the institution’s formulary or that are on the formulary with restrictions. In all cases, you must accurately and clearly represent the formulary status of the product being discussed.

Promotional Materials

Do not leave promotional materials in patient areas without first obtaining approval from the institution. In addition, be aware of rules pertaining to how you are expected to conduct yourself when leaving promotional materials for HCPs at federal institutions. For example, some institutions have particular requirements related to leaving promotional materials for non-formulary products.

Starters

Many government institutions, such as Department of Veterans Affairs (VA) clinics and hospitals, may prohibit pharmaceutical companies from leaving starters. Other government institutions that do accept starters generally require them to be provided to the Chief of Pharmacy and not to individual physicians. As noted above, you must always learn the sample policies of any institution that you call on and follow those rules, unless those rules conflict with Pfizer policy or the PDMA. If a Sales Colleague has questions about whether a customer’s sample policies are consistent with Pfizer policies on starter distribution, contact Starter Administration or the relevant Regional Attorney before leaving starters with that customer.

Even if intended for use in private practice, starters should not be left for VA or Department of Defense (DoD) physicians at the government institution in which they work. However, “free goods” may be provided to the VA as a donation as long as they are delivered through the VA’s normal channel of distribution (i.e., not from Sales representatives directly to HCPs).

VA Appointment Requirement



- Q. Do Sales Colleagues have to make an appointment before calling on HCPs who work at VA facilities?
- A. Always consult the local rule regarding appointments. However, best practice is to schedule appointments with all HCPs who work at VA facilities. Under the expired VHA Directive, pharmaceutical representatives were required to schedule all appointments in advance. Although the Directive has expired, some VA institutions have incorporated this requirement into their local site rules. Accordingly, you must review and comply with the site rules of any facility that you visit.

Providing Starters to the VA



- Q. I've been told by an HCP at a VA facility that pharmaceutical companies can leave starters with the Chief of Pharmacy at the VA. Why does Pfizer's policy prohibit this?
- A. VA policy permits "free goods" to be donated to the VA. To do this, the free goods must be delivered through the VA's normal channel of distribution – not from sales representatives. In addition, in most cases, the donation must be pre-approved by the Chief of Pharmacy and the local P&T Committee and the starters cannot be labeled as professional samples. The distribution of starters to VA facilities by colleagues does not comply with this policy and is prohibited.

Gifts to Federal Employees (HCPs at VA and DoD Facilities)

Under federal gift rules, a federal government employee may not accept any single gift that has a retail value of more than \$20, nor can a federal government employee accept an aggregate value of more than \$50 in gifts (retail value) from a single "source" given over a consecutive 12 month period. Pfizer, not each individual colleague, is considered the "source" of the gift when determining whether the \$50 limit has been reached. In order to avoid having to track the value of all gifts given to HCPs employed by the federal government and to ensure that Pfizer maintains compliance with the federal rules at all times, the only "gifts" that colleagues can provide to federal HCPs are Pfizer approved educational items and modest meals under the circumstances outlined in this Chapter.



Meals in Connection with Promotional Presentations

Colleagues must review the local site rules of any VA, DoD or other federal healthcare facility to determine whether in-office or in-hospital meals are permissible. When meals are permitted by local rule, in addition to following any site rules, you must also ensure the following conditions are met:

- Meals are not offered on a regular, repeated or routine basis to an HCP or group of HCPs;
- Each meal has a total value of \$20 or less;
- The aggregate value of all meals and educational items given by Pfizer to an HCP during a calendar year does not exceed \$50;
- The meal takes place at the HCP's office or hospital when hosted by a representative or District Manager; and
- The VA or DoD employee confirms that he or she is permitted to accept the in-office or in-hospital meal under the Standards of Ethical Conduct and local site rules.

Until December 31, 2008, VA Directive 2003-060 prohibited Colleagues from providing in-office or in-hospital meals, in most circumstances, to HCPs employed by the VA. However, the Directive has expired and has not yet been replaced. Presently, colleagues are permitted to provide meals to VA HCPs if they comply with the rules set forth in this Chapter and the particular institution's site rules.

Sales Colleagues must coordinate with each other to ensure that in total, Pfizer does not provide more than \$50 of value per HCP per year for meals and educational items.

Remember that any meals and educational items provided to HCPs employed by the VA, DoD or any federal government institution will be subject to Pfizer's HCP Payment Disclosure Policy. All HCPs, including those employed by the VA and DoD, may "opt-out" of receiving these items by notifying their sales representative or by contacting PTI@Pfizer.com. For additional information on Pfizer's HCP Payment Disclosure Policy, see Chapter 18: Meals, Educational Items, and HCP Payment Disclosure.

Meals in Connection with Speaker Programs

Meals may also be provided to HCPs employed by the federal government (including VA employees) as part of an off-site educational speaker program that is a "widely attended gathering" as determined by



the hosting colleague and with approval the colleague’s manager. In order to qualify as a “widely attended gathering” under Pfizer guidelines and the rules of the Office of Government Ethics:

- Attendance at the speaker program must be open to non-federal employees;
- A large number of people must be expected to attend;
- Persons with a diversity of views or interests must be expected to attend (e.g., persons from more than just one practice, specialty area, or government agency); and
- The government agency or branch the employee works for must determine that his/her attendance will further agency programs and operations.

In addition, the meal must be provided in connection with a legitimate educational speaker program that:

- Satisfies Pfizer’s standards for a speaker program as set forth in Orange Guide Chapter 9: Speaker Programs for HCPs; and
- Is not offered on a regular or repeated basis to the HCP.

If you are ever in doubt as to whether an event satisfies the “widely attended gathering” standard, check with the ethics counselor for the relevant government branch, and/or contact the relevant Regional Attorney. If an HCP you know to be an employee of the federal government indicates (by formal RSVP or otherwise) that he or she is coming to a speaker program you are planning, you must confirm with that HCP that his or her agency or branch has determined that attendance at the program is in the branch’s interest.

Lunch and Learn



- Q. A Sales representative would like to call on an HCP employed by the VA who has a busy schedule. Because of her crowded schedule, the HCP has offered to meet with the representative during her lunch hour every other Tuesday. May the representative have a “lunch and learn” with the HCP on alternating Tuesdays and bring a modest lunch, such as a sandwich and soda?
- A. No. Although the market value of each proposed lunch is modest (below the \$20 limit), it is improper to give gifts of any value, including meals, on a regular and recurring basis. If you ever have a question on what constitutes a regular and recurring gift, check with the ethics officer at the DoD facility and/or the relevant Regional Attorney.

Speaker Program Meals



- Q. A Sales Colleague has invited a DoD HCP to a speaker program that qualifies as a “widely attended gathering.” If the DoD HCP attends the speaker program after confirming in writing with her employer that attendance is in the best interest of the agency, is it permissible for the DoD HCP to receive the same meal as the other attendees if it’s more than \$20 in value? Or, is Pfizer required to provide a meal of \$20 or less in value?
- A. If a VA or DoD HCP attends a widely attended gathering with the permission of their employer, the meal is considered exempt from the federal gift limitations.

Providing Refreshments



- Q. I understand that light refreshments, like coffee and donuts, do not count toward the \$50 annual limit that government HCPs are permitted to accept from Pfizer. Will a VA HCP who accepts light refreshments (but not meals or other items) appear in Pfizer’s payment disclosures?
- A. Yes. Pfizer’s disclosures include all meals, refreshments and other approved items provided to HCPs, regardless of value. For additional information on Pfizer’s HCP Payment Disclosure Policy, see Chapter 18: Meals, Educational Items, and HCP Payment Disclosure.

Part-Time VA Employees



- Q. One of my customers works three days a week at his private practice and two days a week at a VA hospital. When I provide him meals at his private office, am I required to follow the VA/DoD limitations set forth in the Orange Guide?
- A. It depends. HCPs who work part-time for the VA are still required to follow the policies of the VA as if they are full-time employees. You should verify with your customer if he is employed by the VA, or if he is an independent contractor, in which case the rules governing interactions with VA employees may not apply. If your customer is an independent contractor or if you are not sure of his status, check with the ethics counselor of the government facility and/or your Regional Attorney to ensure compliance.

Educational Items

Remember that when given to a VA or DoD HCP, the value of the RC-approved educational item may not exceed \$20 and the total aggregate of all gifts (meals and educational items) for the calendar year to each HCP cannot exceed \$50.

Compliance Responsibility



- Q. If an HCP at a VA facility asks me to provide him with a gift, other than refreshments, isn't it the HCP's responsibility to make sure that he is in compliance with applicable gift rules? How can Pfizer get in trouble?
- A. It depends. Both the HCP and Pfizer have responsibilities under the federal gift rules. If Pfizer provides a gift to a federal HCP, it may trigger certain reporting obligations for Pfizer. In addition, providing the gift may violate the local institution's policies and result in Pfizer being excluded from the facility. Accordingly, at no time should you ever provide an HCP employed by the federal government with any gift or meal, except as described above, even if the item has been approved for distribution to non-government HCPs or the item is requested by the HCP. If you are ever in doubt, treat the HCP as if he or she was a government employee and follow the applicable rules herein and at the HCP's local facility.

Non-Promotional Activities

Selecting HCPs Employed by the Government as Speakers

HCPs employed by the federal government are generally prohibited from accepting compensation for speaking engagements that relate to the employee's official duties. This includes receiving compensation to speak to other HCP government employees on behalf of Pfizer. In limited circumstances, HCP federal employees may be compensated to speak on Pfizer's behalf if they are permitted by their government agency or institution to accept outside consulting engagements and they:

- Are speaking in their individual capacity and not as part of their official duties;
- Are speaking because they are a subject matter expert on a topic and not because of their official position;
- Are not speaking on a matter pending before their government agency or institution;
- Are speaking on their personal time rather than government working time; and
- Are not conveying information which draws on ideas or official data that is nonpublic information.

Before seeking to engage a speaker who works in any capacity for a federal government agency or institution, Sales Colleagues must first verify that the speaker has received prior approval from their agency or institution.

Engaging Part-Time Government Employees as Speakers



- Q. May I engage an HCP that works part-time at a federal government institution to be a speaker?
- A. Yes, provided the conditions listed above are met. HCPs who work part-time for a federal government agency are still required to follow the policies of that agency as if they are full-time employees. Of course, all of Pfizer policies related to engaging HCPs as speakers and properly conducting speaker programs must be followed.



Supporting Independent Medical Education

Federal government agencies and institutions often ask Pfizer to support their independent medical education programs. Pfizer may be permitted to support these activities through unrestricted educational grants. Grant requestors must submit all requests for funding through www.pfizermededgrants.com. Requests will be reviewed according to Pfizer's standards for supporting independent medical education. For more information on Pfizer's educational grant process, see the Support of External Organizations Chapter.

Lobbying

Federal and state lobbying laws regulate interactions with government officials and public employees that are intended to influence legislation, regulations or government policies. Pfizer is required by federal law and many state laws to publicly disclose its lobbying expenditures on a regular basis.

In 2007, Congress amended the Federal Lobbying Disclosure Act (LDA) in an effort to make lobbying activity and expenditure disclosure more transparent. Although the requirements of what must be disclosed remain largely the same, the Honest Leadership and Open Government Act (HLOGA) increased the number of times reports must be filed from twice a year to four times a year.

The LDA requires Pfizer to report expenses incurred for all its federal lobbying activities. This includes not only time and expenses spent by those Pfizer colleagues who are registered as federal "lobbyists," but also time and expenses of those Pfizer colleagues who support Pfizer's federal lobbying effort.

Pfizer's grassroots lobbying programs present additional opportunities for colleagues to interact with government officials and public employees about healthcare policy. To help ensure that Pfizer complies with all registration and reporting requirements, all of your interactions with government officials must be coordinated through a Pfizer Government Relations Director (GRD).

Like the rules that govern your interactions with healthcare professionals (HCPs), lobbying, ethics, gift and campaign finance laws regulate interactions with government officials and sometimes public employees as well. In addition to becoming familiar with the information in this Chapter, you should check with your GRD, relevant Regional Attorney or team attorney about the relevant laws in your



region, since the specific state or local laws applicable to you may vary depending upon the state in which you work.

Key Points to Ensure Compliance

- Only RC-approved nominally-priced educational materials may be provided to a government HCP.
- Government officials may be given RC-approved educational materials only—gifts of any value, including meals, are prohibited.
- Public employees may be given approved educational materials subject to each institution’s policies and applicable law.
- Every communication with a government official or his or her staff must be coordinated through the relevant GRD.
- Sales Colleagues should spend no more than one hour per week or four hours per month, if at all, on political activities related to Pfizer business.
- Do not suggest, offer or provide campaign contributions in exchange for a promise to perform any official act.
- Pfizer must report certain expenditures made towards lobbying efforts to the federal government as well as many state governments.
- Even if you are not a “lobbyist,” your time spent supporting the lobbying efforts of others within the Company is reportable under federal law.
- Each state’s reporting requirements are different – be sure to check with your Government Relations Director or team attorney if you are unsure whether you need to register as a lobbyist and/or which activities must be reported.
- For more information on state specific restrictions on interactions with state-employed HCPs, see the State Laws: HCP and State Employee Restrictions Chapter.

Who Is a “Lobbyist”?

Under the federal law, a “lobbyist” is any individual who is employed by Pfizer and has: (1) made more than one “lobbying contact” within a three-month period; and (2) spends at least 20% of his or her time engaged in lobbying for Pfizer in that three-month period.

This only pertains to Pfizer colleagues, and not independent contractors retained by Pfizer. A “lobbying contact” is any oral or written communication, including e-mail, with certain executive and legislative branch employees made with regard to federal legislation, a rule, regulation, or any other program, policy or position of the United States Government. Affected executive and legislative branch employees include Members of Congress and their staff, the White House, Secretary and Deputy Secretary positions within the federal agencies, and some members of the military.

Most Pfizer colleagues do not qualify to be registered as lobbyists because they do not spend 20% of their time “lobbying” during the reporting period (three-month intervals); however, it is important to remember that even if you are not a “lobbyist,” your time spent supporting the lobbying efforts of others within the Company is still reportable under federal law.

Calculating Lobbying Contacts



- Q. I am a Public Affairs Colleague. I called Congressman A’s office and spoke with a member of his staff to request the congressman call me back. Two days later, the congressman returned my call, and I explained I was calling about access to medication for the elderly, and we set up a time to meet. Does this count as two “lobbying contacts” for purposes of determining whether I am a lobbyist under federal law? I thought requesting meetings did not count as lobbying?
- A. This would likely count as one lobbying contact. The purpose of your first call was to contact the congressman, which you were unable to do. On the second call, however, you did speak with the congressman, and you explained the purpose of your call, which was to discuss some aspect of federal law or policy. While you did call to set up a face-to-face meeting, you also discussed policy issues during the telephone call. The two telephone calls would be considered one lobbying contact and the in-person meeting would count as a second lobbying contact.

Determining Time Engaged in Lobbying Activities

- Q. I am a Public Affairs Colleague. From time to time, I call congressional staff members and ask a series of prepared questions to gauge perceptions of healthcare issues or policy perspectives. Does the amount of time I spend on those calls factor into the 20% threshold for registering as a lobbyist?
- A. It depends. If the questions pertain to the status of legislation affecting Pfizer's interests, the calls may have been made in an effort to influence the congressional members for whom the staff members work, and the calls therefore would be considered lobbying contacts. If the questions constitute routine information-gathering and there is not an attempt to influence a covered official, then the communications will not amount to lobbying contacts. If you are unsure if your call would count towards the 20% threshold, please consult your GRD or team attorney. Remember, even if you do not qualify as a "lobbyist," you still may need to keep track of your time spent on some of these types of activities for the Company's federal lobbying disclosure report.

What Is Lobbying?

The LDA defines "lobbying activities" as lobbying contacts, as defined above, and any efforts in support of these contacts, including preparation and planning activities, research, and other background work intended for use in lobbying contacts. Reportable expenses include time spent by Pfizer colleagues in meetings with federal officials for the purpose of influencing federal laws, regulations or policies, and expenses incurred in connection with lobbying, such as expenses for travel, lodging or food. The LDA (as amended by HLOGA) requires Pfizer to file quarterly reports. The reports must provide a list of the specific issues that were addressed by "lobbying activities" and an estimate of the total expenses incurred in connection with the lobbying activities.

Although most Pfizer colleagues do not qualify as "lobbyists," the time Pfizer colleagues spend in *supporting* the lobbying efforts of others within the Company is reportable, including:

- Developing "talking points" or "white papers" if they are used for lobbying purposes;
- Attending internal meetings or discussions regarding lobbying strategy (e.g., identifying federal officials who should be targeted or developing and testing messages);



- Fees paid to outside consultants for analyses, studies or reports, if they are used for lobbying;
- Communicating with government officials as part of Pfizer’s grassroots lobbying programs;
- Negotiating contracts with government agencies;
- Providing educational information or materials to influence government formulary decisions; and
- Promotional interactions with certain state hospital administrators or HCPs.

The federal definition of lobbying does not include:

- Drafting and developing comments to proposed regulations in a *formal* agency rulemaking proceeding;
- Representing Pfizer in an agency adjudicatory matter or criminal proceeding;
- Drafting legislation, regulations or legal analyses (applicable to attorney work-product only);
- Preparing for and providing “on the record” testimony in a congressional or agency hearing;
- Requesting a meeting with a congressional or agency official or his or her staff, if the request does not include an attempt to influence the official; and
- Responding to a request by an official for reports, information, statistics, subpoenas or similar documents.

Pfizer’s grassroots lobbying programs include Pfizer in Action, Congressional District Captains, and certain other programs aimed at influencing the environment. There may be other activities developed by a State Action Team (formerly called the State Resource Team) or the Regional Council that involve interaction with government officials or public employees and would be subject to the Pfizer policies in this Chapter.

To help ensure that Pfizer complies with all registration and reporting requirements, all of your interactions with government officials must be coordinated through a GRD. If calling on HCPs who work for a state or federal facility or institution, check with your team attorney to find out whether your promotional activities are considered “lobbying” in your state.



Lobbying Do's and Don'ts	
Do	Don't
Provide only RC-approved educational materials to government officials	Discuss Pfizer products or specific Pfizer activities
Coordinate all your activities with government officials through your GRD	Spend more than one hour per week or four hours per month, if at all, on political and lobbying activities related to Pfizer business
Report your political and lobbying activities as required	Experiment or try something new without checking with your GRD or team attorney

Reporting Lobbying Time and Expense

As discussed in this Chapter, the laws in the state in which you work will determine whether you are engaged in "lobbying" activities which require Pfizer to register the time and expenses related to them.

If you have performed "lobbying activities," you must track and report the following on the form available at <http://ecf.pfizer.com/sites/LobbyingDisclosureReporting>.

- A reasonable estimate of the time spent on lobbying activities, rounded to the nearest hour;
- A description of the specific activity;
- The policy topic(s) worked on; and
- Any expenses associated with these efforts.

You can take a quick [online training module](#) on how to use the form. The form is on-line and can be accessed on a daily basis. You should fill it out only when you have engaged in federal lobbying activity. **Do not** fill it out when you have engaged in state lobbying activity (see the section on state-specific State Laws below). The information from the on-line form is collected for the Company's quarterly federal LDA reports which are filed on April 20, July 20, October 20 and January 20 of each year with both the U.S. House of Representatives and the U.S. Senate. **If you have engaged in federal lobbying activity during a reporting period, please make sure you complete an on-line form(s) no later than**

one week after the close of the reporting period, or by April 7th, July 7th, October 7th, and January 7th.

Determining Time Engaged in Lobbying Activities



- Q. When I fill out Pfizer’s lobbying form, I have to include the issue that pertained to the lobbying efforts I supported. If the work I did was about a particular Senate bill, can I just write the bill number?
- A. No, while the bill number must be reported under the law, the number alone is not a sufficient description of the issue for purposes of disclosing Pfizer’s lobbying contacts and filing the Federal report. You should try and be as specific as possible, and include, in addition to the bill number, the bill’s name, the bill title and/or section heading if one exists, and the specific provisions that were the subject of your work.

If ever in doubt, consult with a GRD or your team attorney to verify whether your activities subject you to registration or reporting requirements.

Gifts to Government Officials

Like the PhRMA Code’s guidelines on gifts to HCPs, almost all states and the federal government prohibit or restrict officials and their staff from accepting gifts from outside sources.

Pfizer colleagues are prohibited from giving any gift to a government official, no matter how inexpensive. Prohibited gifts include meals (food and beverage), travel, lodging, and entertainment. The only items that may be provided to government officials are RC-approved educational materials of nominal value.

Gifts to Public Employees

HCPs in government institutions, such as VA hospitals or federal or state prisons, are considered to be public employees. Unless otherwise restricted by state law or a particular institution’s policies (such as with the VA), Pfizer policy permits Sales Colleagues to provide public employees with RC-approved and nominally priced PhRMA Code compliant educational items. For more information on state specific laws, see the State Laws: HCP and State Employee Restrictions Chapter. If you have any questions about whether an item can be left with a public employee, consult with a GRD or your team attorney.

Leaving Educational Items with Public Employees



- Q. If I leave RC-approved, nominally priced educational (PhRMA Code compliant) items with an HCP at a federal prison, do I have to track it? What about a state prison system?
- A. Yes. Under Pfizer’s HCP Payment Disclosure Policy, educational items valued \$10 or more must be disclosed and items valued less than \$10 may also be subject to disclosure so all items must be tracked for reporting purposes. Also, a reporting obligation may be triggered under applicable state law. Because state laws differ by state, it is imperative that you check with your Regional Attorney before leaving any item with an HCP at a state prison.

HCPs Who Sit on State Formulary Committees



- Q. One of the physicians I call on also happens to sit on a state formulary review committee. If I am calling on this physician to discuss his private practice only, and not his role on the state formulary review committee, must I treat him differently than any other physician who does not sit on a formulary committee?
- A. Maybe. The extent to which HCPs who sit on state formulary committees can interact with pharmaceutical representatives varies widely, depending on the specific laws in your state. Check with the relevant Regional Attorney to ensure your interactions are compliant with applicable state law.

State-Specific Laws

There are two types of lobbying disclosure laws enacted by states that may require you to record and report certain information. The first category is similar to the federal LDA and requires Pfizer to report on a regular basis the lobbying activities undertaken in or directed towards a particular state. The second category affects colleagues who meet with certain state officials or state employees.

States’ General Lobbying Disclosure Laws

Pfizer has a State Government Affairs program which is active in almost all 50 states. As part of this effort, Pfizer Inc. and/or Pfizer colleagues have registered as lobbyists and have reporting requirements similar to those on the federal level. The laws differ in each state. Depending on the particular state law, if you participate in Pfizer’s grassroots advocacy programs and other interactions with state government officials or public employees, Pfizer may be required to register you as a lobbyist or make



certain disclosures about your activities. If you have questions regarding whether your participation in state lobbying activities triggers disclosure requirements, you should consult with the GRD responsible for the state. If the GRD determines that you are required to disclose your activities, you will receive a compliance form or timesheet to complete.

Reportable lobbying activities and expenses may include:

- Meetings with government officials or staff;
- Time spent reviewing policy issues in preparation for a meeting with government officials;
- Time spent communicating, including by letter or e-mail, with government officials about policy issues; and
- Any food, travel, lodging or other expenses you may incur while engaged in lobbying activities.

State procurement or contract lobbying laws may also apply to you if you are involved with the sale of Pfizer products to state institutions (such as public hospitals and state prisons), or their reimbursement through state agencies (such as Medicaid). These laws seek to prevent inappropriate influence over state employees responsible for purchasing products with taxpayer money.

While procurement and contract lobbying laws vary from state to state, most involve registering individuals who interact with state officials regarding state purchase contracts and disclosing lobbyist compensation and lobbying expenses incurred, such as meals (i.e., food and beverage), travel and lodging. To ensure appropriate tracking and disclosure, check with a GRD or your team attorney before engaging in these or related activities.

States' Lobbying Laws Impacting Marketing

Several states have enacted laws that require pharmaceutical representatives who interact with state officials or state employees to register with the state and report their "lobbying" expenditures. **In particular, numerous states have laws which may consider marketing activities involving Medicated Pharmaceutical and Therapeutics Committee members as lobbying.** For example, when certain threshold limits are met, Louisiana requires pharmaceutical representatives to register with the



Board of Ethics and file semi-annual reports detailing expenditures as they relate to marketing activities directed towards members of the Medicaid Pharmaceutical and Therapeutics Committee.

In Colorado, an amendment to the Colorado Constitution prohibits individuals considered lobbyists from giving anything of value, including gifts and meals, to government employees. Various other states, and even counties, also have lobbying registration and disclosure requirements (e.g., New York and Miami-Dade County, Florida). To ensure that expenses and interactions are properly tracked, please consult with the relevant Regional Attorney before engaging in any marketing interactions with state or local government employees.

State Formularies

Attempts to influence state formulary decisions is currently considered lobbying in many states. As a result, registration and/or reporting may be required. If you are interacting with members of a state committee or agency that make decisions with respect to their state's formulary you should check with the GRD with responsibility for that state prior to those interactions to determine whether any of your activity could be considered lobbying.

Each Pfizer colleague is responsible for adhering to Pfizer's policies regarding lobbying registration and disclosure. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination.

Campaign Contributions

It is important to understand the difference between lobbying and grassroots efforts and campaign contributions. Lobbying and grassroots efforts are intended to influence government policy. Campaign contributions are intended to influence campaigns and elections.

While corporations like Pfizer are permitted to lobby government officials, federal and various state laws prohibit corporations from making financial contributions to support a candidate's election. This prohibition applies to both monetary and "in kind" donations, such as employee time and the use of corporate resources on behalf of a campaign committee.



In addition, federal and state anti-bribery laws impose criminal penalties for offering gifts or campaign contributions to government officials in exchange for a change in policy, entering into a federal or state contract, or agreeing to engage in any other official act.

For this reason, you are prohibited from discussing past, present or future campaign contributions with a government official or public employee.

The Pfizer Political Action Committee

Corporations are not allowed to make direct contributions to any candidates running for federal office, and similar restrictions may apply in certain states as well. However, corporations can sponsor political action committees (PACs), which are supported by voluntary contributions from eligible employees. These corporate-sponsored PACs can then contribute directly to candidates running for federal office and for state office where applicable. A PAC is subject to federal laws and regulations, reporting requirements and monetary limits on campaign contributions.

Pfizer sponsors a PAC. The Pfizer PAC is a non-partisan PAC that supports candidates who value biopharmaceutical innovation and are open to real dialogue on healthcare reform. For more information on the Pfizer PAC, please visit www.epacweb.com/Pfizer.

Before interacting with any federal or state government official or public employee in a way not described here, seek guidance from a GRD or your team attorney.

FOR MORE INFORMATION

- Lobbying questions may be referred to the relevant GRD or team attorney.
- For more information on state specific laws, see the State Laws: HCP and State Employee Restrictions Chapter.
- For more information on Pfizer’s HCP Payment Disclosure Policy, see the Meals, Educational Items and HCP Payment Disclosure Chapter.
- For more information on Pfizer’s educational grant process, see the Support of External Organizations Chapter.



- For more information about the Pfizer PAC, visit www.epacweb.com/Pfizer.
- Take the online training module on how to complete the federal Lobbying Disclosure form.
- Federal Employee Interaction questions may be referred to your manager or team attorney.



Chapter 5: PAYMENTS TO MANAGED CARE CUSTOMERS

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Chapter 5: PAYMENTS TO MANAGED CARE CUSTOMERS

Introduction

In 2009, Pfizer entered into a Corporate Integrity Agreement (CIA) with the U.S. Department of Health and Human Services, Office of Inspector General (OIG). The 2009 CIA is discussed in detail in Chapter 1: Overview and Key Principles. In 2002, Pfizer entered into a different CIA in connection with allegations that it provided an improper educational grant to a managed care organization. Under the terms of the 2002 CIA, Pfizer agreed to observe certain integrity obligations. The Managed Care Review Committee (MCRC) was created to facilitate that observance.

The MCRC facilitates the review and approval of proposed non-rebate payments and other transfers of funds to managed care customers and/or their affiliates.

The MCRC provides a streamlined evaluation process to:

- Examine whether proposed transactions with managed care customers would be appropriate by analyzing whether such transactions comply with both Pfizer policy and legal and regulatory standards; and
- Ensure that all payments related to such transactions are appropriately documented and such documentation is readily available and accessible for audits.

The MCRC does not approve any actual payments. Rather, the MCRC reviews and approves proposed transactions and related documentation.

A managed care customer is a non-governmental entity whose principal business is to manage or provide pharmacy and/or other health benefits. If your interaction with a managed care customer involves any type of non-rebate payment or transfer of funds to that customer, you must review the MCRC policy to determine whether MCRC approval is required before any payment can be made or activities associated with the payment can be undertaken. You can access the MCRC policy and related



information by clicking on the “Information about Managed Care Customers and MCRC” link on the [PfieldNet Compliance Page](#).

Each Colleague is responsible for adhering to Pfizer's policies regarding MCRC review. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination.

Key Points to Ensure Compliance

- Always obtain MCRC approval before entering into or agreeing to any arrangement with a managed care customer that involves a non-rebate payment or other financial support. If you are unsure whether a transaction requires MCRC approval, check with your Regional Attorney.
- Send all transactions with managed care customers to the MCRC for review and approval well in advance of the proposed program or activity date (i.e., at least 4–6 weeks prior to the proposed activity date).
- Never promise or imply that funding for any activity or arrangement will be approved until notified by MCRC.
- Direct all requests for educational grants and charitable contributions from a managed care customer to the Medical Education Group (MEG) website at <https://www.pfizermededgrants.com>.
- Regularly check the list of current managed care customers, which you can view by clicking on the “Information about Managed Care Customers and MCRC” link on the [PfieldNet Compliance Page](#).
- Contact the MCRC Coordinator at ManagedCareRC@pfizer.com if you identify a customer that you believe meets the definition of a managed care customer but is not included in the managed care customer list.



The Managed Care Legal Review Process

Managed Care Customer Defined

Pfizer defines a managed care customer as a non-governmental entity whose principal business is to manage or provide pharmacy and/or other health benefits. Such customers include Health Maintenance Organizations (HMOs), **Pharmacy Benefit Managers (PBMs)**, Preferred Provider Organizations (PPOs) and affiliated entities. If you are a Corporate and Government Customers (CGC) Account Manager, most of your assigned accounts are likely to be considered managed care customers, and your interactions with them must be appropriately conducted and documented so as to prevent potential legal issues. Pfizer has special policies and procedures, such as requiring MCRC review, to ensure that your interactions with managed care customers, especially those that involve proposed payments, are in accordance with Pfizer policy.

Pharmacy Benefit Manager (PBM): a third party administrator of prescription drug programs that is primarily responsible for processing and paying prescription drug claims as well as developing and maintaining formularies, contracting with pharmacies, and negotiating discounts and rebates with drug manufacturers.

You can view a list of current managed care customers by clicking on the “Information about Managed Care Customers and MCRC” link on the [PfieldNet Compliance Page](#). This list of managed care customers was created using information about their corporate structures and affiliations, as well as federal tax identification numbers. Some managed care customers have complex corporate structures and multiple federal tax identification numbers. As a result, a company that you might not think is a managed care customer subject to MCRC review may need to be treated as one because of its corporate affiliation with a managed care customer. For this reason, it is especially important that you regularly review the list of managed care customers for updates. A customer's status can change at any time.

If you believe a customer may be a managed care customer but you do not see it on the posted list of Pfizer managed care customers, contact the MCRC Coordinator at ManagedCareRC@pfizer.com for a determination of that customer's status.

Hospitals Affiliated with Managed Care Customers



- Q. Would a hospital affiliated with a managed care customer also be considered a managed care customer, requiring MCRC review?
- A. Yes. Managed care customers include the customer and all its affiliated entities, such as a hospital.

State Medicare, DoD and VA



- Q. Is a state Medicaid agency, DoD facility or VA facility considered a managed care customer for purposes of MCRC review?
- A. No. Managed care customers include non-governmental institutions, like HMOs and PBMs. They do not include governmental institutions. Nor do they include employers, long-term care groups or private medical groups.

Interactions that Require MCRC Review

The MCRC must review all proposed financial transactions with managed care customers that involve non-rebate payments. MCRC approval is required before payments can be made or activities associated with payments can be initiated. Therefore, you must submit the required documentation to MCRC for review and approval prior to entering into any arrangement with a managed care customer involving payment or financial support. You must **never** promise payment until approval by the MCRC has been confirmed.

The following are examples of types of funding or payment requests related to managed care customers and their employees that require MCRC approval:

- Exhibits and Displays
- Collaborations
- Formulary Stickers
- Market Data Purchases
- Push Through Formulary Communications
- Push Through Medication Adherence
- Service Agreements
- Product Information Co-Promotes

Examples of interactions and payments to managed care customers that fall outside the scope of MCRC review include Clinical Trials, Employee Benefits, Gifts and Business Courtesies, Corporate Sponsorships, Speaker Programs, Insurance Premiums, and Patient Assistance Programs.

Please contact the MCRC Coordinator at ManagedCareRC@pfizer.com if you need additional guidance regarding the types of transactions that require MCRC review.

Amendments and Changes to Service Agreements



- Q. There is a current service agreement in effect for a managed care customer to execute a lipid adherence program. The customer has agreed to add a hypertension adherence program to the initiative. Does the addition of this adherence program have to be submitted to the MCRC if the existing agreement was already approved by the MCRC?
- A. Yes. Amendments and changes to existing agreements involving payments to managed care customers must be sent to the MCRC for review and approval.

Required Documents for MCRC Submissions

Required documentation varies depending on the type of proposed interaction. A list of required documents can be found on the MCRC submission form. For additional guidance on the documentation that is required for MCRC review, please contact the Program Activities Coordinator (PAC) in your Regional Office or the CGC Legal Team.

MCRC Submission Process

With the exception of educational grants and charitable contributions, which follow the MEG submission process below, you must submit the required documentation to MCRC at least four (4) to six (6) weeks before the activity date to allow sufficient time for MCRC review.

Managed care customers must submit all requests for unrestricted educational grants and charitable contributions online directly through the Medical Education Grants (MEG) website at <https://www.pfizermededgrants.com>. For more information about MEG and the application process for unrestricted educational grants and charitable contributions, see the Support of External Organizations Chapter.



Frequency of MCRC Review

Submissions for interactions that require MCRC review will be evaluated weekly. The projected turnaround time for submissions is about one week from the time a completed file is submitted to the MCRC for review. Incomplete submissions or those requiring additional follow-up may take longer to review. Once a decision has been made about your proposed interaction, you will receive notification either by e-mail or directly from a MCRC representative. Please e-mail all questions about the status of your submission to ManagedCareRC@pfizer.com.

FOR MORE INFORMATION

- For more information about the MCRC, including MCRC forms and a list of managed care customers, visit <http://pfieldnet.pfizer.com/compliance> and select the “Information about Managed Care Customers and MCRC” link. You may also contact the MCRC Coordinator at ManagedCareRC@pfizer.com.
- For more information about the 2009 CIA, see Orange Guide Chapter 1: Overview and Key Principles.
- Questions may be referred to your manager, Regional Attorney, a member of the CGC Legal Team, or the MCRC Coordinator at ManagedCareRC@pfizer.com.



Chapter 6: CLINICAL RESEARCH AND INVESTIGATOR-INITIATED RESEARCH

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Chapter 6: CLINICAL RESEARCH AND INVESTIGATOR-INITIATED RESEARCH

Supporting Legitimate Medical Research

Pfizer engages scientists, healthcare professionals (HCPs), research institutions, and academic institutions to conduct research and development, including in vitro experiments (discovery), pre-clinical animal studies, and clinical studies. Research sponsored by Pfizer, as well as research that Pfizer supports that is sponsored by others, can generate important information about Pfizer products as well as valuable medical and scientific information that can lead to improvements in clinical care, the development of new treatments, and better delivery of healthcare to patients.

Pfizer-sponsored clinical studies are designed, conducted, overseen, and analyzed by Pfizer. Thus, Pfizer is generally responsible for all of the regulatory obligations applicable to research and development. Pfizer also provides support for studies designed and sponsored by outside investigators or institutions, referred to as **investigator-initiated research (IIR)** studies. Pfizer may choose to support IIR studies that advance medical and scientific knowledge and are of interest to Pfizer through a grant, but Pfizer is not the sponsor of IIR studies. With limited exception, IIR grants may not support studies that involve new product registration, a change in product labeling, or other regulatory efforts. (See the section on Collaborative IIRs in Clinical Trial SOP CT25 for additional information on using IIR data for regulatory submissions.)

For many HCPs, conducting pharmaceutical company-funded medical research can be a significant source of income. As a result, selecting an HCP to be a **clinical investigator** or to receive a grant for IIR from Pfizer could raise significant issues under the healthcare laws if done for the wrong reasons.

Investigator-Initiated Research (IIR): a grant to support an investigator, institution or organization (e.g., cooperative group, government agency or network) that will be the sponsor of a study that is designed for the development of specific and defined medical knowledge. IIR support may be provided in the form of funding and/or study medication.

Clinical Investiagor: a medical researcher who carries out a clinical trial or another type of clinical research.



As with other financial transactions that occur between Pfizer and HCPs, attempting to influence an HCP's prescribing behavior by providing money for research is illegal. The impact on an HCP's prescribing behavior must not be taken into consideration when deciding whether to engage him or her as an investigator, or fund or support his or her independent medical research.

All requests for medical research support must be referred to Pfizer Medical Colleagues. Only Pfizer Medical Colleagues may commit to and provide funding and/or drugs for medical research, in accordance with applicable Clinical Trial SOPs.

Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination.

Key Points to Ensure Compliance

- All decisions to engage a physician as a clinical investigator or to provide support for an IIR study must be made by colleagues in a medical, clinical or scientific function.
- Funding or other support for medical research may never be provided to:
 - Establish or improve Pfizer's relationship with an HCP;
 - Gain or improve access to an HCP;
 - Reward past prescribing or induce future prescribing; or
 - Influence an upcoming formulary decision or reward a past formulary decision.
- Do not attempt to influence a decision by Pfizer's Medical Division to hire clinical investigators or award grants for IIR based on the potential impact to Pfizer sales.
- Do not provide starters (samples) to HCPs for use in clinical trials.

Types of Funding or Support

Pfizer will only fund and support legitimate medical research. Such research must seek to answer a genuine scientific or clinical question through the researcher's active scientific pursuit. The researcher must be qualified to conduct the intended research, and be selected on the basis of his or her applicable



experience and training. Compensation will be based on the value of the research services provided. Pfizer's reason to support an HCP's medical research must **never** be to:

- Establish or improve Pfizer's relationship with the HCP;
- Gain or improve access to the HCP;
- Reward past prescribing or induce future prescribing; or
- Influence formulary decision making.

Payments to HCPs may violate federal or state anti-kickback laws if such payments are made to reward or influence the recipient's prescribing practices or to establish or improve Pfizer's relationship with an HCP. In addition, both the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals (PhRMA Code), and the U.S. Department of Health and Human Services, Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers, forbid the use of "token" consulting arrangements, which might include payments to investigators to encourage the use of a Pfizer product or to reward an investigator for previous use of a Pfizer product, rather than to address a genuine scientific issue or obtain meaningful clinical information. Pfizer policies and procedures, including Direct-to-Consumer (DTC) Clinical Trials Standard Operating Procedures (SOPs), help ensure that Pfizer-sponsored clinical research and Pfizer support of IIR studies comply with applicable healthcare laws, regulatory requirements, ethical standards, and Pfizer-endorsed industry guidelines.

Pfizer-Sponsored Trials

Pfizer-sponsored trials are those studies that are designed, conducted, supervised and funded by Pfizer and where Pfizer holds regulatory responsibility. Pfizer compensates investigators who participate in these trials based on the fair market value of their expertise and effort in conducting the research.

Pfizer-Sponsored Trials: studies that are designed, conducted, supervised and funded by Pfizer and where Pfizer holds regulatory responsibility.

HCPs often ask colleagues how they can be hired as clinical investigators. Pfizer's decision whether to hire an HCP must be made without regard to the HCP's prescribing history or relationship with Pfizer.

You may never commit to hiring an HCP as an investigator or make any other promises relating to the hiring of an HCP as an investigator. All decisions about clinical investigators must be made by the Pfizer Medical Division.

For guidance on responding to HCP questions about participation in Pfizer-sponsored research or clinical trials, see the section titled “Responding to Requests from HCPs Regarding Medical Research” found later in this chapter.

Clinical Studies and Prescribing Habits



- Q. A very influential physician is reluctant to prescribe a certain Pfizer product. Can I recommend to my Regional Medical Research Specialist (RMRS) that this physician be selected as an investigator in an upcoming clinical trial for that product so that he can gain additional first-hand experience on the product’s use?
- A. No. You may not recommend a physician to be an investigator if a purpose for choosing the physician is to influence prescribing habits. Investigators must be selected solely on their research experience and clinical training, not on their current or future prescribing habits.

Investigator-Initiated Research Grants

Pfizer provides support to investigators, institutions or organizations (e.g., cooperative groups, government agencies, or networks) that sponsor studies that advance medical and scientific knowledge and are of interest to Pfizer. These grants may be in the form of money, study medication or pure substance. Pfizer may not design, conduct, or supervise IIR studies. Rather, they must be conducted independent of any influence or guidance by Pfizer. The evaluation of an IIR request cannot be influenced by an investigator’s, institution’s or organization’s generation of past or potential future business for Pfizer.

All proposals for an IIR grant must be referred to your RMRS or Asset Team Medical Colleague, who will ensure that the proposal is submitted through the application website at www.pfizer.com/iir (as required by SOP CT25). Such proposals will then receive requisite medical evaluation. Because IIR support could potentially influence prescribing patterns, the decision to fund an IIR study must be made without any input from the Sales Division. This minimizes the risk that an HCP’s past support of Pfizer or future prescribing habits might be considered in any grant decision.

Investigator-Initiated Research Grant



- Q. I am developing a relationship with a customer who is an expert in her field and who does a significant amount of clinical research involving a Pfizer drug. She is seeking funding for a research proposal. Is it OK for me to suggest she submit a proposal for an IIR grant?
- A. Yes, within limits. Sales Colleagues must not proactively solicit the submission of IIR proposals by their customers. However, if a customer independently expresses an interest in applying for research funding, it is permissible to suggest that the physician submit a proposal for an IIR grant, as long as you have no other involvement in the request or funding decision and you do not create the impression that you can influence the funding decision. It is your responsibility to ensure that the HCP understands that all funding decisions are made independently by the Pfizer Medical Division based upon the scientific merits of the proposal. Further, you should never attempt to influence a funding decision made by Pfizer's Medical Division. When you speak with the HCP about Pfizer's IIR program, do not make any promise or suggestion that the IIR proposal will be funded or assist in any way in drafting the IIR proposal. Information about the requirements and application process for IIR grants can be found at www.pfizer.com/iir.

Requests for Study Medication or Pure Substance

A request for study medication to support legitimate medical research should be referred to your RMRS for consideration as an IIR grant request. Likewise, requests for pure substance (for pre-clinical studies) should also be referred to your RMRS. Starters may never be used for clinical trials, and it is inappropriate for you to try to obtain or promise samples for any research purposes.

"Compassionate Use" Requests

From time to time, you may receive requests from HCPs to provide one of Pfizer's investigational drugs for a seriously ill patient. Such requests on behalf of patients are called "compassionate use" requests. To meet the criteria for a compassionate use request, a seriously ill patient must have exhausted all approved treatment options as well as all opportunities to participate in clinical trials.

If a physician asks you about compassionate use of a Pfizer product, refer the inquiry promptly to Pfizer Medical Information. The Pfizer Medical Colleagues assigned to the relevant drug are the only individuals at Pfizer authorized to approve compassionate use requests. Remember, you must never



discuss unapproved products or indications with HCPs, and you must direct all requests to Pfizer Medical Information.

Responding to Requests from HCPs Regarding Medical Research

You may be asked by HCPs for information on being a clinical investigator for a Pfizer clinical trial or to provide financial or other support for their independent medical research. Because these requests often involve requests for compensation, how you respond has both federal and state healthcare law implications.

Responding to Requests to be a Clinical Investigator

Not all interested HCPs will qualify to be clinical investigators. In addition to requiring appropriate expertise and training, being a clinical investigator may require a significant financial investment. For example, the HCP may be required to make changes to his or her office to accommodate research patients, study monitors, additional equipment and secured storage for both drugs and files. The HCP will also need to have knowledge of informed consent and patient protection issues.

For more information on managing an HCP's expectations about clinical trials, go to the "Clinical Investigator Submission Tool" at <http://fieldsites.pfizer.com/pfieldnet/MI/MAG.asp>. There you may register the HCP in Pfizer's investigator database and order the *So You Want to Be a Clinical Investigator* pamphlet (publication ID WX269X01) to provide to HCPs interested in learning more about the application and funding process.

Referring Physicians to be Clinical Investigators for Pfizer-Sponsored Studies

- Q. As part of our overall plan to improve Pfizer’s relationship with a key institution, my team wants to alert qualified physicians to (non-IIR) Pfizer-sponsored research opportunities. Is this OK?
- A. Yes. It is permissible to encourage physicians who, based on their training and experience, would be appropriate investigators to seek out opportunities to participate in Pfizer-sponsored studies. It would not be permissible, however, to encourage Pfizer Medical Colleagues to select these physicians to be investigators or show them any special treatment. Decisions on who shall be engaged as clinical investigators must be based on the physicians’ expertise, training, and other relevant factors, such as availability of appropriate facilities and staff, and access to the target population of study participants, and not on their potential prescribing of Pfizer products.

No Assistance with IIR Protocols

All protocols for IIR studies must be written by the sponsor or principal investigator, not by Pfizer. Colleagues may not write protocols for independent investigators. If you receive a request from a sponsor or principal investigator for assistance with this process, you must direct the applicant to the Pfizer Medical Division.

No Assistance with Patient Recruitment

It is not appropriate for members of Pfizer’s sales force to assist investigators in recruiting patients for Pfizer-sponsored studies or IIR studies. Similarly, it is not permissible for you to offer additional compensation to an investigator in order to offset higher than expected recruitment costs. Any requests for additional funding must be made directly to the Pfizer Medical Division.

Collaboration with Physicians on Questionnaires and Surveys

- Q. May I provide protocols for surveys, data collection tools, or other materials to my physicians to help them conduct patient research about different interventions?
- A. Yes. You may provide only those protocols for surveys, data collection tools and other materials that have been approved for promotional use by a Pfizer Review Committee. You are prohibited, however, from customizing any approved material for particular physicians or institutions unless such customization is also approved by a Pfizer Review Committee.



FOR MORE INFORMATION

- For more information on managing an HCP's expectations about clinical trials, visit <http://fieldsites.pfizer.com/pfieldnet/MI/MAG.asp> and click on the "Clinical Investigator Submission Tool".
- More information on IIRs can be found at the Investigator-Initiated Research website www.pfizer.com/iir.
- More information on participating as a clinical investigator can be found at <http://iq.pfizer.com> available on <http://pfieldnet.pfizer.com/Pages/Welcome.aspx>, and questions can be e-mailed to IQ@pfizer.com.
- Questions may be referred to a Pfizer Medical Colleague, your manager, or Pfizer Legal Counsel.



Chapter 7: P&T COMMITTEE INTERACTIONS

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Chapter 7: P&T COMMITTEE INTERACTIONS

P&T Committees

Many healthcare organizations, such as hospitals, state Medicaid agencies, and managed care organizations, maintain lists of preferred drugs that can be prescribed by healthcare professionals (HCPs) within the organization or that are eligible for reimbursement by the organization. These lists are commonly called formularies. The **Pharmacy and Therapeutics (P&T) Committee** of an organization decides which pharmaceutical products are included on the formulary.

Pharmacy & Therapeutics (P&T) Committee: the committee within an institution or managed care organization that decides which pharmaceutical products are included on the formulary.

P&T Committees typically make formulary decisions based upon assessments of safety, efficacy, tolerability and, increasingly, cost-effectiveness. In some cases, organizations with P&T Committees may be acting on behalf of Medicaid, Medicare Part D or other government healthcare programs. P&T Committee members are charged with an important responsibility and therefore are expected to avoid both actual and perceived conflicts of interest when making formulary decisions. It is Pfizer policy not to engage in any activity that could be construed as improperly influencing the independent judgment of a P&T Committee member. In fact, consistent with the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals (“PhRMA Code”), any HCPs hired by Pfizer as speakers or consultants who also serve as members of a P&T Committee must disclose to the Committee the existence and nature of his or her relationship with Pfizer. This requirement should generally extend for at least two years beyond the termination of any speaker or consulting arrangement.

Non-compliance with these policies puts the Company at risk and can subject colleagues to disciplinary action up to and including termination.

Key Points to Ensure Compliance

- Interact with P&T Committee members the same way you interact with other HCPs – by following the four Core Compliance Principles.
- Do not show HCPs "special treatment" because of their status on a P&T Committee and notify your manager promptly if a committee member requests "special treatment." Note, however, that the mere increase of detailing or calls during a pending formulary decision in and of itself is generally not considered "special treatment."
 - Treat a P&T Committee member the same as you treat any HCP.
 - Do not treat a P&T Committee member any differently during a pending formulary decision than at any other time.
 - Call on a P&T Committee member as a normal part of business.
- Do not engage in any activity that could be construed as improperly influencing the independent judgment of a P&T Committee member.
- Do not link any financial transactions (other than disclosed rebate or discount arrangements) to formulary decisions or formulary placement of a Pfizer product.
- Direct all questions about **off-label information** to Pfizer Medical Information. If such a request is submitted to you in connection with an upcoming P&T Committee formulary review, you may also contact a Regional Medical Research Specialist (RMRS) or Medical Outcome Specialist (MOS), depending on the question, to ask that he/she present and respond to the Committee if appropriate.
- During P&T Committee presentations where both Medical and non-Medical Colleagues are present, colleagues are prohibited from participating in any discussion on unapproved or off-label information.

Off-Label Information: statements about a product's safety or efficacy which are not consistent with the product labeling. Examples include: (1) statements about an unapproved use; (2) statements regarding efficacy within a population of patients excluded from studies of the product; and (3) statements about safety that minimize or are inconsistent with the information in the package insert.

Interacting with P&T Committees and Members

Day-to-Day Interactions

It is likely that you will come in contact with P&T Committee members as part of your normal Pfizer activities. Your day-to-day interactions with P&T Committee members are governed by the same policies that govern your interactions with other HCPs. The four Core Compliance Principles (as discussed in Orange Guide Chapter 2: Detailing to HCPs) will guide you in these interactions:

- Use only RC-approved materials and selling statements;
- Stay on-label and discuss only approved products and indications;
- Provide an accurate and balanced presentation; and
- Never engage in actual or perceived quid pro quo.

When interacting with HCPs who may also be P&T Committee members, you must:

- Not show them "special treatment" because of their status on a P&T Committee (notify your Manager promptly if a committee member requests special treatment);
- Not discuss an HCP's P&T Committee membership status with other colleagues in a manner that implies preferential treatment based on their committee membership; and
- Not treat P&T Committee members differently during a pending formulary decision than at other times.

Questions From a P&T Committee Member About Their Status

- Q. If a physician asks if I know whether he or she is a P&T Committee member, what should I say?
- A. Always answer truthfully. While P&T Committee members often do not wish to be identified as such, answering honestly is the best way for you to demonstrate the core value of integrity with the HCP.

Buying Lunch for a P&T Committee Member

- Q. If I run into a member of a P&T Committee in the hall at a hospital, may I offer to buy him or her lunch and discuss the benefits of a Pfizer product while we eat?
- A. Yes, as long as the hospital's P&T Committee does not restrict this type of interaction. Your interactions with P&T Committee members are governed by the same Pfizer policies that govern your interactions with HCPs. If the hospital doesn't prohibit it, Pfizer policy permits you to engage in a product promotional discussion over an occasional modest meal. Pursuant to the PhRMA Code and Pfizer policy, field colleagues (PHRs, TSRs, DMs, and CSs) may only provide a meal to HCPs at in-office or in-hospital settings and in conjunction with informational presentations/discussions.

Calling on a P&T Committee Member Not in Call Cycle

- Q. A physician on a state Medicaid P&T Committee is in my territory but is not part of my normal call cycle due to low prescribing potential. Can I still call on him to discuss the clinical benefits of my products as they relate to his Medicaid duties?
- A. Maybe. Presenting product information to an HCP who is a member of a state Medicaid P&T Committee is appropriate as long as the guidelines in this Chapter are followed. However, you should consult with your manager before adding the HCP to your call cycle.

Calling on a P&T Committee Member During a Formulary Decision

- Q. If an HCP who is a P&T Committee member is part of my normal call cycle, can I call on the HCP more frequently when I know that there is a pending formulary decision for one of the products I carry?
- A. Maybe. Increasing the number of calls to the HCP in and of itself is not considered "special treatment" and may be appropriate so long as the provisions of this Chapter are followed and the purpose for the increase in call volume is to provide relevant on-label information for the HCP to consider in making a decision. However, you should consult with your manager before deciding to call on an HCP more frequently under these circumstances.

Generating Support for Formulary Placement

The appropriate way in which to attempt to influence P&T Committee members is by advocating for Pfizer products based on the strength and weight of the scientific, medical and clinical evidence. Remember that any discussions you have with an HCP regarding an upcoming formulary decision are governed by Pfizer's policies on product promotion, including the four Core Compliance Principles, at all times.

“Asking for the Business”

Similar to other HCPs you call on, it is permissible to ask a P&T Committee member for his or her support of your product. It is also appropriate to ask influential HCPs to write letters or otherwise communicate with members of the P&T Committee to show their support for a Pfizer product. Although you may ask for this support, the HCP cannot be compensated or otherwise rewarded for this activity.

Generating Support for Formulary Decisions



- Q. May I tell other (non-P&T member) physicians about upcoming formulary decisions involving Pfizer products? May I encourage physicians to contact Committee members or to attend Committee meetings to voice their support for our products?
- A. Yes. Colleagues can ask HCPs who support the use of a Pfizer product to express their opinions to P&T Committee members. Although colleagues cannot create talking points or write letters for an HCP who would like to advocate for a Pfizer product, you may discuss the product's safety and efficacy and provide the HCP with RC-approved materials.

It should never appear that Pfizer is engaging in a concerted effort to improperly influence an upcoming formulary decision. Examples of activities that could be construed as improperly influencing a P&T Committee decision and which are prohibited include:

- Inviting a P&T Committee member to become a speaker, consultant, or member of an advisory board when a reason for doing so is to influence an upcoming formulary decision;
- Taking a P&T Committee member out to an extravagant meal;



- Providing any payment (such as an exhibit/display fee or speaker fee) to a P&T Committee member or their institution if a reason for the payment is to influence an upcoming formulary decision;
- Providing any unapproved item to a P&T Committee member; and
- Linking financial support from Pfizer, either directly or indirectly, with influence over that P&T Committee member's exercise of judgment in serving on their P&T Committee.

Discussion of Extraneous Financial Transactions

To avoid violating the anti-kickback laws, Pfizer strictly prohibits linking financial transactions (other than disclosed rebate or discount arrangements) to P&T Committee decisions. Outside of certain limited exceptions, anti-kickback laws prohibit manufacturers from providing anything of value in order to influence formulary decisions. Any separate financial arrangements could also be required to be incorporated into a calculation of Pfizer's "best price" under the Medicaid Best Price Law.

Thus, when discussing formulary placement or Pfizer products with a P&T Committee member, you must never include offers of any sort to provide quality or product support programs, educational or research grants, charitable contributions, exhibit or display payments, or other arrangements (including speaking engagements) in exchange for formulary positioning. Consistent with the PhRMA Code, Pfizer requires any HCP who is a member of a P&T Committee and also speaks or consults for Pfizer to disclose to their P&T Committee the existence and nature of their relationship with Pfizer.

Responding to Requests for Funding by P&T Committee Members



- Q. What if, while I am giving a presentation on a Pfizer product under formulary review, a P&T Committee member asks for a grant or charitable contribution? Should I schedule a separate meeting to explain Pfizer's process for considering these requests?
- A. A separate meeting is not required. You must never affirmatively raise the topic of providing a grant or charitable contribution to a P&T Committee member, but if the member makes a specific unsolicited inquiry about it you may address it by doing the following:
- Stating that, at the conclusion of your product discussion, you can provide information about the procedures for submitting a request to Pfizer;
 - Stating that a decision to provide the requested funds will in no way be influenced by the P&T Committee member's status in making formulary decisions; and
 - Explaining that the decision on whether to provide requested funds will be made by an independent multi-disciplinary group and will not be impacted by the pending formulary decision.

Formal Product Presentations to P&T Committees

Who May Present?

P&T Committees often ask pharmaceutical manufacturers for product information and invite them to present data that supports putting their products on formulary.

Any knowledgeable colleague (or qualified consultant approved by Pfizer Headquarters) can appear before a P&T Committee on Pfizer's behalf. Most often, Medical Colleagues (RMRS or MOS) appear before these Committees. However, in some settings, other colleagues may present information.

What Information May Colleagues Present?

There are differences in the types of information colleagues may present at these meetings, especially regarding off-label information or new data that is not approved for product promotion. The key to determining the appropriate content of the presentation (and the identity of the Pfizer colleague presenting) turns on who requested the formulary presentation—Pfizer or the P&T Committee.



If Pfizer Requested the Opportunity to Present Information

When Pfizer asks for the opportunity to present information, the presentation is promotional and the FDA rules surrounding product promotion apply. Accordingly, any colleague (including a Medical Colleague) that presents information in this situation must abide by the four Core Compliance Principles:

- Use only RC-approved materials and selling statements;
- Stay on-label and discuss only approved products and indications;
- Provide an accurate and balanced presentation; and
- Never engage in actual or perceived quid pro quo.

Each Pfizer product team is responsible for creating and maintaining a slide deck that is appropriate for use during formulary presentations. Only these and other RC-approved materials can be used when Pfizer has requested the opportunity to present information. If you would like to add slides to the slide deck, the slides must be approved by the appropriate Pfizer Review Committee before use. When proactively providing product information, colleagues must never include information about off-label uses, including efficacy or safety information that conflicts with the approved labeling. Colleagues must never include new clinical data that has not yet been approved for product promotion in the presentation materials. If a P&T Committee makes a specific unsolicited request for off-label information, only Medical Colleagues (or a Headquarters approved physician consultant) may respond to the request in accordance with the guidelines set out for them. The response must be truthful, not misleading, based on substantial scientific evidence and non-promotional in tone.

P&T Committee Standing Requests for Off-Label Information



- Q. If a P&T Committee has a standing written request for certain information to be provided during any formulary presentation, and that information includes information that is off-label or unapproved for promotional use, can a Pfizer Medical Colleague provide the information even though Pfizer originally asked for the opportunity to present to the Committee?
- A. Yes. Even though Pfizer asked to make the formulary presentation, the P&T Committee's standing request to be provided with off-label or unapproved information is considered an unsolicited request for the information. A Pfizer RMRS is permitted to respond to this standing written request for off-label information, in accordance with the policies set out in the Green Guide: Governance for Field-Based Medical Activities.

If the P&T Committee Requested that Pfizer Provide Information

If a P&T Committee makes a documented, unsolicited request for information from Pfizer related to a formulary decision, you must assess whether the anticipated response will require Pfizer to provide off-label or other information that is not approved for promotional use.

- **If the response will not include off-label or unapproved information**, any colleague, including a Sales Colleague, can respond to the request using RC-approved materials.
- **If the response will likely include off-label or unapproved information**, only a Pfizer Medical Colleague (or Headquarters approved consultant) can deliver the response in accordance with the guidelines set out for them. Any information provided must be:
 - In response to a specific request for that information;
 - Truthful and not misleading;
 - Based on substantial scientific evidence; and
 - Non-promotional in tone.

A MOS Medical Colleague may respond to requests for unapproved but on-label information (e.g. where no RC-approved materials exist to use in a response). Because of their background and training, they may also respond to requests for pharmacoeconomic or outcomes information if they have materials approved for such responses. A RMRS Medical Colleague may respond to requests for both unapproved and off-label information. In the absence of a specific request for information about our

products, no colleague can present unapproved or off-label information about Pfizer products to a P&T Committee or one of its members.

Joint Sales and Medical P&T Presentations



- Q. May Sales and Medical Colleagues present together to a P&T Committee?
- A. Maybe. If the presentation consists of on-label information which the Sales Colleague could otherwise present by himself or herself, then Sales and Medical Colleagues may present together. The Sales Colleague must not participate in any unsolicited scientific exchange of information which might occur during or after the presentation. On the other hand, if the Medical Colleague intends to present scientific information which is in response to a medical inquiry made by the P&T Committee, the Sales Colleague cannot present together with the Medical Colleague. In those instances, only the Medical Colleague should present the information.

FOR MORE INFORMATION

- Questions may be referred to your manager or Regional Attorney.
- For medical inquiries, call Pfizer Medical Information at 1-800-438-1985.



Chapter 8: PRIVACY: PROTECTING PERSONAL INFORMATION

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Chapter 8: PRIVACY: PROTECTING PERSONAL INFORMATION

Privacy

We are all familiar with the notion of personal information from our own daily lives. Some personal information identifies who we are and where and how we live; other personal information is medical in nature; still other forms of personal information relate to finances, political affiliations and philosophical beliefs. Pfizer’s corporate policies require that the confidentiality and security of personal information be maintained in accordance with state and federal law.

This Chapter highlights certain key Pfizer policies regarding the protection of Personal Information. Examples of such activities include health screenings, surveys, clinical outcomes research, and mentorships as well as managing personal information in your possession—such as on your computer.

Non-compliance with these policies can put the Company at risk and can subject you to disciplinary action up to and including termination.

Patients’ Privacy and Personal Information

Personal Information “Personal Information” (**PI**) includes any information that can be used to identify a person. **Sensitive Personal Information (SPI)** is a subset of Personal Information which includes personal information about a person’s physical or mental health (e.g., a person’s medical history, physical or mental condition, diagnosis or treatment or the identity of the person’s health care provider or health insurer).

Governing Laws and Pfizer Policies. There are many federal and state laws applicable to the use of Personal Information and Sensitive Personal Information. Regardless of the circumstances under which Personal Information is disclosed, when an individual chooses to share such information with a person they trust, they generally expect the person to hold that information in confidence and to keep it secure. Pfizer respects this expectation and is committed to appropriately protecting all Personal



Information in its care in compliance with applicable privacy laws and regulations and Pfizer's corporate policies and procedures. Pfizer's policy is to employ appropriate safeguards to protect all Personal Information it receives and maintains, regardless of the form, format, location, or use. See **Corporate Policy 404 (Protecting the Privacy of Personal Information)** <http://policysource.pfizer.com/Corporate/PDFDocuments/404.PersonalInformation.pdf>.

Key Points to Ensure Compliance

- Always disclose that you are a Pfizer employee when interacting with patients, such as at a consumer health fair or during a mentorship by wearing your Pfizer name tag at all times.
- **Corporate Policy 404, (Protecting the Privacy of Personal Information)** <http://policysource.pfizer.com/Corporate/PDFDocuments/404.PersonalInformation.pdf> requires all Pfizer colleagues to employ appropriate safeguards to protect Personal Information they have access to, including the Personal Information of customers.
- Do not request or collect Sensitive Personal Information for any reason unless you have specific approval to do so.
- Avoid situations likely to lead to the inadvertent disclosure of Sensitive Personal Information, such as private conversations between HCPs and patients.
- When setting up a mentorship or preceptorship, Pfizer colleagues must remind physicians serving as mentors or preceptors that they have a legal obligation to obtain their patients' written authorization before Pfizer colleagues may be allowed to observe any consultation, examination, and/or treatment of any patient.
- Pfizer usually does not perform work on behalf of an HCP or other "covered entity" under HIPAA. Therefore, it is not appropriate for any field-based colleague to enter into a Business Associate Agreement. If you are asked to sign a Business Associate Agreement, you must consult with Legal.
- Do not sign any non-Pfizer Confidentiality Agreement without consulting with with Legal.
- Do not discuss with an HCP that you know their prescribing practices based on their prescriber data.
- Do not share an HCP's prescriber data with anyone outside of Pfizer.

Key Points to Ensure Compliance

- Pfizer colleagues should not engage health fair attendees in discussions regarding their specific health status, symptoms, diagnosis or treatment. These discussions should occur between the patient and appropriate HCP.
- Employ the same safeguards to protect the confidentiality of prescriber data as you would any other Personal Information. As a general rule, it should be used only for internal business purposes and not in dealings with Pfizer’s customers (such as the HCPs themselves) or external third parties.

Laws Protecting Personal Data

One of the most important federal healthcare laws in the area of privacy is called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA was significantly expanded by the Health Information Technology for Economic and Clinical Health Act (HITECH). HIPAA and HITECH impose strict limitations on the use and disclosure of Sensitive Personal Information by “covered entities” and their “business associates.”

Business Associate Agreements and Confidentiality Agreements

Sometimes HCPs may incorrectly request that you sign a Business Associate Agreement (BAA). A BAA is an agreement that is entered into between a “covered entity” (e.g., an HCP or a health insurer) and a “business associate.” Generally, “business associates” are defined as entities or persons who perform work on behalf of a covered entity (e.g., certain types of vendors are considered “business associates”). **Because Pfizer does not perform work on behalf of HCPs, it is not appropriate for Pfizer or for you to enter into a BAA.**

Some HCPs will request a BAA when what they really are seeking is a confidentiality agreement to protect their patients’ Sensitive Personal Information in the event it is inadvertently disclosed in your presence. To address such requests, Pfizer has developed two Pfizer template forms, either of which you are permitted to offer to the HCP as assurance of your intent to keep Sensitive Personal Information confidential. The Privacy Pledge can be signed and provided to HCPs or customers who

might have general concerns about Pfizer’s position on HIPAA as it relates to its representatives. The Patient Health Information Confidentiality Agreement can be signed and provided to an HCP or institution that would like a specific agreement to cover situations where a Pfizer representative inadvertently comes into contact with Sensitive Personal Information. No changes can be made to these templates before signing them unless Legal has approved the change in advance.

A copy of the Privacy Pledge and Patient Health Information Confidentiality Agreement can be downloaded from PfieldNet at <http://PfieldNet.pfizer.com> under the “Compliance” tab.

Business Associate Agreements



- Q. What should I do if a physician insists that I sign a Business Associate Agreement before I enter the patient clinic? Can I sign the Business Associate Agreement to avoid being shut out?
- A. No. You must not sign a Business Associate Agreement, even if required by an HCP in order to be allowed access to a facility. Colleagues are able to sign the Pfizer Privacy Pledge or Patient Health Information Confidentiality Agreement template found on PfieldNet. Providing a copy of one of these documents with your signature is usually enough to satisfy the HCP’s concerns about patient privacy. If the HCP continues to insist on a Business Associate Agreement, please promptly contact your Regional Attorney who may be able to provide assistance to you.

Signing Customer Confidentiality Agreements



- Q. If an HCP insists that I sign a facility’s Confidentiality Agreement, even after I sign and show him or her Pfizer’s Privacy Pledge and Patient Health Information Confidentiality Agreement, can I sign what the HCP wants me to sign?
- A. Maybe. Sometimes these agreements are acceptable to sign, but you should never do so unless your Regional Attorney has first reviewed and approved the agreement.

State and Other Privacy Laws

Although many of Pfizer’s activities are not covered by HIPAA, some of our activities still may be covered by other laws and regulations, including state privacy laws. **Therefore, except as expressly authorized by your manager or Regional Attorney, you must avoid collecting, maintaining, or using Sensitive Personal Information.** If you inadvertently come into contact with Sensitive Personal



Information or are asked to collect it, you should contact your Regional Attorney immediately to discuss Pfizer's policies regarding safeguarding such information.

Steps to Protect Patient Privacy

Avoid Intentional and Inadvertent Disclosure of Sensitive Personal Information

HCPs are subject to many restrictions regarding the use and disclosure of Sensitive Personal Information. Generally, HCPs are not permitted to disclose a patient's SPI to a third party unless they receive prior written authorization from the patient. You must avoid situations in which you may be exposed to SPI without an individual's consent. In the event an HCP or other person exposes you to SPI, you should not document or reproduce the information in any media or form. You must strictly maintain the confidentiality of such information in accordance with Pfizer's policy of safeguarding the privacy of all patient-related data. Even if an individual has consented to a use or disclosure of SPI, such as during a mentorship, you must still abide by the rules discussed in this Chapter and consult your Regional Attorney to ensure compliance with Pfizer policies and applicable laws regarding the use, disclosure, and destruction of any SPI to which you are exposed.

Seek Only De-Identified Data

Under limited and specific circumstances, and in consultation with your Regional Attorney, it may be appropriate for colleagues to receive certain "aggregated" or "de-identified" patient information from an HCP or other third party. "**Aggregated**" data is information about multiple individuals that is compiled and does not allow for the identification of any one individual. "**De-identified**" data is data that cannot be attributed to any specific individual or used to identify any individual and usually has been stripped of certain key identifiers which, either alone or in combination with other available information, could link the information with a specific individual or be used to identify a specific individual (including the individual's name, many elements of the individual's address, telephone number, and social security number, among others). HIPAA regulations include strict standards for what is "de-identified." Accordingly, before assuming information is "de-identified," consult Legal.



To assist in the collection of permitted data, Pfizer has approved surveys and screening tools that have been designed specifically to collect only appropriate, de-identified patient information. Most of these tools are approved for use only by field-based Medical Colleagues.

Obtain Patient Consent (via Signed Authorization) Where Appropriate

In certain circumstances, it may be appropriate or even necessary for Pfizer to receive Sensitive Personal Information from patients or consumers as part of certain *approved activities*. You must ensure that the appropriate patient consent has been obtained by the HCP or health plan prior to:

- Engaging in approved Pfizer-sponsored third party communications;
- Engaging in a mentorship or preceptorship involving patient contact;
- Collecting Sensitive Personal Information as part of an approved survey, screening tool or other similar activity that you have received advance approval to use;
- Using or disclosing Personal Information from consumers in connection with coupon programs or other consumer offerings; and
- Collecting, using or disclosing Personal Information in connection with Pfizer patient assistance programs.

Mentorships and Preceptorships

A mentorship allows colleagues to observe or “shadow” an HCP engaged in his or her daily office or institutional practice. Payment to an HCP for serving as a mentor is prohibited. A preceptorship, on the other hand, is a training presentation by an HCP to a team or group of colleagues about a particular therapeutic area or the clinical use of one or more Pfizer products in professional practice.

The need for mentorships and preceptorships is limited; therefore, you should conduct these events infrequently and only when there is a documented need. These events may impact patient privacy if colleagues are permitted to observe treatment or consultation sessions with a patient, or if colleagues discuss an individual’s treatment with a patient’s HCP.

When setting up a mentorship or preceptorship, colleagues must remind physicians serving as mentors or preceptors that they have a legal obligation to obtain their patient’s written authorization before

colleagues may be allowed to observe any consultation, examination, or treatment. Pfizer has created a Patient Authorization template, available at [http://pfieldnet.pfizer.com/Compliance/Documents/MentorshipGuidelines\(2\)\(mv\).doc](http://pfieldnet.pfizer.com/Compliance/Documents/MentorshipGuidelines(2)(mv).doc) to offer HCPs for use in obtaining a patient's permission. The signed authorization form should be maintained as part of the patient's record by the physician, and a copy should be given to the patient. There is no need or reason for you to have a copy of the form, so you should not collect or retain a signed copy of the form.

Because patient privacy issues are often implicated when Pfizer employees are permitted to observe treatment or consultation sessions with patients and HCPs, colleagues must identify themselves as Pfizer employees so that the patient is fully aware of and understands the colleague's role.

For additional rules regarding the appropriate use of mentorships and preceptorships, please see Orange Guide Chapter 2: Detailing to HCPs. If you have any questions about Pfizer's Patient Authorization language, please contact your Regional Attorney.

Consent Forms and Mentorships



- Q. Does a patient have to sign a written consent form before I can observe an examination or treatment as part of a mentorship, or is verbal permission sufficient?
- A. Oral permission is not acceptable. As a convenience to your HCP mentor, you can download a template Patient Authorization Form from PfieldNet for the HCP to use. Ultimately, it is the responsibility of the HCP to obtain the appropriate written authorization from the patient.
- Remember, you must also wear your Pfizer name tag at all times during mentorships.

Handling Patients' Personal Data

Pfizer-Sponsored Third Party Communications to Patients

Occasionally, and within strict limitations, Pfizer pays entities such as managed care organizations and retail pharmacies to mail Pfizer-approved disease management or educational materials to patients who have agreed to receive such mailings from the managed care organization or pharmacy. Pfizer may also pay for medication compliance mailings to certain consenting patients in order to inform or

remind them of the schedule to fill or refill a prescription for a chronic medication. These payments are made in accordance with applicable state and federal laws.

These types of activities must be documented in a written Service Agreement between Pfizer and the managed care organization or pharmacy. Pfizer Legal Counsel (and in some cases, Pfizer’s Managed Care Review Committee) must approve the form of the Service Agreement in advance.

The Service Agreement is designed to ensure protection of patients’ privacy as well as compliance with applicable laws and Company policy. The Service Agreement requires the applicable pharmacy or health plan to guarantee and certify that it has permission to send the Pfizer-approved information to the recipients. The Service Agreement also requires the sender to adhere to Pfizer’s personal data protection policies. Among other things, this obligates the health plan or pharmacy to refrain from disclosing to Pfizer any patient names, addresses or other Sensitive Personal Information. Only the pharmacy or health plan can have access to this information. In instances where a third-party mailing operation is hired to send the approved information to patients, an approved Pfizer Authorization for Mailing must be signed by the health plan or pharmacy to ensure compliance with these principles.

All materials sent to patients must be approved by the appropriate Pfizer Review Committee (RC), which will consider potential issues of patient privacy and patient consent as part of its review process.

Chart Reviews



- Q. Is it permissible to conduct chart reviews as part of our collaborative studies/programs with customers? If I sign a Business Associate Agreement, would that make it allowable?
- A. No. It is Pfizer policy that colleagues should never conduct a chart review. In addition, as discussed earlier, Pfizer is not a Business Associate of an HCP and, therefore, field-based colleagues must not sign Business Associate Agreements under any circumstance.

Consumer Health Fairs and Screenings

Consumer health fairs and screenings may raise patient privacy concerns since Personal Information is often obtained in the presence of sales representatives or other Pfizer colleagues attending the health fair. Pfizer Colleagues should not engage health fair attendees in discussions regarding their specific health status, symptoms, diagnosis or treatment. These discussions should occur between the patient

and an appropriate HCP. Should a patient attempt to initiate such a discussion, the Pfizer colleague should make clear that he or she is not an HCP and should redirect the patient to an HCP at the fair or to his or her physician.

Interaction with Consumers at Health Screenings by Pfizer Colleagues with Medical Background



- Q. May a colleague with a medical background counsel consumers on how to interpret their screening results at a Pfizer-sponsored health screening?
- A. No. Pfizer colleagues are not permitted to counsel patients about screening results, regardless of their education background or experience. The patient should be referred to his or her HCP.

REMEMBER

If you are present during ANY patient/consumer interaction at a health fair or screening, you:

- **MUST** wear your Pfizer name tag and clearly identify yourself as a Pfizer employee; and
- **MUST NOT** offer any medical opinions, advice or consultation even if you have a license to practice medicine or are any other type of HCP.

For more information and guidelines on when and how Pfizer may hold health screenings and hire vendors to conduct the screenings, see Orange Guide Chapter 13: Health Screenings.

For more information and guidelines on appropriate consumer interactions, see Orange Guide Chapter 16: Consumer and Employee Interactions.

Securing Consent and Personal Information from Consumers

As a general policy, Pfizer does not use Personal Information to communicate directly with patients unless the patient has consented (or “opted in”) to receiving such communications.

Pfizer has detailed guidelines for all of our permitted activities that involve the collection and use of patients’ personal information to ensure compliance with all applicable laws and Pfizer policies. These activities include, but are not limited to:

- Disease management program enrollment forms;



- Coupons and rebate offers;
- Literature requests;
- Loyalty programs; and
- Health screenings.

These guidelines apply only when consumers are asked to provide Personal Information, such as name, address, e-mail address or phone number. When a Pfizer program requires a consumer to provide Personal Information as a term or condition of use of or access to the program, a simple, timely, cost-free mechanism (toll-free number or prepaid mail-in form) must also be provided that allows the consumer to discontinue or “opt-out” of the program at any time.

These guidelines apply to all Pfizer personnel, including disease management teams and non-branded teams. In addition, they also must be communicated to and followed by any Pfizer-approved vendors undertaking such activities on behalf of Pfizer.

Handling HCP Personal Data

Restricting Access to Personal Information to a “Need to Know” Basis

As a general policy, Pfizer restricts access to sensitive information to individuals who “need to know” the information. In general, most Pfizer colleagues, including Sales Colleagues, do not need access to Personal Information about HCPs for any reason and should not request, collect or retain any such information. This type of information includes, but is not limited to:

- Social Security or other government-issued numbers;
- Driver’s license numbers;
- Health insurance identification numbers;
- Credit card, debit card, bank account numbers, or any other financial account identifiers (with or without associated security numbers);
- Employment identification numbers; and
- Biometric data (fingerprints, voiceprints, or retinal scans).



Access to Personal Information and, in particular, collection of Personal Information imposes an obligation to keep that information confidential and secure and inform Legal when such information is lost or stolen. Disclosure of certain types of Personal Information, even if accidental, can expose Pfizer to legal liability, create a risk of fraud or even identity theft for the information owner, and erode confidence in Pfizer and its commitment to privacy and information security.

Proper Use of HCP Prescriber Data

Certain states have enacted legislation that limits the use of prescriber data in certain contexts, including marketing and promotional activities. Pfizer adheres to all applicable state laws regarding the use of prescriber data.

From time to time, Pfizer may use de-identified prescriber data to facilitate effective marketing communications with HCPs. HCP prescriber data serves a variety of purposes, including the tracking of Pfizer-product adverse events. In addition, the proper use of prescriber data can help you to focus your activities on those HCPs who would most likely benefit from a promotional presentation on one of your products. It is vital, however, not to use the data in a manner that compromises its confidential nature or your integrity as a Pfizer colleague.

You may engage in an on-label discussion directly with the HCP to solicit and learn information about his or her clinical approach and use of specific products in order to tailor your promotional presentation; however, you may not directly convey the data you possess on his or her prescribing. You are also prohibited from sharing an HCP's prescriber data with other individuals and entities outside of Pfizer. Within Pfizer, you should discuss an HCP's prescriber data only with your manager, other colleagues who call on the same HCP in developing your team's promotional strategy at other appropriate Pfizer colleagues on a strictly need-to-know basis. Using prescriber data inappropriately not only compromises your credibility with the HCP, but it is also a violation of Pfizer policy, may subject you to disciplinary action up to and including termination, and may violate state laws limiting the use of such data.

The American Medical Association (AMA) administers a program by which physicians can opt-out of having their prescriber data released to pharmaceutical companies for use in marketing. Pfizer is required to check the opt-out list quarterly and has 90 days to comply with a prescriber's request. If an HCP has opted-out, Pfizer will respect that preference and will not use his or her prescriber data in



connection with promotional activities. If you learn that an HCP whom you call on has asked for his or her prescriber data not to be released, even though you would not have access to the HCP's prescriber data, you should be especially careful to avoid any discussion of prescribing habits in your promotional presentations to the HCP. The AMA program allows physicians to report specific instances of inappropriate behavior by pharmaceutical sales representatives or companies. Thus, it is important that you familiarize yourself with these rules and conduct your activities accordingly.

Providing Your Personal Information When Required By Vendor Credentialing Processes

As you have seen, Pfizer is committed to protecting the privacy of patients' and customers' Personal Information. Pfizer is also committed to protecting your privacy and the privacy of other colleagues from inappropriate use by or disclosure to third parties. Moreover, Pfizer also wants to ensure that when colleagues' information is entrusted to third parties, it is properly protected from unauthorized disclosure. Pfizer's Institutional Access Guidelines demonstrate this commitment to colleagues and their privacy. These Guidelines can be found on PfieldNet under the "Compliance" tab.

More and more hospitals and health care institutions are conditioning site access on colleagues' submission of Sensitive Personal Information and compliance with other vendor credentialing requirements. Often the stated purpose of these submissions and requirements is to make sure that people with access to personnel, patients and visitors do not have serious communicable illnesses or a history of violent acts. Required Personal Information can include immunization status, copies of medical records demonstrating inoculation or immunity to certain illnesses, whether you have had a background check (and its outcome), your training history and your professional qualifications.



Pfizer respects the hospital's or vendor's desire to secure the health and safety of its personnel, patients and visitors. Accordingly, the Institutional Access Guidelines were created. In particular, Pfizer has created a Vendor Credentialing team to help you respond to these requests. You can find the team's contact information on PfieldNet at <http://PfieldNet.pfizer.com>, under the "Compliance" tab. Regardless of whether a customer or institution asks for your Personal Information directly or indirectly (e.g., through a vendor hired to collect data on behalf of the customer), Pfizer wants your privacy to be respected and your Personal Information appropriately protected. Here are some key points for you to remember:

- Always tell your manager if a hospital or institution (or institution's vendor) wants you to provide your Personal Information to gain site access.
- If the hospital or vendor has a written credentialing policy, be sure to provide a complete and current copy to the Vendor Credentialing team and your Regional Attorney to review in advance.
- Give the hospital or vendor Pfizer's approved template Confidentiality Letter Agreement (available through a link in the Guidelines, accessible on PfieldNet at <http://PfieldNet.pfizer.com>).
- Do not share your Personal Information before the health care provider and/or vendor signs an approved Confidentiality Agreement to protect your information.
- Do not modify Pfizer's approved template Confidentiality Letter Agreement without your Regional Attorney's approval.
- Do not sign a non-Pfizer Confidentiality Agreement without your Regional Attorney's approval.

Pfizer Regional Attorneys will review relevant hospital and HCP policies to ensure that any agreements are acceptable for you to sign and do not pose potential legal issues for Pfizer. Regional Attorneys will review the agreements in light of Pfizer's interests and cannot offer you personal legal advice regarding your personal privacy or other concerns. Once the Regional Attorney has approved an agreement, it is your responsibility to carefully read and understand it because you will be held accountable by the institution for compliance with it. Violations of an institution's policies may lead to Pfizer being denied the ability to visit or hold programs at that institution.



Corporate Policies on Your Responsibility for Safeguarding Personal Information

You should familiarize yourself with the following Pfizer corporate policies and guides:

- [Corporate Policy 404](#) on Protecting the Privacy of Personal Information;
- [Corporate Policy 403](#) on the Acceptable Use of Pfizer Information Systems; and
- [Corporate Policy 405](#) on Enterprise Records and Information

These documents provide important **guidance** about appropriate information handling and security procedures, which include, but are not limited to:

- Not leaving your Pfizer equipment or Personal Information unattended or in an unsecured location, e.g., an unlocked car;
- Encrypting your computer and using encrypted USB flash drives;
- Properly destroying media or paper containing Personal Information;
- Promptly reporting lost or stolen Pfizer equipment and other potential data incidents to Pfizer's Global Security Operations Center (GSOC) (212-733-7900 or GSOCwatchroom@pfizer.com) or to the local IT Service Desk (the worldwide list of contact telephone numbers is available online at <http://ITSupport.pfizer.com>); and
- Never using unencrypted e-mail to transfer Personal Information outside of the Pfizer network.

If you have additional questions about appropriate information handling and security procedures, you should consult the Privacy reference guide or speak with the Global Privacy Office or your team/Regional Attorney.

FOR MORE INFORMATION

- For more information on information system policies, see Corporate Policy 403, *Acceptable Use of Pfizer Information Systems* at <http://policysource.pfizer.com>.
- For more information on protecting the privacy of Personal Information, see Corporate Policy 404, *Protecting the Privacy of Personal Information* at <http://policysource.pfizer.com>.

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- For more information on records management, see Corporate Policy 405, *Records and Information Management* at <http://policysource.pfizer.com>.
- For more information on handling sensitive information, see *Handling Sensitive Information: Safeguarding Our Information* on the Pfizer intranet at: <http://legal.pfizer.com/About/PracticeAreas/GlobalSecurity/Pages/InformationSecurity.aspx>.
- For copies of the Privacy Pledge and Patient Health Information Confidentiality Agreement, see the "Compliance" tab on PfieldNet at <http://pfieldnet.pfizer.com>.
- For access to the Patient Authorization template, see the "Compliance" tab on PfieldNet at <http://pfieldnet.pfizer.com>.
- For more information on health screening and hiring vendors, see Orange Guide Chapter 13: Health Screenings.
- Questions may be referred to your manager or Legal.
- You can also call the Privacy Office Helpline at 212-733-0228 (worldwide) or 877-356-6195 (within the U.S.), or you can e-mail the Privacy Office at Privacy.officer@pfizer.com.



Chapter 9: SPEAKER PROGRAMS FOR HCPs

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Chapter 9: SPEAKER PROGRAMS FOR HCPs

Introduction

A speaker program is a promotional activity controlled by Pfizer in which an approved speaker, generally an external healthcare professional (HCP) under contract with Pfizer, presents information on products, disease states or other healthcare topics to a group of HCPs and/or other appropriate attendees. Promotional speaker programs allow Pfizer to present experts to educate HCPs about our products and other relevant topics.

The Food and Drug Administration (FDA) considers HCP speakers to be representatives of Pfizer. Thus, **Pfizer is responsible for the content and conduct of speaker programs.** This includes all information presented by the speaker, any payments related to the program, as well as the venue and other details of the event. When you organize or host a speaker program, you are responsible for ensuring that the conduct and content comply with the rules set forth in this Chapter.

Additional information and guidance for conducting compliant speaker programs is available in EZSpeak. Pfizer's policies for conducting compliant speaker programs for consumers are discussed in Orange Guide Chapter 16: Consumer and Employee Interactions.

Non-compliance with these policies puts the Company at risk and can subject you to disciplinary action up to and including termination.

Speaker Program Checklist

- Speaker programs must be submitted and approved in EZSpeak prior to the program date. All speakers must be active in EZSpeak and selected based only on expertise, credentials and ability to communicate with the target audience.
- You must have a pre-program discussion with each speaker to review Pfizer’s speaker policies and the proposed slide deck. You must download and review a copy of the speaker’s slide deck from EZSpeak prior to your discussion.
- At the program, you should be prepared to project the slides using your Pfizer laptop. This ensures that all slides are current and have been approved by the Pfizer Review Committee. You must be familiar enough with the deck to identify any inappropriate statements or other issues with the speaker’s presentation.
- Speakers may only present RC-approved slide decks. It is inappropriate for a speaker to skip required safety slides or to present no slides during a program.
- The information provided verbally by the speaker must be consistent with the RC-approved slides and the product labeling, and must be fair and balanced with respect to benefits and risks. Off-label information may be provided only in response to a specific unsolicited question, in accordance with the rules set forth below.
- Only RC-approved educational information can be handed out to attendees.
- At the start of all speaker programs, speakers must clearly state that Pfizer is sponsoring the presentation and that they are presenting on Pfizer’s behalf.
- Speakers must engage the attendees for a minimum of 45 minutes to one hour, inclusive of Q&A for all venue programs. However, for programs with attendees in an in-office setting, a minimum of 30 minutes is acceptable.
- The speaker program venue must be appropriate and conducive to a scientific or educational presentation.
- HCPs and appropriate non-HCP office staff may be invited to speaker programs. For each invitee, colleagues are responsible for determining whether the program contents are appropriate in light of the attendee’s role and responsibility for patient care.

Speaker Program Checklist

- There must be a legitimate expectation that at least two HCPs will be in attendance and that the audience will not consist solely of HCPs from the speaker's own practice group or institution.
- Unless further restricted by state or other laws, food and beverages must be modest by local standards and must not exceed \$135 per attendee, including tax and tip.
- You must make a good faith effort to ensure that all attendees: (1) practice in an appropriate specialty that is not excluded for the promoted product; and (2) do not hold active licenses from states that impose restrictions on providing meals (if you choose to provide one at the program).
- Pfizer's national payment disclosure policy applies to all speaker fees and reimbursable travel expenses, as well as the value of meals provided to speakers and attendees. The disclosure policy pertains to all U.S. HCPs who can prescribe medicines, including physicians, nurse practitioners and physician assistants. Until further notice, Pfizer's disclosure policy will allocate the costs of meals equally among all attendees, regardless of actual consumption.
- If the speaker commits a violation of Pfizer policy, you must identify the violation during the EZSpeak closeout process.

Your Role in Setting Up a Speaker Program

When you engage an expert to speak to HCPs on Pfizer's behalf, you are engaging in a promotional act. Speakers hired by Pfizer are considered representatives of Pfizer, and Pfizer is responsible for all content presented at the program. In addition, whenever an HCP is paid to speak for Pfizer, the engagement is subject to scrutiny under anti-kickback and other healthcare laws.

Choose the Relevant Topic and Select an Appropriate Speaker

All speaker programs must be submitted and approved in EZSpeak **prior** to the event date. This is a critical requirement for ensuring compliance with policies governing interactions with speakers, including accurately determining when a speaker has reached his or her annual speaking fee cap.



The topic of each speaker program must be RC-approved and included in EZSpeak. You may not modify the title of the presentation or the language used in any program invitations. After choosing a topic, you should select a speaker from EZSpeak with expertise on the approved topic and the ability to effectively communicate to the targeted audience.

Speaker selection must be solely based on the HCP's expertise, credentials, and ability to effectively communicate to the targeted audience. You cannot engage a speaker in order to establish a relationship, gain or improve access to the speaker, reward past prescribing, or induce future prescribing.

After selecting the speaker, you must verify that he or she is on the list of "active" Pfizer speakers maintained in EZSpeak by the Speaker Operations Team. Speakers may be designated "active" only when they have completed the relevant brand's Core Product or Topic Training (as applicable) and Pfizer's compliance training, and have signed a Pfizer Speaker Agreement.

Violations of these policies, including holding a program without prior approval in EZSpeak or entering a fictitious program date in EZSpeak, could subject you to disciplinary action. For more information on how to activate a speaker in EZSpeak, consult your manager, AHM Meeting Planner or the Pfizer Speaker Operations Team.

Speaker Selection



- Q. Can experts other than physicians be hired to speak at promotional speaker programs?
- A. Yes. Any person with the requisite expertise and credentials may be hired to speak on Pfizer's behalf. It may be appropriate to use nurses, pharmacists or patient advocates to speak to targeted audiences.
- Q. Can I hire a physician who works at the VA to be a speaker for Pfizer?
- A. Possibly, but you may not engage a speaker who works for the VA until you know and understand the special rules that apply to speakers who work for the VA. Please see Chapter 4: Federal Employee Interactions and Lobbying for information about these rules.
- Q. I understand that Pfizer Science Ambassadors and some other Pfizer groups (e.g., Public Affairs) are permitted to present information to the public about Pfizer's research and development activities. Can I schedule one of the Science Ambassadors to present to HCPs that I detail?
- A. No. These individuals do not currently have any approved presentations in EZSpeak, and therefore, they cannot participate in a promotional speaker presentation. Likewise, you may not attend or otherwise participate in a Science Ambassador presentation (or similar program) in a promotional capacity.

Scheduling Issues



- Q. An out-of-town speaker has asked a colleague to schedule a speaker program to coincide with the speaker's personal travel schedule, so that Pfizer can reimburse his personal travel expenses. Is this permissible?
- A. No. You cannot conduct a speaker program for the benefit of the speaker. Out-of-town speakers should only be utilized when there is a legitimate business reason to do so, and your scheduling decisions should only be motivated by the availability of the appropriate audience.

Speaker Program Content

All slides presented by a speaker must be from the RC-approved slide kit available to the speaker through the Pfizer Speaker Resource Center at www.pfizerspeakers.com. The speaker is prohibited from creating or inserting his or her own slides (including introduction, speaker bio, case study or disease state slides). Speaker slide decks are locked to prevent the addition of slides or changes to



approved slides. It is inappropriate for a speaker to skip required safety slides or to present no slides during a program.

In very limited circumstances, the Review Committee may permit a speaker to present slides that are not contained in the approved speaker kit. Colleagues must submit the speaker's proposed slides for RC review and approval **prior** to the speaker program (the "Exceptions Process"). Please refer to EZSpeak for details on the Exceptions Process.

Remember, any information provided by a speaker, whether verbally or as part of a slide presentation, must be:

- Accurate and truthful;
- Consistent with product labeling;
- Supported by substantiated and scientifically-sound data; and
- Appropriately balanced with information on both benefits and risks.

Investigational or unapproved uses of Pfizer products may not be proactively discussed. Off-label information may be provided only in response to a specific unsolicited question from an attendee. Before briefly answering the question, the speaker must state that the information to be discussed is off-label and is based on the speaker's personal experience or opinion. The speaker may not use unapproved slides to support the answer. If the HCP asking the question requires additional information or the question cannot be adequately answered briefly, the speaker (or Pfizer representative) must refer the HCP to the Medical Information department.

Speakers may not engage in a consultation during the speaker program and may not review charts or files of individual patients in an attendee's practice.

Use of Pfizer Approved Speaker Slide Kits

- Q. Is a speaker required to use all slides contained in a Pfizer approved slide kit?
- A. It depends. A speaker must appropriately emphasize all slides that relate to safety, risks, and contraindications to ensure fair balance (these slides are typically designated in EZSpeak as “mandatory” slides). Speakers are not required to use slides addressing other issues as long as the information presented is accurate and truthful, consistent with approved product labeling, supported by substantial evidence, and includes a balanced discussion of benefits and risks. (Note that for speaker slide decks intended for use with consumers, all slides must be used.)

Review Policies with Speakers

Before the program, you are responsible for downloading a copy of the speaker’s slides from EZSpeak and must hold a discussion with the speaker to review Pfizer’s promotional speaker policies and to ensure that he or she understands Pfizer’s requirements for the presentation. A copy of Pfizer’s Promotional Speaker Policy is provided to all speakers as part of their contract. Your pre-program discussion with the speaker must include the items outlined in the Speaker Program Checklist located at the beginning of this Chapter, including:

- A reminder that the speaker is speaking on Pfizer’s behalf and that discussions must be on-label;
- A reminder that the speaker must present the current RC-approved slide deck, without any unapproved materials or modifications, and that you will be prepared to project the slides from your Pfizer laptop (except at roundtable programs where handouts may be used);
- A reminder of the appropriate duration of the program (45 minutes for venue programs, or 30 minutes for programs with attendees in an in-office setting);
- A reminder that the speaker must start the program by clearly stating that Pfizer is sponsoring the presentation and that he/she is presenting on Pfizer’s behalf; and
- A reminder that if an attendee asks the speaker an unsolicited off-label question, the speaker may answer briefly, and limited to the specific question asked, after stating that the information to be discussed is off-label and is based on the speaker’s personal experience or opinion.

Use of RC-Approved Slides/Content

- Q. Can a speaker at a Pfizer promotional program for HCPs describe a case study during his or her presentation?
- A. During a speaker program, a speaker may verbally describe a case study if their comments are consistent with the approved slides and product labeling and if they make clear that their comments are based on their personal experience.
- Q. Can a speaker add case study slides? Can he or she add slides that are approved for use by Pfizer Medical, Public Policy, or other non-commercial colleagues?
- A. No. Speakers may only present and speak to slides from RC-approved slide decks. A speaker may not add slides to the presentation that have been approved by Pfizer for other (e.g., Medical or Policy Group) uses. In very limited instances, a speaker can obtain pre-approval from the Review Committee to present slides that are not contained in the EZSpeak slide kit through the Exceptions Process.

Use of Unapproved On-Label Clinical Reprints

- Q. Can a speaker present data from an unapproved clinical reprint that is substantiated, scientifically sound and seems to be on-label but is not RC-approved?
- A. No. All information presented must be RC-approved. A speaker at a promotional program represents Pfizer and must follow the same promotional policies as a member of the Pfizer sales force, with two exceptions:
1. He or she may provide off-label information or refer to an unapproved clinical study (if appropriate) only in response to a specific, unsolicited question; and
 2. He or she may create and use his or her own slides only if they are approved by the Review Committee prior to the speaker program in accordance with the Exceptions Process.

Roundtables and Use of Approved Materials

- Q. When a speaker is presenting information to a small group of HCPs in a “roundtable” format, does the speaker have to use Pfizer approved slides?
- A. Yes, a speaker must always use only RC-approved slides. Where projecting the approved slides is not feasible, the approved Pfizer slides may be handed out (in their entirety) to attendees, unless prohibited by the product review committee. The relevant product package insert must also be made available to all attendees.

Arrange Meeting and Speaker Logistics with Meeting Planner

All speaker programs must be arranged through a Meeting Planner. Meeting Planners will assist you in setting up programs that are effective and compliant by, among other things, booking and confirming speakers, coordinating speaker travel arrangements, securing a venue, and creating invitations. You can refer to EZSpeak at <https://www.ezspeakprograms.com/> or contact the appropriate marketing agency for details on Meeting Planners.

Venue Requirements

In determining where the program will be held, be sure that the venue:

- Is conducive to the exchange of scientific information. The purpose of the program is to convey information. The venue’s environment should not detract from that purpose.
- Is considered modest by local standards. No more than \$135 per attendee may be spent on food, beverage, tax and tip for a speaker program for HCPs. What is considered a modest meal in one part of the country may not be appropriate in another part of the country.
- DOES NOT involve recreation or any other entertainment component. The PhRMA Code expressly prohibits any kind of entertainment at industry sponsored programs.

Speaker Program Venue Do’s and Don’ts	
Permitted	Prohibited
Private room at a restaurant (subject to price restrictions)	Private Box at a theatre performance or sporting event
Conference room at a hotel or convention center	Conference room at a museum or location of a celebrity event
Program held at a moderately priced local restaurant	Program held on a dinner boat cruise or a restaurant that offers or is associated with any form of entertainment

Speaker CVs

- Q. I'd like to schedule a speaker program at a nearby hospital. An HCP leader at the institution has asked to review the Speaker's CV in advance of the program. Can I send a copy to her?
- A. No. Although Pfizer maintains copies of speaker CVs on EZSpeak, they are for internal use only and have not been RC-approved for external distribution.

Programs at Private Clubs

- Q. May I hold a speaker program in a private room at a restaurant located within a country club or golf club?
- A. Generally, no. Holding a program at a country club or golf club, where recreation is often provided, may have the appearance of impropriety and is therefore discouraged. In the rare instances where this type of venue is used, the program must not involve any recreational activities and the cost of using the venue as well as payment for the meal must be billed directly to Pfizer. It is not acceptable to make payment through an HCP country club member.

Preparing and Distributing Invitations

Your Meeting Planner will prepare invitations for your event. The use of invitations is strongly recommended because they contain important disclaimers and information for attendees (e.g., prohibition on bringing spouses, state law restriction reminders, etc.) that help you and Pfizer further ensure compliance. As a general matter, colleagues should also communicate to prospective speaker program attendees the expectation that they will be present for the entire program (a reminder of which is included in the approved invitation).

Only approved invitations available from your Meeting Planner can be used. You may not alter the approved invitations in any way. Similarly, any communications accompanying the delivery of speaker program invitations to HCPs and other appropriate attendees must be strictly controlled in order to ensure compliance with regulatory requirements and to prevent such communications from being perceived as making inappropriate or incomplete promotional claims.

Invitations that have been properly approved for use should normally be distributed in person or by regular mail with no additional written statements beyond the content of the invitation itself. Colleagues may also deliver approved speaker program invitations via e-mail but only if the following language is used in the e-mail accompanying the invitation(s).

Pfizer Speaker Program Invitation Template

Subject: "Pfizer Speaker Program Invitation"

"Dear [insert name],

Attached please find an invitation to a Pfizer speaker program. I hope you'll be able to attend.

Per Pfizer policy, please do not forward the invitation to others. If you know of another healthcare professional who might also be interested in attending, please let me know.

Also, if you would prefer not to receive Pfizer speaker programs invitations by e-mail from me in the future, please don't hesitate to advise me.

Sincerely,

[Colleague name]

[Include your contact information, but do not use any other signature message or information]

No other information may be included in the e-mail message – including the name of any Pfizer products, indications, disease states, therapeutic areas or similar matters, (including in the colleague's e-mail signature). Colleagues who e-mail an invitation also must refrain from changing the file name of the pdf document, which should generally reflect only the meeting number. Under no circumstances should the file name include a product name or indication.

If a recipient informs the applicable Sales Colleague that he or she does not wish to receive speaker program invitations via e-mail, the Sales Colleague will be responsible for honoring that request.

Sales Colleagues should consult with their District Managers if they have any questions or concerns about a specific message.

Determine the Appropriate Audience

You, not the speaker, are responsible for selecting the audience for your speaker program. The audience should consist of HCPs with a legitimate interest in the scheduled topic, and the invitees must not be chosen for the purpose of encouraging referrals for the speaker. It is impermissible for a speaker to promote his or her own practice in connection with a Pfizer speaker program.

You must also make a good faith effort to ensure that all attendees: (1) practice in an appropriate specialty that is not excluded for the promoted product; and (2) do not hold active licenses from states that impose restrictions on providing meals (if you choose to provide one at the program).

Remember that some states may prohibit or limit providing food or beverages to HCPs licensed in those states, including during speaker programs (regardless of where the HCP practices or where the speaker program occurs). For instance, you may not invite HCPs who are licensed to practice in **Minnesota** or **Vermont**, or employees of Vermont HCPs, to any speaker program (in-office or out-of-office) if food will be provided. Similarly, you may not invite HCPs licensed in **Massachusetts** or their staff to an out-of-office speaker program if food will be provided (although in-office programs are permitted). To determine whether an HCP is licensed in one of these states, consult your iCUE tablet or the HCP License List on the [PfieldNet Compliance page](#). In addition, some state employees may be prohibited from accepting gifts (which often include meals at speaker programs) from pharmaceutical companies by state law. For more information about state laws that limit the provision of gifts to HCPs, please see Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions.

A speaker program may include non-HCP attendees, such as case managers and clinical coordinators, if there is a legitimate business reason for them to attend. However, they should only be invited if the colleague determines that the program contents are appropriate in light of the attendee's role and responsibility for patient care.

The audience of a speaker program must include at least two HCPs (or other appropriate attendees) who are not part of the speaker's medical practice, practice group, or institution. If HCPs receive compensation as employees from the same business entity, even if they work in different locales, they are considered members of the same practice or institution.

Providing In-Office Meals to Office Staff



- Q. When conducting a speaker program at a medical office, is it ok to provide a meal to the office staff in addition to the HCPs at the program?
- A. Yes, it is generally permissible to provide them with a meal so long as the staff members attend the program and are provided with scientific or educational information.

Appropriate Audience

- Q. May non-prescribing HCPs (such as nurses) and appropriate office staff (such as case managers) attend a speaker program held outside of the office?
- A. Generally, non-prescribing HCPs may attend Pfizer speaker programs. Office staff, including office managers and clinical coordinators, may only be invited if a colleague determines that the program contents are appropriate in light of the attendee's role and responsibility for patient care. Non-prescribing HCPs and office staff members may be provided meals when they attend speaker programs.
- Q. What should I do if an HCP's receptionist attends a speaker program to which he or she was not invited?
- A. If the receptionist's responsibilities are purely administrative, he or she is not an appropriate attendee. It is your responsibility to ensure that all speaker program attendees are appropriate, given their role and responsibilities in patient care.

Specialty Exclusions

- Q. May I invite HCPs to a speaker program if they belong to a specialty that is excluded for the product being discussed?
- A. You should not invite an HCP that belongs to a specialty that is excluded for the particular product being discussed. If you are unsure whether a prospective attendee is subject to an applicable exclusion, consult the HCP profiles on your iCUE tablet to verify his or her status before extending an invitation. Remember, if you cannot detail an HCP on a particular product, you are not permitted to invite the HCP to a speaker program on that product.

Remote Attendance at Speaker Programs

- Q. Is it permissible for HCPs to attend speaker programs remotely (e.g., WebEx or teleconference)?
- A. Yes. HCPs may attend speaker programs by remote means as long as an appropriately trained colleague monitors the program to ensure compliance with all of the policies set forth in this Field Guide. HCPs who attend a program remotely are counted toward Pfizer's two-HCP attendance policy (i.e., it is permissible for one HCP to attend live and one HCP to attend remotely). For other details on conducting remote programs, consult the "Planning a Sponsor or Link Telecon or Web Conference" Job Aid available on the EZSpeak Resources page.

Speaker Inviting or Suggesting Attendees

Q. May a program speaker or invitee personally invite other prospective attendees? May a speaker suggest attendees?

A. A speaker or invitee may suggest other attendees, but it is your responsibility to determine that each of the prospective attendees is appropriate. For instance, it would be inappropriate for you to invite HCPs who practice in excluded specialties. If a speaker or invitee wishes to invite others to attend, they must let you know in advance of the program so you can determine their appropriateness. RSVPs for the program should not be collected by the speaker or other HCPs.

You cannot conduct a speaker program for the benefit of the speaker, and therefore, it would be improper to invite attendees at the request of a speaker without a justifiable business rationale for including them. Although speakers sometimes inappropriately consider speaking engagements to be opportunities to increase referrals from other physicians, your sole purpose in running the speaker program must be to educate HCPs about Pfizer or Pfizer products.

Speakers to One Medical Office or Practice

Q. Can a representative invite a speaker to speak to HCPs at a single medical office or practice?

A. Yes, if at least two or more HCPs not affiliated with the speaker are invited and in good faith are expected to attend. Pfizer cannot compensate members of the same business organization to educate each other on topics related to improving patient care within their organization.

U.S. HCP Payment Disclosure Policy

Pfizer collects data on all payments, meals, reimbursable travel expenses and educational items provided to U.S. licensed HCPs. Pfizer has committed to publically disclosing these payments. The disclosures will include speaker honoraria, travel expenses, and meals provided to speakers and attendees of speaker programs. Effective January 1, 2012, this information will also be collected for Pfizer reporting in accordance with federal transparency requirements.

If an HCP does not want to have items reported, he or she must not attend a speaker program that contains a meal and must not otherwise accept or receive meals or speaker fees from Pfizer. Pfizer maintains a record of HCPs who have “opted out” of receiving disclosable items from Pfizer, which you

can view on the [PfieldNet Compliance page](#) or at <http://OpSource.Pfizer.Com>. Colleagues should review the list prior to choosing a speaker, inviting attendees and conducting a speaker program.

For additional information on Pfizer's HCP payment disclosure Policy, see Chapter 18: Meals, Educational Items, and HCP Payment Disclosure.

Spouses or Domestic Partners as Guests

Guests of HCPs, including their spouses or domestic partners, are not permitted to attend Pfizer promotional speaker programs unless they independently qualify as HCPs or are appropriate office staff members for whom the informational presentation is appropriate.

How to Handle Uninvited Guests



- Q. What should I do if an HCP brings a non-HCP spouse or guest to a speaker program? Is it OK for the guest to stay if the HCP agrees to pay for his or her meal?
- A. No. You should remind the HCP that Pfizer guidelines and the PhRMA Code prohibits guests, spouses or domestic partners from attending Pfizer speaker programs. This is clearly stated on the approved speaker program invitation. If the guest does not independently qualify as an HCP or other appropriate office staff attendee, you must respectfully ask that the guest leave the program.
- Q. What should I do if I believe that an uninvited HCP belongs to a specialty that is excluded for the product being discussed at the speaker program I'm sponsoring?
- A. If an uninvited HCP arrives whom you know (or are able to reasonably ascertain) is subject to an applicable specialty exclusion, you must respectfully ask that the HCP leave the program.

Your Role During a Speaker Program

Monitor for Consistency with Labeling

The information presented during a speaker program must be consistent with the FDA-approved labeling for Pfizer's products and present a fair balance of the benefits and risks.

During the program, you must be prepared to project the RC-approved slide deck from your Pfizer laptop and you must monitor the presentation to ensure that the speaker's discussion is consistent with the slides and the product's labeling. You must ensure that the speaker presents appropriate safety information, consistent with product labeling. If a speaker discusses any product that contains a "Black Box" warning, you must ensure that the speaker appropriately presents the warning and the Other Safety Information in order to provide a fair and balanced presentation. Further, if any attendee arrives after fair balance content (safety, risks and contraindications) has been presented to the audience, the speaker must review that content with the late attendee(s).

HCPs may not use speaker opportunities to generate business and may not distribute business cards during programs.

A speaker may only discuss off-label information in response to a specific unsolicited question from the audience. Any answer by the speaker to an off-label question must be brief and limited to the specific question asked. If the HCP asking the question requires additional information or the question cannot be adequately answered briefly, the speaker (or Pfizer Representative) must refer the HCP to the Medical Information department. A mandatory compliance slide at the beginning of each speaker program notifies attendees that you must make a clarifying statement if the Speaker presents information that is inconsistent with an FDA-approved label or Pfizer policy.

Different rules apply to consumer audiences. For Pfizer's policies regarding presentations to consumers, see Chapter 16: Consumer and Employee Interactions.

Off-Label Information

Q. What should I do if a speaker presents off-label information during his or her presentation that was not in response to a question?

A. You should:

- Promptly and courteously clarify to the audience that the off-label information provided is not within product labeling (this should be done as soon as possible after the speaker has presented and prior to the Q&A).
- Remind the speaker after the presentation that Pfizer’s guidelines require that off-label information be provided only in response to a specific, unsolicited question.
- When you close out the program in EZSpeak, indicate, as prompted in the system, that a violation was committed by the speaker. Once submitted, your Regional Manager, District Manager, and Regional Attorney will receive an e-mail that summarizes your report. Speakers who proactively speak off-label may be subject to further action, up to and including deactivation.

Note: If the speaker answers an unsolicited off-label question briefly and as permitted by policy, no “corrective” statement is required and no policy violation should be indicated when you close out the program.

Handouts and Give-aways

Copies of the approved package insert for each Pfizer product being discussed must be available at each presentation. Only RC-approved educational materials may be provided to attendees. Unless prohibited by the Review Committee, you may disseminate paper copies of EZSpeak slides at a program if the relevant package insert is also made available to attendees. However, you should not distribute electronic copies of EZSpeak slides without first consulting your Regional Attorney. You are responsible for copying and disseminating these approved materials to attendees – not the speaker. Copies of slides created by the speaker cannot be handed out (even if they have been RC-approved through the Exceptions Process).

Gifts to Attendees of Speaker Programs

- Q. Can I purchase token gifts for attendees at my speaker program? Can I purchase a token thank you gift to give to the speaker?
- A. No. HCP attendees may only be given RC-approved educational promotional items that comply with Pfizer guidelines and the PhRMA Code and that are permissible under state law. You are not permitted to provide speakers with any additional items of value for speaking on Pfizer's behalf.

Payment and Reimbursement**Speaker Fees**

You are not responsible for negotiating the amount of a speaker's speaking fee. Fees are determined based on criteria that are identified in EZSpeak.

Each speaker has a limit on the total speaking fees (not including travel expenses) that he or she can earn from Pfizer in a calendar year. An individual speaker's annual limit will be set through Pfizer Headquarters and any increases must be approved in advance by Headquarters.

You are responsible for providing accurate and truthful information about a proposed program so that the appropriate speaking fee can be paid.

Speaker Fees

- Q. May a speaker waive his or her fees, or request that Pfizer donate the honoraria to charity or to his or her institution?
- A. A speaker may agree to waive the fees and speak for free (or for less than the contracted rate). However, for tax purposes, Pfizer cannot donate fees on a speaker's behalf.

Closeouts

After a program, representatives must enter program information in EZSpeak to close out the program, including flagging any policy violations that may have been committed by the speaker. In addition, speakers must close out a program to initiate payment. Speakers must review the speaker invoice online in Speaker Resource Center (SRC) and acknowledge that the meeting date, location, speaker,

and speaking fee are correct. Alternatively, speakers may submit a signed hard copy invoice to AHM or other designated meeting vendor.

Cancellation and Payment



- Q. I received RSVP's from multiple prospective attendees of a speaker program, but several of them cancelled at the last minute. Should I cancel the program?
- A. You should invite enough HCPs to ensure that at least two or more HCPs not affiliated with the speaker are expected to attend. However, if you receive unexpected cancellations and only one HCP attends, you are not required to cancel the program. You should explain the circumstances around the potential policy deviation during the EZSpeak close out process. Meanwhile, if there are no appropriate attendees, a speaker program must be cancelled.
- Q. What should I do if I decide to continue the program, but the unexpected no-shows cause me to spend more than \$135 per attendee on the meal (including food, beverage, tax and tip)?
- A. You must always accurately record expenditures on meals for HCPs, even if they exceed the \$135 per attendee cap. You will be asked to document the circumstances around the potential policy deviation after you close out the program in EZSpeak. You can reduce your risk of violating this important policy by selecting inexpensive menu items and by planning speaker programs at venues that do not require large minimum guarantees.
- Q. In the event that Pfizer has to cancel a speaker program, do I still have to pay the speaker?
- A. If Pfizer cancels a speaker program within five business days of the scheduled engagement, and the speaker requests payment, Pfizer is contractually obligated to pay the speaker his or her speaking fee with very limited exceptions. However, if the same speaker program (i.e., same colleague, speaker, and product) is rescheduled within 90 days from the date of the cancelled program, the speaker must speak at the rescheduled program for no additional speaking fee. You must make every reasonable effort to reschedule the cancelled speaker program within this timeframe. If a program is cancelled more than five business days in advance, Pfizer is not required to pay the speaker's fees.

Attending the Speaker Program

- Q. Do I have to be present during a speaker program?
- A. You always must be present with the speaker during a live speaker program you host to ensure that Pfizer guidelines are followed (and must monitor any program conducted remotely via WebEx or teleconference). If you cannot attend, you may ask your manager or other appropriately trained colleague to attend on your behalf. However, if no representatives are available to attend, the program must be cancelled.

Speaker Programs at Third Party Meetings

Third party meetings held by groups such as local medical associations or residents at institutions may provide you with an excellent opportunity to promote Pfizer products to HCPs who are gathering together for another purpose.

When deciding whether to hold promotional programs in connection with such meetings you must evaluate whether your business purpose is appropriate and you must exercise good judgment. Holding a promotional program in this circumstance must be based on a legitimate business purpose to present information about Pfizer products, and cannot be based on a desire to support or otherwise fund an independent meeting.

Follow these key principles to ensure that the speaker programs conducted in conjunction with third-party meetings are appropriate:

- You must have a legitimate promotional speaker program in connection with the meeting.
- A speaker must make a presentation similar in duration and substance to other speaker programs.
- All Pfizer policies and processes regarding speaker programs must be adhered to—for example, if the customer permits spouses or guests to attend its meeting, holding a Pfizer speaker program in connection with the meeting would not be appropriate.
- You must make it clear to the customer or organization that Pfizer is not a “sponsor” of its business meeting. Explain that Pfizer is engaging in a separate promotional activity with attendees of the meeting. Identify to the audience a clear start and end to the Pfizer

promotional program to avoid the misperception that Pfizer is supporting any part of the meeting itself.

- If you provide a meal it must be offered as part of the Pfizer program, and must be incidental to and not otherwise the focus of the program.
- Pfizer cannot split the cost of a meal with the host of a third party meeting. However, you may conduct a Pfizer speaker program during a meal that is provided and paid for entirely by a third party, as long as you make clear that Pfizer is not responsible for providing the meal. Meals provided by third parties will not be reported as part of Pfizer’s payment disclosure policy.
- Before or after the Pfizer program, you should avoid being present during any discussion of any Pfizer product that you anticipate will be inconsistent with that product’s labeling.
- As with traditional speaker programs, you must capture all appropriate attendee information in EZSpeak. Before confirming the program, you should coordinate with the third party to ensure that you will receive all necessary information about the attendees.

If a colleague participates in any way in the content of the non-Pfizer meeting, the entire meeting may be considered a promotional event and is then governed by the same promotional rules that apply to all Pfizer speaker programs or other promotional activities.

You may conduct a speaker program in connection with an accredited medical education activity (ACCME, ACPE, or ANCC) **only** under the following additional conditions:

- The Pfizer program must be conducted in a room physically separated from the space where Continuing Education (CE) activity is conducted.
- At the start of the program, you must clearly communicate to attendees that it is a separate Pfizer promotional presentation not accredited for Continuing Medical Education (CME) credit.
- Pfizer cannot provide meals or beverages in connection with the Pfizer program. Any meals provided by a CME provider must be made available to all CE event attendees, including those not attending the Pfizer presentation.

- No advice or guidance may be provided regarding the content of the medical education activity.
- No financial or other support, including payment for event expenses or meals, assistance with setting up logistics or handling non-Pfizer speaker arrangements, may be provided in connection with the Pfizer program (subject to very narrow exception for logistical expenses discussed below). Financial support may only be funded by an independent medical education grant requested through Pfizer's Medical Education Grants website. For more information, see Orange Guide Chapter 3: Support of External Organizations.

Third-Party Meeting Venues



- Q. I have been offered an opportunity to conduct a promotional speaker program as part of a local medical group's two-day annual meeting. However, the meeting venue is a lavish country club and I understand that the group is providing various entertainment activities in connection with the meeting (e.g., rounds of golf). May I still conduct the program?
- A. Possibly. If Pfizer has no control over the venue and we are reasonably comfortable that Pfizer can provide an educational presentation segregated from any entertainment component, this may be acceptable. Please remember that Pfizer cannot support, nor may you participate in, any of the entertainment activities. Consult with your Regional Attorney for guidance in these situations.

Meals Provided by Medical Education Organizers During a Pfizer Speaker Program



- Q. The organizers of the medical education event intend to offer a meal to attendees during my promotional speaker program. Can I still conduct the program?
- A. Yes. As long as Pfizer is not paying for the meal and it will be made available to all event attendees (including those not attending the Pfizer presentation), it is acceptable for the meal to be provided at or during the Pfizer program.

Physical Separation of Speaker Programs at Medical Education Events

- Q. The organizers of the medical education event require that Pfizer pay a fee to cover expenses that are directly associated with the promotional speaker program, such as the cost to rent the separate presentation room. Must this fee be paid through the Medical Education Grant process?
- A. No. Standard fees required to cover the fair market value of logistical expenses associated with the Pfizer speaker program may be paid by the appropriate Pfizer Sales Colleagues.
- Q. I've been offered an opportunity to provide a promotional speaker program during a medical education event, but the organizers have told me that no separate room will be available. Can I still hold the program?
- A. Generally no. However, if it is possible to physically separate your presentation space within the event room, you may consult with your Legal Counsel about an exception to determine if and how the program may be conducted appropriately under the circumstances.

FOR MORE INFORMATION

- For more information about Pfizer's policies and procedures for conducting speaker programs, please refer to EZSpeak.
- For more information about retaining HCPs for activities other than speaker programs, including preceptorships and colleague training, refer to the "HCP Engagements" tab at <http://OpSource.Pfizer.Com>.
- For more information about Pfizer's policies for conducting compliant speaker programs for consumers, see Orange Guide Chapter 16: Consumer and Employee Interactions.
- To determine whether an HCP is licensed in Massachusetts, Minnesota or Vermont, consult your iCUE tablet or the HCP License List on the [PfieldNet Compliance page](#).
- For more information about state laws that limit the provision of gifts (including meals) to HCPs, see Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions.
- For more information about the HCP payment disclosure policy, see Chapter 18: Meals, Educational Items, HCP Payment Disclosure.



- Refer any additional questions to the Speaker Operations Team, your manager or Regional Attorney.

Chapter 10: STARTERS

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Chapter 10: STARTERS

Introduction

Pfizer provides healthcare professionals (HCPs) with free pharmaceutical drug product samples (referred to as “starters”) to give to patients so that they can evaluate the efficacy and tolerability of our products for the patient before filling a prescription. Starters also provide HCPs an opportunity to become familiar with a drug and its properties, thereby enhancing their ability to make appropriate prescribing decisions. The distribution of starters is highly regulated under federal and state law and the misuse of drug samples can have severe implications for both individual colleagues and Pfizer.

The Prescription Drug Marketing Act of 1987 (PDMA) is the key federal law governing the distribution of drug samples. Pfizer policies for complying with the PDMA are listed in the Starter Administration Compliance Manual and the key points are summarized in this Chapter. The distribution of starters is also impacted by other healthcare laws such as those dealing with fraud and abuse and off-label promotion.

In addition, several states have laws that affect whether and to whom starters may be distributed. For example, some states have particular limitations on distributing starters for controlled substances like Lyrica. Likewise, some states impose requirements (that differ from federal law) on when that were lost or stolen starters must be reported, as well as which mid-level practitioners (e.g., nurse practitioners, physician assistants) may prescribe drugs and are authorized to accept starters.

This Chapter summarizes certain key Pfizer policies regarding distribution of human biopharmaceutical starters. Non-compliance with these policies can put the Company at risk and can subject Pfizer Colleagues to disciplinary action up to and including termination.

Key Points to Ensure Compliance

- It is illegal to sell, purchase, or trade, or offer to sell, purchase or trade, starters. Starters may be provided only to licensed healthcare professionals eligible to receive starters and only if they are expected to distribute them for free on-label use by their patients.
- Only licensed HCPs authorized by their states' laws to receive and prescribe medications may sign a request for starters. Pfizer policy requires sales representatives to personally witness the signature on every starter request.
- Sales Colleagues using an iCUE tablet are required to utilize the electronic Starter Activity Form (eSAF) on the tablet for every starter transaction. A paper Starter Activity Form (SAF) may not be used except in the very limited circumstances described in this Chapter.
- All starter transactions must be documented completely and accurately at the time of the transaction. (Those limited transactions that utilize paper SAFs must be entered into iCUE as soon as possible after the call is made.)
- Starters may be packaged separately or in kits that may include PhRMA Code compliant educational items. All of the patient and provider materials packaged with starters must be reviewed and approved by the applicable Review Committee (RC) prior to distribution.
- The amount of starters allocated by each brand team must be based on the expected on-label use of the product. Starters must not be provided to HCPs in quantities that may appear to be intended as an inducement to use Pfizer products (i.e., a kickback). Providing starters in amounts or dosages based on off-label use is not permitted.
- Individual starter units cannot be altered in any way either before or after they are delivered to an HCP.

Key Points to Ensure Compliance

- Starters may not be provided to HCPs for use in clinical trials, other research activities or for distribution to patients in order to mitigate the cost of their treatment. HCPs seeking to assist patients that cannot afford their medications should be referred to Pfizer Helpful Answers. Starters may not be provided for charitable activities or an HCP's other philanthropic endeavors, nor may they be provided to missions or nonprofit organizations under any circumstances.
- Starters are not to be provided to HCPs for their personal use or taken by colleagues for their personal use ("personal use" includes use by family or friends).
- Any loss or theft of starters must be reported immediately to the Starter Operations Compliance Team and the responsible District Manager. Significant losses and thefts must be reported by the Starter Operations Compliance Team to the FDA within 5 days of becoming aware of the loss or theft.

Starter Allocation

A prescription drug starter sample is defined under the PDMA as a product unit that is packaged for distribution to healthcare providers free of charge. Such items must be clearly labeled to reflect their intended use and are intended to promote the sale of the drug. Off-label uses of a product should not be considered for starter allocations. Although HCPs may prescribe our products for off-label uses, our products cannot be promoted outside the approved labeling and therefore Pfizer may not knowingly provide starters for such uses.

When Sales representatives distribute starters, they are engaging in product promotion. Leaving a starter with an HCP implicitly delivers a message that the product is appropriate for its labeled use. When an HCP implies or states that he or she is using a Pfizer product for an off-label use, providing starters to that HCP for the off-label use may be considered off-label promotion and can subject Pfizer to prosecution.

Teams determining starter allocations should also consider the potential demand for a product on the black/grey market and/or the potential risk of diversion. If the product has a greater diversion potential, teams should consider limiting the number of starters distributed to the minimal amount necessary.

On-Label Use Starter Allocation



- Q. I am on a product team reviewing starter allocations for a product that physicians often prescribe for off-label uses. I would like to take the market for these uses into consideration when planning starter allocations, even though Sales representatives will not detail these uses. Is this permissible?
- A. No. Off-label uses should not be considered when determining starter allocations. When Pfizer distributes starters, it is engaging in product promotion. Leaving a starter with an HCP implicitly delivers a message that the product is appropriate for its labeled use(s).

Starter Packaging

Separate starter packaging, including the sample identification on the label (i.e., “Sample – Not for Sale”), is required by FDA. Also, the [OIG Compliance Program Guidance for Pharmaceutical Manufacturers](#) notes that companies should clearly and conspicuously label individual samples as units that may not be sold (thus minimizing the ability of recipients to advertently or inadvertently commingle samples with purchased product).

Starter “packaging” includes all product containers (e.g., blister cards and bottles), individual unit boxes (e.g., the box containing a sample bottle) and starter packs. Starter packages must remain intact and, as the labeling on starters is FDA approved, Pfizer colleagues may not alter starter labeling or packaging. Applying stickers or writing on starter packaging is prohibited. Any alteration or removal of starter packaging can render the product “misbranded” under the law.

However, the outer shelf display packaging that holds together product containers with individual unit boxes or starter packs typically does not contain the FDA approved labeling. Its removal does not, therefore, result in the misbranding of the product. If asked to do so by the recipient HCP, a Sales Colleague may remove the product containers or starter packs from the outer display packaging if it will allow the starters to more easily fit in the space available. Sales Colleagues must ensure that at least one package insert is left with each type of product starter left.

Stickers

- Q. Can a Sales representative place Pfizer Review Committee approved (“RC-approved”) product stickers on starters?
- A. No. Stickers or labels may not be affixed to any starter packaging. Starter packaging has been approved by the FDA, and altering it by affixing stickers or labels may “misbrand” the package, rendering it a homemade and in violation of the law. If an HCP requests adhesive tracking labels for use in recording their practice’s receipt of starters or distribution to individual patients, colleagues may follow the instructions found in the “Starter Information” section of PfieldNet at <http://pfieldnet.pfizer.com> and use the accompanying template to create them. Please note, however, that while these can be left with the starters they are not, under any circumstances, to be affixed to them.

Appropriate Uses for Formulary Stickers

- Q. Can a Sales representative put “Now on Formulary” or other approved stickers in the sample closet?
- A. Yes. With the approval of the HCP’s office staff, a Sales representative can place RC-approved stickers in the sample closet to identify Pfizer’s starters, but the stickers cannot be placed on starter packaging itself and may never be placed on a competitor’s product or product packaging.

If a colleague has any questions about what he or she can or cannot do with respect to a particular product’s starter packaging, he or she should consult his or her manager, Starter Operations, the relevant Regional Attorney or team attorney.

Key Points: Basic Rules Regarding Handling of Starter Packaging

- DO NOT alter or remove product packaging as it contains information required by law and approved by the FDA;
- DO NOT remove starter bottles from the individual boxes in which they were provided; and
- DO NOT apply stickers or labels to any starter packaging, including the individual boxes, product containers, sample packs or outer display packaging.

Inclusion of Materials with Starters

Provided that starter product packaging remains intact, starter kits may be offered in kits that include PhRMA Code compliant educational items, such as patient journals or other disease state educational booklets. Before such materials are distributed, they must be reviewed and approved by the applicable RC. When presenting such items for review, the RC team must be advised that the items will accompany starters as part of a starter kit or other promotional program. Like all promotional items, materials included in Pfizer starter kits must be factually accurate and must not be misleading in any respect. All promotional statements made about a Pfizer product must be consistent with the information contained in the product's approved package insert and/or in an approved promotional piece. These additional materials must be submitted to the FDA at the time of first use.

As with any promotional materials, Sales representatives may not alter these additional materials in any way or add their own promotional materials to them.

Distribution of Starters to Approved Recipients

Detailed procedures for starter accountability and compliance are set forth in the Starter Operations Compliance Manual. Sales and other colleagues involved directly in starter distribution should be familiar with the policies and procedures set forth in this manual.

By law, pharmaceutical companies may provide starters only to licensed HCPs with authority to prescribe medication or, at the prescriber's direction, to the pharmacy of the institution in which the licensed HCP works. Only a licensed HCP may sign a request for starters. The authority to prescribe and/or accept starters varies by state. Certain restrictions may apply to mid-level HCPs (i.e., NPs and PAs) and their ability to prescribe and/or receive starters within each state.

In addition, some states have particular limitations on distributing starters for controlled substances like Lyrica. Sale Colleagues should check with their manager, Starter Operations, or Regional Attorney if they have questions about who can receive particular Pfizer starters in their particular state.

Starters cannot, under any circumstances, be provided to an HCP:

- If the HCP intends to seek reimbursement from the government for the starter;

- If the HCP is within an excluded medical specialty;
- If the HCP intends to use the starter for his or her personal use;
- To reward the HCP for past prescribing or as a financial inducement for future prescribing;
- If it is reasonably certain that the HCP intends to prescribe the starters for an off-label use;
or
- If the prescriber's license number has not been verified in iCUE as that of an HCP to whom starters are permitted to be provided.

Sales Colleagues may not initiate any starter transactions with an HCP until the State License Number (SLN) for that HCP is "verified" as valid in iCUE.

In the past, other pharmaceutical companies and individuals have been charged under the False Claims Act and the anti-kickback laws, and fined hundreds of millions of dollars, for encouraging HCPs to bill government programs for starters. For this reason, HCPs must confirm their understanding and acceptance of the fact that **starters "cannot be sold, traded, bartered, returned for credit or utilized to seek reimbursement"** by signing the eSAF (or paper SAF, in those limited circumstances where paper SAFs are permitted).

Pfizer policy further provides that Sales representatives must witness the signature on Starter Activity Forms.

If a Sales Colleague suspects that an HCP is charging the government or patients for starters, the colleague must immediately stop providing starters to that HCP and discuss the situation with his or her manager, Starter Operations, or Regional Attorney.

Pharmaceutical companies must maintain records tracking the movement of all starters from the time they leave the distribution facility to the time they are delivered to the healthcare provider. Significant losses, including inventories with unacceptably large negative variances and all thefts of starters, must be reported by Starter Operations to FDA within five business days. It is essential, therefore, that Sales representatives notify Starter Operations of all thefts and starter losses immediately upon becoming aware of them. Some states also have reporting obligations which are more stringent than federal law. Record falsification and diversion of starters must also be reported to FDA. Pfizer Starter Operations handles all FDA reporting.

Additionally, Pfizer routinely conducts reviews and audits of colleagues' starter activities. Failure to comply with the PDMA and Pfizer's policies may result in disciplinary action, up to and including termination, and may cause both a Sales Colleague and Pfizer to be liable for substantial penalties under the PDMA.

On-label Use of Starters



- Q. If a specific dosage of a starter package of a product is not used on-label by a particular specialty because they never see the appropriate type of patient, but there is a dosage that can be used on-label by the same specialty, is there any limitation on what Sales representatives can distribute to them?
- A. Yes. Sales representatives may only distribute starter packages which are consistent for the on-label use of the product for each particular specialty. Thus, if a Pfizer product has various approved dosages for various indications, it is essential that Sales reps only distribute the starter packages to specialists which are on-label for the particular patient population that they would see.
- Q. If physicians can prescribe drugs for both on-label and off-label uses, can a Sales representative leave starters with a physician who wishes to use them in the treatment of a patient for an off-label purpose?
- A. No. When a Sales representative distributes starters, he or she is engaging in product promotion. Leaving a starter with an HCP implicitly delivers a message that the product is effective and safe for its labeled uses. When an HCP implies or states that he or she is using a Pfizer product for an off-label use, providing starters to that HCP may be considered off-label promotion and subject Pfizer to prosecution under the False Claims Act. Off-label use can also be implied if Pfizer provides starters to a specialist that does not treat the condition for which the product is indicated (e.g., Detrol LA to pediatric urologists or Viagra to OB/GYNs).

Distribution of Starters to Physicians for Personal Use



- Q. If one of a Sales representative's physicians asks her for additional Lyrica starters because the physician's spouse suffers from fibromyalgia, can the representative give them to the physician?
- A. No. Federal and state laws, as well as industry guidelines (the PhRMA Code on Interactions with Healthcare Professionals and the American Medical Association's Code of Ethics) prohibit the distribution of starters to HCPs for their own or their family's personal use.

Distribution of Starters to Colleagues for Personal Use

- Q. If a colleague is suffering from an infection and he or she asks a Sales representative for one or two doses of an antibiotic that the representative promoted while on a field ride, is it ok to provide it?
- A. No. It is not permissible to give any person, even a colleague, any starter for his or her personal use. This could be considered practicing medicine without a license under various state laws. If a colleague makes such a request of a Sales representative, he or she must decline and report the request to his or her (or another) manager, Regional Attorney or through the Corporate Compliance Hotline. Failure to bring such a request to Pfizer's attention, or knowingly giving any starter away for personal use, is a violation of the Duty to Act and a violation of Pfizer policy and the law.

Hospitals, VA and DoD Institutions

Sales Colleagues are permitted to provide starters to hospitals and other healthcare institutions that use them in the treatment of their patients. In all cases, Sales Colleagues must deliver the starters to an HCP eligible to receive the starters on behalf of the hospital or institution (this would include the pharmacist in charge of handling starters for the hospital).

Some hospitals and healthcare institutions have policies that require starters to be left in the pharmacy and not with the individual physicians who have requested them. Sales Colleagues may do this only after completing a dual-signature paper "In House Pharmacy" Starter Activity Form. This form is used to document the physician's request for starters and the pharmacist's receipt of the starters in the institution pharmacy. The "In House Pharmacy" Starter Activity Form can be ordered from Starter Operations by calling Standard Register at 800-313-8263 and following the caller-directed prompts. As further described in this Chapter, for colleagues using an iCUE tablet, this is one of only two very limited exceptions under which a paper SAF may be used.

Meanwhile, many government institutions, such as Department of Veterans Affairs (VA) clinics and hospitals, may prohibit pharmaceutical companies from leaving starters. Other government institutions that do accept starters generally require them to be provided to the Chief of Pharmacy and not to individual physicians. Even if intended for use in private practice, starters should not be left for VA or Department of Defense (DoD) physicians at the government institution in which they work. For

more information on the distribution of starters in these government institutions, see the White Guide and Orange Guide Chapters on Federal Employee Interactions and Lobbying

Sales Colleagues must learn the sample policies of any institution that they call on and follow those rules, unless they conflict with Pfizer policy or the PDMA. If there are any questions about whether a customer's sample policies are consistent with Pfizer policies on starter distribution, colleagues should contact Starter Operations or a Regional Attorney before leaving starters with that customer.

Starters May Not Be Distributed for Research, Charitable Activities or To Defray Patients' Pharmacy Expenses

Starters may not be used for clinical trials or other research activities; nor may they be provided to non-profit organizations for missions or other charitable activities or to HCPs for distribution to patients as a means of mitigating their medication costs. A request for medication or other clinical supplies to support legitimate scientific investigations must be referred to the relevant Medical team for consideration as an Investigator-Initiated Research (IIR) grant. (For more information on scientific research, see the White Guide and Orange Guide Chapters on Clinical Research and Investigator-Initiated Research.) HCPs seeking to assist their patients in mitigating their medication costs can be referred to Pfizer Helpful Answers. (For more information, see the Patient Assistance Programs Chapter.)

Requests for medication from charities or from healthcare providers for charitable missions should be directed to the [Pfizer Corporate Responsibility department](#).

Managing Starters

As required by law and Pfizer policy, Sales Colleagues must adhere to strict requirements regarding documentation of their receipt and delivery of starters, and management of their starter inventory.

Accurately Document Receipt and Delivery of Starters

To accurately document receipt and delivery of starters, Sales Colleagues must strictly adhere to the policies and procedures in the Starter Operations Compliance Manual, including:

- Guidelines for acknowledging the receipt of starter shipments;
- Documentation of the starters delivered to licensed HCPs;
- Procedures for transferring starters between colleagues; and
- Timely entry of starter transactions into iCUE.

Failure to adhere to these policies and procedures can place Sales Colleagues and Pfizer at risk under the PDMA, distort their on-hand reported inventory balance, and undermine the reconciliation of their annual starter inventory.

Key Points: Documenting the Receipt and Delivery of Starters

- Document all starter transactions completely and accurately at the time they occur.
- Utilize the iCUE tablet to document all starter transactions (unless one of the limited exceptions permitting paper SAFs described in this Chapter apply).
- Provide complete, accurate and truthful information on all eSAFs (and paper SAFs, in the very limited circumstances when a paper SAF is permitted).
- Witness the receiving HCP sign the iCUE screen (or paper SAF) at the time of delivery.
- Immediately report any and all shipment shortages or overages, starter losses, and thefts to Starter Operations for further evaluation and reporting to the FDA.

Completion of eSAFs and SAFs

Sales Colleagues using an iCUE tablet must utilize the tablet for every starter transaction – subject to two very limited exceptions outlined below. A paper Starter Activity Form (SAF) may only be used:

- When a Sales representative is dropping starters at an institution that requires the starters its HCPs request to be distributed to its pharmacy and not with the individual requesting

them (in this case, the dual-signature “In House Pharmacy” SAF described in this Chapter must be used), or

- With prior written approval from Starter Operations, in very limited, infrequent circumstances where the iCUE system is experiencing certain significant hardware or software malfunctions for an extended period of time, until such time as the underlying causes of the malfunction are resolved. (Sales Colleagues should ensure that their iCUE tablets are charged; drained batteries do not qualify as an iCUE malfunction.) Written requests may only be submitted by Sales Managers by e-mailing a description of the issue, and information provided as part of the CSC Help Center assigned ticket, to StarterCompliance@pfizer.com.

If a paper SAF is utilized as permitted above, colleagues must enter the information into iCUE as soon as possible after completing the paper SAF transaction.

The iCUE and paper SAF starter call records are designed to document requests from licensed prescribers for starters and confirm their receipt of provided starters (or a pharmacist’s receipt of starters in the case of “In-House Pharmacy” Forms). The iCUE (and paper SAF) starter transactions are Pfizer’s legal record of each starter transaction and must accurately reflect the date on which the request and delivery occurred, the name, address, license number and professional designation of the prescriber and the products and quantities that they are given.

The iCUE eSAF (or paper SAF) must be completed in its entirety before it is presented to the prescriber for signature. If a prescriber does not provide his/her signature to confirm request/receipt of starters, the Sales Colleague must not provide him/her with starters. A receipt form may be provided to a physician when using the iCUE tablet by checking the receipt requested by mailbox option on the screen. (If using a paper SAF in the limited circumstances described above, the yellow copy of the form must be left with the recipient to retain for their records.)

Witnessing Signatures for Starters

- Q. When a Sales representative delivers starters to a physician's office, can the receptionist take the iCUE tablet to the HCP for signature?
- A. No. The iCUE tablet should never be given to anyone and should always remain in the Sales representative's possession. Pfizer policy requires that the Sales Colleague always witness the HCP signing the form or iCUE tablet. In this way, if questions come up regarding the HCP signature (e.g., during a subsequent audit or inspection), the Sales Colleague will be able to verify that he or she witnessed the HCP signing and receiving the starters. (However, in the limited circumstances where a paper SAF is permitted, a receptionist may take the SAF to the HCP for signature as long as you can clearly see the HCP signing the form.)

Reconciling Starter Inventory

The PDMA requires that every Sales Colleague have at least one physical inventory count of their starters taken within each 12 month period. Successful reconciliation requires accurate starter recording in iCUE, timely call reporting and the correction of any errors or discrepancies found in the course of recording starter information.

Colleagues should regularly review their weekly iCUE Starter Activity Reports (SARs) and periodically conduct their own physical inventory count. This count should be reconciled against the Ending Balance Report that is sent to each Sales Colleague with their SAR. If a Sales Colleague finds an error or discrepancy when reconciling starters, he or she should immediately contact Starter Operations for further guidance.

In addition, all starter losses and thefts should be reported to Starter Operations immediately so that the required notification can be submitted to the FDA within five days.

Reminder on Expired Starters

Expired starters cannot be given to a healthcare provider under any circumstances and should be shipped promptly to Pfizer's authorized destruction facility. Sales Colleagues should rotate their starters upon receiving each delivery, placing those closest to date of expiration in front to ensure that they distribute them first.

HCPs seeking to return expired or damaged starters should be directed to call Pfizer’s Starter Customer Service Team (800-533-4535) to schedule an appointment for the pickup of those items.

Paying for Bins in Starter Closets



- Q. Can a Sales representative pay for bins or space in starter closets in physicians’ offices?
- A. No. Paying for space in starter closets could violate anti-kickback laws.

Free Trial Vouchers: An Alternative to Starter Distribution

Some product teams use free trial voucher programs as a substitute for, or alternative to, the physical distribution of starters.

In a voucher program, instead of providing HCPs with starters for patient use, Pfizer (via Sales Colleagues and/or through Pfizer’s patient websites, for example) provides HCPs or patients with certificates (vouchers) that patients can redeem at a pharmacy for a free “trial prescription” of a medicine. The HCP must give the patient a prescription for the amount of product covered by the voucher. The patient takes the prescription and voucher to the pharmacy, where he/she receives the product free of charge. A third party administrator that contracts with pharmacy networks then reimburses the pharmacy. Pfizer teams implementing voucher programs follow the [Free Trial Vouchers, Co-Pay Relief and Similar Consumer Programs, Updated Free Trial Voucher Policy](#) and [related FAQs](#).

Improper use of vouchers can implicate the state and federal false claims acts and anti-kickback laws. Vouchers could also be deemed to impact the “best price” of a product (i.e., the discount the Company is required to give the Medicaid program on every unit of product it reimburses). For more information, see the White Guide Chapter 6: Government Health Care Programs.

Key Points for Developing a Voucher Program and Distributing Vouchers

- Vouchers must never be offered or provided to HCPs contingent upon the HCP's past, current or future prescribing practices;
- Vouchers may not be provided to HCPs to substitute for a discount, i.e., contingent upon sale of the product to that customer. Vouchers may not be offered to HCPs for personal use; and
- Vouchers are a form of product promotion. They may not be offered to HCPs for off-label uses; nor may they be offered to an HCP that practices in a specialty that is excluded for that specific product.

FOR MORE INFORMATION

- For Pfizer's policies for complying with the PDMA, see the *Starter Administration Compliance Manual*.
- Sales Colleagues needing to order the "In House Pharmacy" Starter Activity Form should call the Standard Register at 800-313-8263.
- For more information on scientific investigations, see the White Guide and Orange Guide Chapters on Clinical Research and Investigator-Initiated Research.
- For more information on distributing starters in government institutions, see the White Guide and Orange Guide chapters on Federal Employee Interactions and Lobbying.
- Questions may be referred to Starter Operations, or relevant Sales manager, Regional Attorney or team attorney.



Chapter 11: PATIENT ASSISTANCE PROGRAMS

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Chapter 11: PATIENT ASSISTANCE PROGRAMS

Introduction

A Patient Assistant Program (PAP) is a program that can help eligible patients obtain medications at a lower cost or, in some circumstances, at no cost.

Pfizer and the Pfizer Patient Assistance Foundation™ offer prescription assistance to patients through [Pfizer Helpful Answers® \(PHA\)](#). PHA is a family of assistance programs for the uninsured and underinsured who need help getting Pfizer medicines. These programs provide Pfizer medicines for free or at a savings to patients who qualify. Some programs also offer reimbursement support services for people without insurance.

This Chapter summarizes certain key Pfizer policies regarding Patient Assistance Programs. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination.

Key Points to Ensure Compliance

- Marketing teams must follow the requirements described in this Chapter when creating marketing materials that reference Pfizer patient assistance programs (PAPs).
- Field Force Colleagues must follow the requirements described in this Chapter when discussing PAPs with customers.
- Internal questions about Pfizer PAPs should be e-mailed to the Pfizer Helpful Answers team at PfizerHelpfulAnswers@pfizer.com.
- Patients and healthcare professionals should contact a customer service representative for [Pfizer Helpful Answers](https://www.pfizer.com/helpful-answers)® at 1-866-706-2400.
- A PAP:
 - May not make assistance determinations with regard to any provider, practitioner, supplier, or insurance plan used by the applicant;
 - Should assess applicants on a first-come, first-serve basis;
 - Should not exhibit any characteristics of a marketing program or in any way promote Pfizer products; and
 - Should have written formal guidelines establishing the criteria for assistance eligibility and the policies and procedures for administration of the programs.

Pfizer Programs

[Pfizer Helpful Answers](https://www.pfizer.com/helpful-answers)® is a joint program of Pfizer Inc and the Pfizer Patient Assistance Foundation™ and is designed to create options for patients who may need help accessing their Pfizer medicines. These programs provide savings on Pfizer medicines and/or free Pfizer medicines to qualifying patients.

Pfizer may also provide general reimbursement support services through Pfizer reimbursement assistance programs. Generally, however, Pfizer cannot represent individual patients or fund representation for them regarding a particular claim.



There are several programs that fall under the Pfizer Helpful Answers umbrella. When calling the PHA toll free number (866-706-2400) or by visiting the PHA website (www.PfizerHelpfulAnswers.com), patients or their advocates will be directed to the PHA program that might best meet their needs. Also, if Pfizer learns that patients are taking a medicine not made by Pfizer, the patients will be referred to other industry resources that might be able to help.

Additionally, some of the medicines sold by Pfizer are manufactured by partner organizations. Patient assistance programs for these medicines are often run by the product manufacturer, not Pfizer. Patients who call Pfizer looking for assistance with medicines in this category will be referred to the appropriate partner PAP. Information on these programs can also be found on the [Pfizer Helpful Answers® website](#).

Industry-Sponsored Programs

Pfizer also participates in industry-sponsored programs. [Together Rx Access®](#), sponsored by several leading pharmaceutical companies including Pfizer, provides savings on brand-name prescription products and generics. In addition, the [Partnership for Prescription Assistance](#) offers a single point of access to more than 475 patient assistance programs and links patients to Pfizer through [Pfizer Helpful Answers®](#).

Patient Assistance Program Compliance Requirements

A PAP:

- May not make assistance determinations with regard to any provider, practitioner, supplier, or insurance plan used by the applicant;
- Should assess applicants on a first-come, first-serve basis;
- Should not exhibit any characteristics of a marketing program or in any way promote Pfizer products; and
- Should have written formal guidelines establishing the criteria for assistance eligibility and the policies and procedures for administration of the programs.

Pfizer and the Pfizer Patient Assistance Foundation have carefully implemented Pfizer PAPs to ensure compliance with the above and relevant laws.

Depending on the particular program, patient access to Pfizer PAPs may be through a call center or paper and/or online applications. Patients must have a valid prescription for the desired Pfizer product. Individuals seeking to participate in a Pfizer PAP may be required to provide information including income, residency, and insurance coverage. This information may include Sensitive Personal Information (SPI) and may not be used or disclosed unless certain conditions are met. For more information on SPI, see the Privacy Chapter.

Referring Patients to Particular Plans



- Q. You are a Sales representative and one of your HCP customers tells you that he has Lipitor patients who are uninsured. He asks you how Pfizer can provide some assistance to cover the costs of their Lipitor. Pfizer Helpful Answers® lists Lipitor as being covered under Connection to Care®. Should you tell him to have his patients apply to Connection to Care®?
- A. No. Consumers should be referred to the [Pfizer Helpful Answers®](#) website or its toll-free number (1-866-706-2400) for information about all Pfizer PAPs. Because each PAP is structured in a fairly specific manner, and because Pfizer may add or remove products to its PAPs at any time, you should never refer individuals to any particular PAP. Also, some products are covered by more than one PAP. All first-time callers to the PHA call center will be asked to complete a phone screening and will be provided with the top three programs based on their eligibility.

Pfizer has checks in place to ensure patients and HCPs do not abuse a PAP. Forms of such abuse include falsifying income information, ignoring refill limits, and supplying or requesting a supply of a product beyond its covered amounts under a PAP.

Guidance for Marketing: Including PHA References in Marketing Materials

Marketing materials that reference PHA or any of its programs, including implementation guides, must be created in line with the below requirements:

- The PHA team will make available to Marketing teams a set of unbranded PHA materials that can be used by Field Force Colleagues for purposes of discussing the PHA programs.



- Marketing teams may include in their marketing materials the PHA logo and PHA pre-approved taglines and logo lock-ups without requiring the approval of the PHA RC. The placement of the logo and tagline should be either at the bottom of the piece or in area where it can be separated from the brand, therapeutic area or other messaging in the materials. Marketing teams should send samples of these materials to PHA to keep on file.
- If a Marketing team wishes to include PHA information beyond the standard PHA logo and tagline, those materials require the approval of both the PHA Review Committee and the brand, therapeutic area or other relevant Review Committee that normally approves these materials.

Guidance for Field Colleagues – Talking About Pfizer Helpful Answers® Programs

Pfizer Field Force Colleagues may engage in limited proactive discussions regarding PHA subject to the following requirements:

- Messaging must be consistent with PHA Review Committee approved materials, including any applicable implementation guides or PHA trainings.
- While Field Force Colleagues can proactively discuss PHA programs with healthcare professionals, messaging must remain broad, consisting of basic information about PHA programs, application processes, and eligibility criteria.
- The call-to-action should still remain, “call the PHA (or specific PHA program, e.g., First Resource) phone number for more information since each patient’s case is unique.”

In addition, the following Do’s and Don’ts apply:

DO	DON'T
Remind HCPs that there are many Pfizer medicines available through Pfizer’s patient assistance programs.	Do not promote Pfizer’s PAPs as a tool to influence prescribing habits and do not overpromise what the programs can deliver.



DO	DON'T
Explain that PHA programs are designed to help eligible patients in need get access to Pfizer medicines for free or at a savings. Some programs may also offer reimbursement support services for people with insurance.	Do not promote Pfizer Helpful Answers as a discounting program.
Remind HCPs that patients with insurance (such as Medicaid, Medicare Part D, or private insurance) may still qualify for Hardship Assistance through some of our programs if the guidelines are met.	Do not describe Hardship Assistance as a way to fill gaps in coverage (e.g., donut hole).

Help for Underinsured Patients

While PHA programs are designed primarily to help uninsured patients – that is, patients without prescription coverage, Pfizer also understands that some patients with prescription coverage through commercial insurance or public insurance such as Medicare Part D sometimes still have difficulty paying for their medicines due to gaps or caps in their plan, high co-pays or other factors. These “underinsured” patients can apply for Hardship Assistance through several of the programs under the PHA umbrella. If they qualify, they will be eligible to receive their Pfizer medicine for free through the end of a calendar year.

A special note about Medicare Part D patients:

As described above, patients with prescription coverage through commercial plans or public plans like Medicare Part D can apply for Hardship Assistance through several PHA programs if they are having difficulty paying for their medicines. This assistance complies with the specific guidelines that have been published about PAPs and Medicare Part D.

Under the Medicare Prescription Drug Improvement and Modernization Act, Medicare beneficiaries may enroll in Part D and thereby have all or part of their prescription drug costs covered by the government. Since its enactment, the Office of Inspector General (OIG) has cautioned that



manufacturer PAPs that donate their drugs that are payable under Medicare Part D are likely to implicate kickback issues.

Cost-sharing subsidies provided by manufacturer PAPs present the typical risks of fraud and abuse associated with kickbacks, such as steering beneficiaries to particular drugs, increasing costs to the federal government, providing a financial advantage over competing drugs, and reducing beneficiary incentives to use less expensive and equally as effective drugs. The OIG's Special Advisory Bulletin entitled [Patient Assistance Programs for Medicare Part D Enrollees](#) explains, for example, that subsidies provided by manufacturer PAPs may lock beneficiaries into the manufacturer's product, even if there are other equally effective, less costly options.

PAPs that operate entirely outside Medicare Part D, however, minimize kickback risks. In these circumstances, a Part D enrollee chooses to obtain medication without using the Part D insurance. The enrolled Part D beneficiary will receive assistance through a PAP but will not file any claims for payment with the Part D plan. The PAP assistance will not count toward the beneficiary's true out-of-pocket costs (TrOOP) or overall Part D spending.

Thus, in connection with providing patient assistance outside of Part D, Pfizer must ensure the following:

- That the applicable PAP includes safeguards that ensure that Part D plans are notified that the drug is being provided outside the Part D benefit;
- That the PAP provides assistance for the whole Part D coverage year or the portion of the year remaining after the beneficiary received PAP assistance;
- That the PAP assistance remains available even if the beneficiary's use of the drug is periodic;
- That the PAP maintains accurate and timely records to verify the provision of the drugs outside the Part D benefit;
- That the assistance is awarded based on reasonable, uniform, and consistent measures of financial need and without regard to providers, practitioners or suppliers; and
- That the arrangement complies with any applicable guidance issued by the Centers for Medicare and Medicaid Services.

Patient Assistance Programs and Medicare Part D

- Q. A patient with Medicare Part D prescription coverage is having difficulty paying for her Pfizer oncology medicine. Can she apply for help through Pfizer Helpful Answers?
- A. Yes. Patients with prescription coverage – such as Medicare Part D, Medicaid, or commercial insurance – who are having difficulty paying for their Pfizer prescription medicines can apply for Hardship Assistance through several of the programs under the Pfizer Helpful Answers umbrella. Patients should call Pfizer Helpful Answers at 866-706-2400 or visit www.PfizerHelpfulAnswers.com to learn more. If eligible, this patient will receive her Pfizer medicine for free through the end of the calendar year, and the assistance will be provided entirely outside of the Part D plan.

Donation of Pfizer Products to Support PAPs

Drug products donated by Pfizer to a PAP, whether or not Pfizer-sponsored, may be considered a charitable contribution and may generate tax deductions. Pfizer colleagues may never provide free product with the intent to motivate the prescribing of a Pfizer product, nor may their actions imply that the purpose of a contribution is intended to motivate prescribing of a Pfizer product. For more information on donating Pfizer products for charitable use, consult your team attorney.

FOR MORE INFORMATION

- The Pfizer Helpful Answers Team at PfizerHelpfulAnswers@pfizer.com
- PfizerHelpfulAnswers@pfizer.com (1-866-706-2400)
- Refer any questions to your team attorney

Chapter 12: CONTRACTING

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Chapter 12: CONTRACTING

Introduction

Contracts are legally enforceable agreements between two or more parties and can be written or oral. If you are in a position that involves negotiating contracts on behalf of Pfizer or Greenstone, you must remember that your actions may bind the companies even in the absence of a written agreement. For this reason, colleagues must never make an oral promise or sign an agreement before receiving all necessary approvals.

Pfizer and Greenstone may enter into discount arrangements with numerous customers, including but not limited to Health Maintenance Organizations (HMOs), Pharmacy Benefits Managers (PBMs), Long Term Care Pharmacy Providers, Large Physician Practices, Group Purchasing Organizations (GPOs), and the government to meet competition and to make Pfizer and Greenstone products available on formularies or source programs, where applicable. Generally, these discounts are made in the form of rebates, which are typically paid based on the units of product utilized. The process of negotiating these discounts with customers is referred to as "contracting."

Each colleague who works with organized customers is responsible for adhering to Pfizer's policies regarding contracting. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination.

Pfizer, Greenstone, and their competitors are prohibited from entering into any agreement that unreasonably restricts competition. To ensure full compliance with U.S. antitrust laws, you should never discuss the following topics with or among customers or competitors at any time:

- Pfizer's or Greenstone's pricing policies;
- Pfizer's or Greenstone's current or future prices, discounts, rebates or other terms and conditions of sale generally or as they relate to other customers;
- Pfizer's or Greenstone's current or projected profits or profit margins;
- Pfizer's or Greenstone's current or projected costs;

- Pfizer's or Greenstone's business, marketing and promotional plans;
- Pfizer's or Greenstone's bidding policy or its intent to bid or not to bid for particular business;
- Pfizer's or Greenstone's plan to do business or not do business with particular customers; and
- Pfizer's or Greenstone's intention to engage or not engage in particular research activities.

Discounting and Price Reporting

Generally, Pfizer and Greenstone must provide the federal government with either the largest discount that they provide to certain eligible customers, or a minimum percentage discount as noted below.

As part of the Medicaid Drug Rebate Program, Pfizer and Greenstone must enter into a national rebate agreement with the Secretary of the U.S. Department of Health and Human Services (HHS) for states to receive federal funding for outpatient drugs dispensed to Medicaid patients. This rebate agreement requires manufacturers to provide the federal government with a rebate equal to the greater of 23.1% of **Average Manufacturer Price (AMP)** or the difference between a manufacturer's **Best Price (BP)** and the AMP for each unit of product paid for by State Medicaid agencies. Notably, any discount Pfizer or Greenstone offers to eligible customers must be included in Pfizer's or Greenstone's price calculations and reporting.

Average Manufacturer's Price (AMP): has historically meant the average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. This definition was clarified by the DRA Final Rule and further modified by the Patient Protection and Affordable Care Act.

Best Price (BP): the lowest price available to any entity unless the sale, discount or other price concession is specifically excluded by law or is provided to an entity specifically excluded by statute or regulation. It includes cash discounts, free goods contingent upon purchase, volume discounts and rebates.

In determining the relevant price points and corresponding rebate amounts, Pfizer and Greenstone follow the guidance promulgated by the federal government, including the Deficit Reduction Act of 2005 (DRA), the final rule promulgated by the Centers for Medicare & Medicaid Services (CMS)

implementing sections of the DRA (Final Rule), and, most recently, The Patient Protection and Affordable Care Act.

Off-Invoice Discounting

Because BP is generally defined as the lowest price made available to eligible entities, Pfizer and Greenstone must make sure they factor into their price reporting all concessions made as part of the sale of products to eligible customers. Failure to do this may be perceived as false reporting of BP. When reporting BP, Pfizer must therefore take into consideration all cash discounts, free goods contingent upon a purchase requirement, volume discounts, and rebates (other than rebates under the Medicaid Drug Rebate Program itself). In addition, free or reduced-price services, grants, other price concessions, or other benefits offered to induce a sale may also be considered pricing terms.

For these reasons, all colleagues are prohibited from discussing grants, sponsorships, additional service contracts, collaborations, CGC Tools & Resources, or other “off-invoice” items of value in connection with discount or rebate negotiations. Additionally, providing grants, additional service contracts or other items of value in order to gain formulary or source program acceptance may also be considered an improper inducement under the anti-kickback laws and is prohibited by Pfizer policy.

Where possible, meetings on formulary or source program negotiations should be kept separate and discussed independently from other potential business opportunities. In addition, the internal contracting analyses should be separate and independent from the analysis of other business with the relevant customer. Where it is not possible or practical to have separate meetings on contracting issues, the following guiding principles will help mitigate the risks. These guidelines can also be used and adapted, as appropriate, when separate meetings on commercial and Medicare Part D arrangements are not possible or practical.

Prior to the meeting:

- Distribute an agenda. The agenda should segregate contracting discussions from other business.
- Limit attendance at meetings to only those colleagues relevant to the business at hand and ask the other side do the same.

During the meeting:

- Stick to the agenda.
- Firewall discussions into appropriate segments. One possibility is to separate all discussions where Pfizer or Greenstone are purchasing goods or services (Pfizer or Greenstone as "customer") from those where Pfizer or Greenstone are providing discounts, goods or services (Pfizer or Greenstone as "seller").
- Manage the other side's attempts to link discussions of multiple projects by deferring the issue for future conversation or delegating the issue to colleagues not in attendance.
- Carefully approach discussions of non-contracting business opportunities during the negotiation period prior to and around the time of rebate contract expiration.

After the meeting:

- Evaluate the contracting offer and other business proposals independently and on their own merits; separate business teams within Pfizer or Greenstone should do the respective evaluations.
- Be mindful of how financial and other notes regarding the contracting offer and other business opportunities may appear in hindsight. For example, the valuations for each business opportunity on the same worksheet may imply that the opportunities are connected and interdependent when the intent was otherwise.

"Swapping" Discounts between Commercial and Part D Plans

Many managed care organizations, including HMOs, currently manage both commercial and **Medicare Part D** books of business. These organizations will negotiate discounts from pharmaceutical companies on behalf of the government under Medicare Part D, as well as on behalf of their commercial business. The government has expressed concern that entities will utilize Medicare Part D leverage to obtain preferential discounts for their commercial books of business.

Medicare Part D: the part of the Medicare program that subsidizes the costs of prescription drugs for Medicare beneficiaries in the United States. It was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and went into effect on January 1, 2006.

"Swapping" describes a situation whereby a managed care organization, such as an HMO, and pharmaceutical company agree to "swap" access to the organization's Medicare Part D book of business in exchange for greater rebates for the organization's commercial books of business. Many HMOs might be willing to accept higher costs under Medicare Part D in exchange for lower commercial plan costs because the government subsidizes a portion of their Part D plan costs while they often remain entirely at risk for their commercial plan costs. Pfizer and Greenstone must never engage in swapping and must additionally avoid situations in which swapping behavior could be perceived.

Meetings on Commercial and Part D Contracts



- Q. May I discuss a commercial contract and a Part D contract in the same meeting with a customer?
- A. Yes. You may do this if the two are not discussed contemporaneously. For example, it is acceptable to discuss the commercial contract during the first half of your meeting, and then indicate to the customer that you are moving on to the Part D contract discussion for the remainder of your meeting.

The following are examples of "swapping":

- A pharmaceutical manufacturer and an HMO have a commercial agreement that provides the HMO with an average 10% rebate on all products. The parties enter into negotiations to reach agreement on new commercial and Part D agreements. In exchange for the HMO placing its products on the new Part D formulary, the pharmaceutical manufacturer offers to increase its rebate on the commercial agreement to an average 12.5% rebate. The additional 2.5% rebate could be considered an improper reward to the HMO for providing the pharmaceutical company with access to the HMO's Part D plan.
- A pharmaceutical manufacturer and an HMO have no existing contractual relationship and seek to negotiate new commercial and Part D rebate agreements. During the negotiations, the parties reference and compare the terms of both agreements. Since the agreements were negotiated at the same time, any concessions made by the HMO to accept lower

rebates on the Part D agreement could be construed to have occurred in order to improperly compensate the pharmaceutical company for providing the HMO with greater rebates on its commercial plans.

Additional Tips when Negotiating Contracts with Customers

- Do not discuss previously undisclosed information that may be material under SEC regulations, including, for example, potential changes in Pfizer's or Greenstone's pricing policy.
- Do not disclose confidential or proprietary information.
- Do not disclose pricing information contained in competitor contracts.
- Do not disclose terms or the existence of contracts with competitors.
- Any purchase of goods or services from a company must be at fair market value and necessary to fulfill a bona fide business need.
- When discussing a Pfizer or Greenstone product, follow the Food Drug and Cosmetic Act's guidance and Pfizer's policies on product promotion.

Key Points to Ensure Compliance

- Do not discuss Pfizer pricing policies or practices with competitors or customers.
- Do not discuss grants, service agreements, other items of value, or CGC Tools and Resources in connection with rebate negotiations.
- Do not offer lump sum payments in exchange for formulary placement or other types of customer access.
- Do not discuss or negotiate commercial and Medicare Part D rebate agreements at the same time.
- Do not link or reference the terms of Pfizer's commercial rebate agreement when negotiating a Medicare Part D rebate agreement, or vice versa.
- Do not attempt to leverage a commercial rebate agreement in order to secure access to a Medicare Part D rebate agreement.
- Do not attempt to leverage any additional (e.g., non-formulary) arrangements in order to secure preferential formulary status.

Contracting in the Generic Market

Generally, the legal risks in the generics market are substantially similar to the legal risks in the branded market. Increasingly, Congress, CMS, the Federal Trade Commission, and other federal and state agencies are scrutinizing branded manufacturers' relationship with generics.

FOR MORE INFORMATION

- Questions may be referred to your manager, CGC Legal, Contracting Development or Compliance Manager, or a member of the Established Products Business Unit Legal Team.



Chapter 13: HEALTH SCREENINGS

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Chapter 13: HEALTH SCREENINGS

Introduction

Colleagues working with Corporate and Government Customers (CGCs) or certain Specialty Markets may wish to support or hold health screenings. These screenings often take place as part of larger health fairs. Pfizer sponsors screenings to benefit the quality of patient health care. Screenings promote the early detection of diseases and offer patients a meaningful opportunity to treat (and possibly cure) a disease or condition.

This Chapter is relevant to all colleagues who have a budget for and are permitted to offer or implement health screenings sponsored by Pfizer. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination.

Key Points to Ensure Compliance

- Only provide health screenings in accordance with the guidelines in this chapter.
 - Do not design your own program for a customer.
 - Do not modify approved health screening tools.
 - Do not alter or customize materials in any way for a customer.
- Offer approved health screenings without any expectation of return to Pfizer.
 - Do not condition the offer of a health screening on increased prescribing or improved formulary status.
 - Do not offer health screenings as an inducement to place Pfizer products on formulary.
- Make health screenings widely available.
 - Do not choose customers to receive screenings based on their likelihood to prescribe Pfizer products.
- Health screenings cannot be tied to the use of Pfizer products in any way.
 - You may seek information about products or programs used by those participating in the screenings, but you may not use such information to promote the use of Pfizer products. For further information on appropriate consumer interactions, see Chapter 16: Consumer and Employee Interactions.

Screenings Offered to an Employer for its Employees

Screenings should be funded out of your promotional budget and approved by your CGC Regional Manager or Sales Director. You should not offer health screenings to employers who are healthcare providers or payers of healthcare items and services, such as hospitals, clinics, medical practice groups and Managed Care Customers (MCCs) who seek reimbursement from the federal government, except for employers who may receive a government retiree drug subsidy for retirees. Unless otherwise approved by your Regional Attorney or CGC Legal, the screening must be limited to current employees



and their beneficiaries and must expressly exclude retirees who are beneficiaries under the employer's retiree health plan.

These screenings are promotional in that they "promote" Pfizer generally (Pfizer is the "product"). Colleagues can promote Pfizer products at the screenings as long as the exhibit and display booth is physically separate and apart from the screening area. However, no financial Return on Investment (ROI) analysis can be tied to a product's sales or market share related to this event. Additionally:

- The screening must be conducted by an approved third-party vendor that routinely conducts such screenings, and the vendor must sign Pfizer's Screening Services Agreement.
- The screening cannot be organized or designed in any way to generate referrals for any particular customer.
- Aggregated de-identified data can ONLY be provided to an employer or MCC IF the screening participant has signed a Pfizer Patient Authorization and Release which specifically provides that the data can be provided to the employer or the managed care plan managing the Rx drug benefit. All screening participants must sign Pfizer's Patient Authorization and Release.
- You may obtain a copy of the Pfizer Patient Authorization and Release form at <http://betsy.pfizer.com> under the "Forms" tab. For more information on the issue of patient privacy, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.

Providing Health Screening Data to a CGC Customer

- Q. One of my CGC customers wants Pfizer to conduct a disease screening for employees of an employer to whom the customer provides pharmacy benefits. The customer also wants Pfizer to provide them with the de-identified, aggregate data from the screening. Can I organize the screening and provide the data?
- A. Maybe. The only reason you can conduct a disease screening is to improve patient care. You cannot subsidize the operating expenses of the customer or the employer by conducting a screening that they would do on their own. If there is an independent valid reason for Pfizer to fund the screening, Pfizer can organize it. Aggregated, de-identified data from the screening can only be provided to the customer if Pfizer's Patient Authorization and Release has been signed and if it specifically provides that the data can be provided to both the employer and the managed care plan administering the drug benefit. Employees of the MCC are not eligible to participate in the screening and the MCC should not appear as a co-sponsor of the event unless the MCC independently provides funding or services.

Screenings Offered to the Public at Large***If organized by a Hospital, Non-Profit Organization, Managed Care Organization or Other Third Party:***

- Pfizer's Medical Education Group (MEG) can support a screening organized by a third party through an unrestricted educational grant, provided that the event meets Pfizer's requirements for unrestricted educational grants. You must NEVER promise that a grant will be provided for a health screening or for any other reason. The requestor must apply directly to MEG for funding, and will receive notice from MEG regarding whether the request has been approved.
- The requesting organization is solely responsible for logistics and content of the event.
- The screening event must be advertised and open to the community at large (e.g., advertised in the newspaper or on TV or radio).
- The screening must not be organized or designed in any way to generate referrals for any particular customer.

If organized by Pfizer:

- The screening may be funded out of your promotional budget and must be approved by your CGC Regional Manager or Sales Director.
- These types of screenings are promotional in that they "promote" Pfizer generally (Pfizer is the "product"). Colleagues can promote Pfizer products at these screenings with an exhibit and display as long as the exhibit and display booth is physically separate and apart from the screening area. No financial ROI analysis can be tied to a product's sales or market share related to this event.
- The screening must be conducted by a third-party vendor that is not a healthcare provider/payer and that routinely conducts such screenings. The vendor must sign Pfizer's Screening Services Agreement, which can be downloaded from <http://betsy.pfizer.com> under the "Forms" tab.
- The screening cannot be organized or designed in any way to generate referrals for any particular customer.
- The screening must be advertised and open to the community at large, but any advertising or publicity materials must be Review Committee approved ("RC-approved") by the CGC Review Committee or other relevant product Review Committee.

On Site Health Screenings "Open to the Community"

- Q. Is a disease screening held on site at a Managed Care Customer's facility but open to the community appropriate for an educational grant request?
- A. No. Even though the event is "open to the community," the benefit to the MCC and its members outweighs the community benefit of the screening. An event held at the MCC location could be seen as an attempt to generate new members for the MCC, something that Pfizer cannot fund. Health screenings that are organized by local not for profit organizations or hospitals and conducted in venues that are likely to attract the broader community are more appropriate for an unrestricted educational grant request. In any event, all requests for educational grants to support health screenings must be submitted by the requestor online to Pfizer's Medical Education Grants Group. For more information, see Orange Guide Chapter 3: Funding of External Organizations.

REMEMBER:

If you are present during ANY patient/consumer interactions at a health fair or screening, you:

- MUST clearly identify yourself as a Pfizer employee; and
- MUST NOT offer any medical opinions, advice or consultation even if you have a license to practice medicine or are any other type of healthcare professional.

Other Key Points for Health Screenings

Sales Colleague Participation

Colleagues may hand out RC-approved materials for use with consumers in spaces separate from the area where the screening is occurring. You should wear your Pfizer name tag throughout the screening, which will help identify you to consumers as a Pfizer employee. For more information on appropriate Sales Colleague interaction with consumers at health fairs and screenings, see Orange Guide Chapter 8: Privacy: Protecting Personal Information and Orange Guide Chapter 16: Consumer and Employee Interactions.

Privacy Issues

Consumer health fairs and screenings implicate privacy issues when they involve obtaining individually identifiable health information. Pfizer's ability to use any personal data that is collected is strictly limited by the terms in the Patient Authorization and Release form. For example, a Pfizer representative cannot pass specific data about an individual's health status to an employer at an employee health fair unless the employee has specifically authorized the representative to provide that data to the employer. Such authorization is contained in Pfizer's form release. For more information on the topic of patient consent, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.

Important Points to Remember

- Do not drive or attempt to generate patient referrals to any HCP participating in a screening.
- Contract with a vendor to perform the disease screening customer program.

- Have Pfizer's approved privacy release signed by all participants and collect only aggregated, de-identified data.
- Clearly identify yourself as a Pfizer employee to all screening participants.
- Use only approved documents and obtain necessary documentation:
 - Pfizer Vendor Agreement;
 - Pfizer Patient Privacy Release; and
 - An invoice from the vendor for the services.

Health Screenings and Exhibit Booths at Health Fairs



- Q. Pfizer is organizing a health screening at a local health fair where we will be conducting lipid screenings. Can Pfizer also have a separate promotional exhibit and display booth where we hand out approved consumer materials on Pfizer products?
- A. Yes. So long as the exhibit booths are separate and not joined with the screening, you can provide RC-approved consumer materials at a health fair where Pfizer is also conducting a health screening. For instance, the exhibit booths and health screenings can be at the venue as long as the two events are held in separate rooms or there is a partition. It should never be the case or appear to be the case that Pfizer is conducting the screening in order to encourage people to ask their doctor about Pfizer products.

FOR MORE INFORMATION

- For more information on requests for educational grants to support health screenings, see Orange Guide Chapter 3: Funding of External Organizations.
- For more information on interactions with consumers at health fairs and screenings, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.
- Questions may be referred to your manager, Regional Attorney, or CGC Legal Team.

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Chapter 14: CGC TOOLS AND RESOURCES

Introduction

Corporate and Government Customers (CGC) Tools and Resources are free, quality-based programs provided by Pfizer that are designed to educate customers, benefit patients, and improve patient outcomes. The purpose of these programs is generally to promote wellness, disease prevention, patient awareness, and high quality health care. CGC Tools and Resources include:

- Unbranded Customer Programs;
- Product Support Programs; and
- Quality Programs.

Please refer to the CGC intranet site <http://mmweb2.pfizer.com> (the “CGC Tools and Resources External Use Policy”) for additional information about CGC Tools and Resources and the requirements regarding who can utilize them.

This Chapter is relevant to all colleagues who are authorized to offer or provide customer programs to healthcare organizations, such as medical groups, long term care, HMOs, VA and DoD accounts, certain hospitals, and pharmacy benefit managers. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination.

Key Points to Ensure Compliance

- Do not offer or provide CGC tools, including Quality Programs that are not RC-approved.
 - Do not design your own program or tool for a customer.
 - Do not modify approved programs.
- When offering or providing approved tools or programs, do so without any expectation of financial return to Pfizer.
 - Do not condition the offer or provision of a program on increased prescribing or improved formulary status.
 - Do not offer or provide programs as an inducement to place Pfizer products on formulary.
- Make all programs and tools widely available.
- The offering or provision of CGC tools cannot be tied or linked to the utilization of Pfizer products.
- Only Product Support Programs can be used to further the utilization of Pfizer products.

Unbranded Customer Programs

Unbranded Customer Programs are used either to educate colleagues or to educate a customer on health-related issues in order to enable improved patient-physician engagement as well as to identify best practices and improve health outcomes. Unbranded Customer Programs must be approved by a Pfizer Review Committee and cannot be modified or changed in any way. If materials need to be modified for a certain activity, modified materials must be approved by a Pfizer Review Committee prior to use.

Product Support Programs

Product Support Programs are activities that aim to promote our products and are intended to educate on the appropriate utilization of our products with Managed Care Customers (MCCs) or to show how

well our products work. These programs are developed by CGC for utilization by certain groups, such as Account Managers and National Directors of Employers.

Product Support Programs, like the materials Pfizer provides to healthcare professionals (HCPs), must be approved by a Pfizer Review Committee and, if they discuss Pfizer products, must be consistent with product labeling. Similarly, Product Support Programs cannot be modified or changed in any way. If materials need to be modified for a certain activity, modified materials must be approved by a Pfizer Review Committee prior to use.

The information obtained from a Product Support Program can be provided to a customer as support for the efficacy and safety of Pfizer products. However, you cannot provide data derived from one customer to a different customer because the data has not been approved by a Pfizer Review Committee and may not be of the type sufficient to support promotional statements.

Quality Programs

Quality Programs Defined

Quality Programs refer to those Headquarters-approved activities that offer information and other resources relating to therapeutic areas, disease states and patient care to healthcare organizations, such as medical groups, long term care, health maintenance organizations (HMOs), the U.S. Department of Veterans Affairs (VA), the U.S. Department of Defense (DoD), and pharmacy benefit managers.

Quality Programs support Pfizer's overall mission of improving the quality of patient care. These programs are not necessarily specific to Pfizer products or even drug therapy generally. Quality Programs focus on improving patient care by providing customers with information about, for example, quality accreditation standards, HCPs' patient interaction skills, and management of medical conditions. However, Quality Programs are not intended to aid a MCC's accreditation. All current Pfizer Quality Programs are identified at <http://mmweb2.pfizer.com>.

All Quality Programs must be approved by a Pfizer Review Committee. These programs cannot be modified or changed in any way without prior RC approval. If materials need to be modified (for legitimate reasons as determined by CGC Legal and the Channel Strategy & Solutions Group), the

proposed modifications must be approved by a Pfizer Review Committee before being provided to a customer. Keep in mind that Quality Programs that underwrite operational services or provide services that the customer would be obligated to obtain on its own will not receive approval by the Pfizer Review Committee.

The Value of Quality Programs in Meeting Objectives



- Q. I know I cannot conduct a financial return on investment (ROI) analysis on Quality Programs since they are not to be tied to prescribing. Can I conduct any analysis to determine whether the Quality Program was valuable to the customer?
- A. Non-financial ROI analyses, like measuring whether a program has improved patient or physician understanding of a disease or enhanced the ability of physicians to effectively discuss sensitive issues with patients, are appropriate to conduct in order to determine whether the Quality Program met its objective of improving patient outcomes or increasing physician understanding.

Quality Program Recipients

Quality Programs must be made widely available to our customers who meet certain capability criteria as part of Pfizer's overall mission to enhance the quality of healthcare. Offering the programs to only select customers could be perceived as providing items of value in order to increase prescribing or improve formulary status in violation of the anti-kickback laws or other healthcare laws.

To ensure that the offering of these programs does not violate applicable law, you must never provide a Quality Program to a customer in exchange for increased prescribing or improved formulary status. Even though a customer may decide to change prescribing habits or formulary status based on the information it receives from a Quality Program, you should never make these changes a condition of receiving the program.

Discussing Pfizer Products While Meeting about Quality Programs

- Q. If I am meeting with a customer to discuss a Quality Program, am I prohibited from discussing Pfizer products during that meeting?
- A. You are permitted to discuss Pfizer products during the meeting only if you ensure that the customer understands that Pfizer does not expect or intend that the customer use our products as a condition of Pfizer providing the program. The program must be provided with no strings attached. Similarly, you cannot use data obtained from the customer program (e.g., the number of patients participating in the program reaching goal) to support the use of Pfizer products. Your discussions about Pfizer products should be clearly separate from your discussions about the Quality Program.

The decision to provide a Quality Program should be based only on the customer's capabilities (as determined by Pfizer), not because providing the program will improve your relationship with the customer or subsidize costs the customer would otherwise have had to pay. Even though an improved customer relationship might be an unintended result of the Quality Program, you should never offer or provide such a program with that intent.

Pfizer's reason to offer or provide a Quality Program must **never** be to:

- Establish or improve Pfizer's relationship with that HCP or institution;
- Gain or improve access to an HCP or institution;
- Reward past prescribing or induce future prescribing;
- Influence an upcoming formulary decision; or
- Offer an implied discount on the price of our products.

Referencing Quality Programs During Formulary Discussions



- Q. If a Managed Care Organization's formulary decision maker asks me for additional reasons why a Pfizer product should be included on its formulary, may I discuss the quality and variety of our Quality Programs?
- A. No. A Quality Program may never be offered as a reason for including a Pfizer product on formulary. The quality program may be perceived as an item of value offered to increase prescribing in violation of the anti-kickback laws. Consequently, you must never affirmatively discuss a Quality Program in relation to a formulary decision. If a customer makes an unsolicited inquiry about the availability of Quality Programs, you may address it by:
- Stating that at the conclusion of your product discussion you can provide information about the Quality Programs that Pfizer makes available to its customers; and
 - Stating that an offer or provision of a Quality Program to the customer is in no way influenced by the customer's pending formulary decision.

FOR MORE INFORMATION

- Consult the CGC intranet site at <http://mmweb2.pfizer.com> for information and guidance on CGC Tools and Resources, as well as a listing of available Quality Programs.
- Questions may be referred to your manager, the Customer Marketing Group, your Regional Attorney or CGC Legal Team.



Chapter 15: OTHER MANAGED CARE CUSTOMER INTERACTIONS

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Chapter 15: OTHER MANAGED CARE CUSTOMER INTERACTIONS

Service Agreements

The term “Service Agreement” refers to contracts between Pfizer and a customer where the customer is hired to perform services for Pfizer. Because customers are in the unique position of having access to their members and providers, Pfizer may from time to time want to retain the customer to disseminate certain information on Pfizer’s behalf. The most common type of Service Agreements are for Patient Education, Medication Compliance, and Co-Promote (also referred to as “Now on formulary”) Programs.

All Service Agreements with Managed Care Customers (MCCs) must be reviewed and approved by a Corporate and Government Customer (CGC) attorney in conjunction with the relevant product attorney. In addition, if the Service Agreement involves direct payment to the customer, it must be reviewed by the Managed Care Review Committee (MCRC) before it can be executed with the customer. For more information about this review process, see Orange Guide Chapter 5: Payments to Managed Care Customers.

The Service Agreement Co-Promotes should not be confused with the co-promote tools in the Key Account Relationship Management Application (KARMA), which are provided to physicians free of charge for promotional purposes.

The Health Information Technology for Economic and Clinical Health (HITECH) Act made significant changes to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) that will impact certain programs and how we interact with MCCs. The new HITECH restrictions impact certain sales and marketing related activities in which our customers are paid or otherwise provided with remuneration, directly or indirectly, in exchange for making a communication to targeted patients or clinicians on our behalf. As a result of the new restrictions, certain communication programs which previously could operate without patient authorization may now require prior written patient authorization. For more information about HIPAA, see Orange Guide Chapter 8: Privacy: Protecting Personal Information. In addition, for guidance related to service agreement arrangements with



customers, see [Guidance on Brand Marketing Programs with Managed Care Customers Under HITECH](#), available at <http://mmweb2.pfizer.com>.

Non-compliance with these policies puts the Company at risk and can subject you to disciplinary action up to and including termination.

Key Points to Ensure Compliance

- Do not discuss Service Agreements or other arrangements in connection with rebate negotiations.
- Service Agreements should not reference existing rebate contracts in any way.
- Do not enter into Service Agreements for the purpose of inducing the placement or maintenance of Pfizer products on a formulary.
- Only enter into Service Agreements that support an identified Pfizer business need.
- All Service Agreements and other arrangements must be approved by CGC Legal.
- Only use Pfizer approved templates unless otherwise instructed by CGC Legal.
- Arrangements must be consistent with Pfizer's [HITECH Guidance on Brand Marketing Programs with MCCs](#).
- Service Agreements must be submitted to MCRC for review and approval (see Chapter 5: Payments to Managed Care Customers).

Patient Education Programs

Patient Education Programs allow Pfizer to provide RC-approved health information to a customer's members. By entering into a Service Agreement with a customer, Pfizer is able to reach patients who are suffering from the conditions which Pfizer products are indicated to treat, which may help them manage their condition. Any compensation to the customer under a Service Agreement must be equal to the Fair Market Value (FMV) cost of developing and/or mailing any program materials, as applicable. In addition, only approved Patient Education materials may be used and the materials must disclose



Pfizer's sponsorship. Any proposed changes to approved materials must be reviewed and approved by a Pfizer Review Committee before the materials can be disseminated.

Medication Compliance Programs

Medication Compliance Programs, most commonly referred to as "refill reminder" programs, are outreach programs directed at patients providing them with information about the product they are taking and reminding them to refill their prescription in order to get the full benefit of their medication.

To ensure that a Pfizer customer is not improperly profiting from providing the disease management or medication compliance services Pfizer is paying for, which could be considered an improper inducement under the anti-kickback laws, the Service Agreement must follow several important rules:

- Where Pfizer provides the materials, the compensation to the customer must be equal to the FMV cost of mailing the materials.
- Where the customer creates the materials, the compensation to the customer must be equal to the FMV cost of creating and mailing the materials.
- Where possible, the FMV amount should be determined on a per-letter basis and, as appropriate, the amount should be validated through internal benchmarking or market research.
- In addition to the above, all materials provided as part of either a Patient Education or Medication Compliance Program must be reviewed and approved by a Pfizer Review Committee.

Co-Promote Programs

Pfizer may enter into Service Agreements with customers for the distribution of nonroutine formulary information about Pfizer products to a customer's members. Typically, these contracts compensate a customer for providing information to its members explaining that a Pfizer product has recently been added to the customer's formulary or reminding them of the availability of Pfizer products on formulary.



Co-Promote agreements cannot compensate a customer for engaging in routine formulary-related communications. Routine communications are those that the customer would do with or without financial support from Pfizer. Examples of routine communications that cannot be funded may include:

- Monthly patient newsletters;
- The annual mailing of the new formulary guide; and
- Routine updates to the formulary which announce all the changes to the formulary since the last update, based on our rebate contracts.

Generally, Pfizer can fund mailings that are unique to Pfizer and announce only the information related to Pfizer's product or the relevant therapeutic category. As with other promotional mailings, Pfizer must compensate the customer only for the FMV of the services determined on a per-letter basis and all materials mailed must disclose Pfizer sponsorship and be reviewed and approved by a Pfizer Review Committee. Additionally, such programs must be vetted by CGC Legal to ensure compliance with relevant privacy laws.

Collaborations

A Collaboration is an arrangement between two or more parties who jointly work together towards a common goal. Periodically, Pfizer engages its customers in collaborations on various health initiatives of mutual interest and value to both companies that have potential benefits to the health community at large. Unlike a Service Agreement, which is more of a vendor-type relationship (Pfizer paying FMV for a service), a Collaboration Arrangement documents a transaction of a more significant nature that involves resources provided by each partner. All Collaborations should be supported by an internal Pfizer business rationale or justification. All collaborations should be discussed, reviewed and approved by a Regional Attorney or CGC Legal Attorney. Collaborations with not-for-profit entities are addressed in Pfizer's Standard Operating Procedure (SOP) entitled [Funding Requests for Not-for-Profit Organizations](#).

Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination.



FOR MORE INFORMATION

- For more information about the MCRC review process, see Orange Guide Chapter 5: Payments to Managed Care Customers.
- For more information about HIPAA, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.
- For additional guidance related to Service Agreement arrangements with customers, see [Guidance on Brand Marketing Programs with Managed Care Customers Under HITECH](#), available under the [HIT](#) market issue tab on <http://mmweb2.pfizer.com>.
- Questions may be referred to your manager, the Customer Brand Marketing Group/ Product Team, the Channel Strategy Solutions Group, your Regional Attorney or CGC Legal Team.



Chapter 16: CONSUMER AND EMPLOYEE INTERACTIONS

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Chapter 16: CONSUMER AND EMPLOYEE INTERACTIONS

All colleagues must provide truthful, accurate and balanced product information to healthcare professionals (HCPs). It is equally important that you understand the rules which govern your interactions with consumers (including patients, potential patients, and all other non-HCPs), as they are distinct from the rules which apply to your interactions with HCPs. Employees are consumers and must be treated according to the guidelines in this Chapter.

Pfizer interacts with consumers at various types of events including speaker programs, health fairs, public screenings, and disease management programs. A variety of laws and industry standards specifically govern your promotional interactions with consumers. These are different from the laws and standards governing your promotional interactions and activities with HCPs. Like interactions with HCPs, however, interactions with consumers can involve promotional risks, including the following:

- The U.S. Department of Health and Human Services, Office of Inspector General (OIG) has warned that offering incentives, such as remuneration or free services, to consumers may implicate the federal anti-kickback laws.
- Some state attorneys general have interpreted state consumer protection laws to encompass off-label promotion.
- The Food and Drug Administration (FDA) has established stringent requirements regarding direct-to-consumer (DTC) communications.

Furthermore, the Pharmaceutical Research and Manufacturers of America (PhRMA) has issued guidance to Pfizer and other member companies related to DTC advertising called *Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines* – This document provides guidance on ways to ensure that DTC communications provide accurate, accessible and useful information to patients and consumers. Pfizer has committed to follow this guidance and has adopted its own *Guidance for the Implementation of the Updated PhRMA DTC Principles*.



Pfizer’s goal when communicating with consumers is to provide useful and understandable information about conditions and treatment options that will help patients partner with their healthcare provider to make more informed decisions about their treatment.

As with HCPs, your discussions with consumers must comply with all FDA regulations, and all information provided to consumers:

- Must be accurate and not misleading;
- May only make claims when supported by substantial evidence;
- Must reflect a balance between the risks and benefits of a product; and
- Must be consistent with FDA-approved labeling.

Colleagues are permitted to provide to consumers Review Committee-approved (RC-approved) disease state and product information approved for consumers in the following circumstances:

- **At consumer events** such as community health fairs, health screenings, state fairs and disease management events where Pfizer has the opportunity to set up a display or exhibit; and
- At speaker programs or presentations organized by Pfizer specifically for consumers, using RC-approved consumer slide decks.

Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination.

Key Points to Ensure Compliance

- At consumer events where you have an opportunity to interact with consumers:
 - Use only RC-approved materials intended for consumers and limit your discussion to the information contained in these materials;
 - Provide fair and balanced information;
 - Do not provide off-label information;
 - Do not provide advice to consumers about their treatment. Refer consumers to their HCP to discuss treatment options; and
 - Do not discuss competitor products.
- Pfizer is responsible for the conduct of the speaker and all content presented at Pfizer speaker programs held for consumers (whether branded or unbranded). The program and speaker must follow all applicable EZSpeak requirements. In addition, the speaker:
 - Must not provide specific medical advice to a consumer attendee and should instead refer the attendee to their HCP;
 - Must not discuss competitor products;
 - Must not provide off-label information in any circumstance; and
 - Must not promote his/her practice or recruit any new patients out of the audience.
- Meals at consumer programs may not exceed \$25 per person (food, beverages, tax and tip included).
- Always disclose that you are a Pfizer employee or representative when interacting with patients. Wear your Pfizer name tag at all times.
- Employees are consumers. Pfizer interactions with company employees (such as at a health fair) must conform to the same principles applicable to consumer interactions.



Colleague Activities at Consumer Events

Exhibits and Displays

Pfizer is committed to providing information to consumers about their health and Pfizer treatment options. You are sometimes provided with opportunities to interact directly with consumers by working at Pfizer exhibits or displays at consumer events such as health fairs, patient advocacy events and health screenings. The goal of these interactions should be to foster a more informed conversation between a patient and their HCP about the patient's health and treatment options.

Always disclose that you are a Pfizer employee or representative when interacting with patients. Wear your Pfizer name tag at all times.

Exhibit Fees, Food and Booth Staff

It is permissible to pay fair market value (FMV) for exhibit and display space at a consumer event. Pfizer may provide a very modest snack or refreshment (e.g., fruit, granola bars, and bottled water) to those consumers who visit the exhibit.

Non-Pfizer employees, including HCPs, should not be present at the Pfizer booth. Remember that Regional Medical Research Specialist (RMRS) and Medical Outcome Specialist (MOS) Colleagues are generally not permitted to interact with consumers pursuant to the Green and Purple Guides, respectively.

Providing Food to Consumers at a Display

- Q. I will be working at a Pfizer display table at a community health fair next week. Can I provide food at my table? What about covering the cost of sandwiches for all the health fair attendees?
- A. You can provide modest hospitality snacks at a display table where you are interacting with consumers. Any food you provide to consumers must be consistent with the level of interaction you are having with them. In this case, because you are interacting at a display table, it would be acceptable to provide modest snack items like fruit, granola bars, and drinks. It would not be appropriate for you to cover the costs of sandwiches or other food items for all attendees since you are permitted to provide food only to those consumers with whom you interact. Remember, even when you have more extensive interactions with consumers (e.g., at a speaker program) the cost of food, beverage, tax and tip should never exceed \$25/per attendee.

Venue

The consumer event where you are displaying must be located at a neutral venue that is open to the public (a doctor's office is not considered open to the public). Pfizer-sponsored health screenings cannot be used to direct consumers specifically to Pfizer products or to get people to ask their doctor about Pfizer products. Therefore, if Pfizer is also sponsoring a health screening at a consumer event, the exhibit booth and the health screening location must be physically separated, such as by a partition or by being in separate locations. If colleagues are exhibiting at an independent, third party sponsored educational event or conference, Pfizer promotional displays must also be separate from the educational presentation areas.

Materials

You may only use materials that have been RC-approved for use with consumers, and you must follow any accompanying instructions on use of the materials. For example, if only unbranded consumer materials have been RC-approved, you may not provide specific product information or discuss that Pfizer product with consumers at the event.

Materials at a Display

- Q. If both consumers and HCPs are expected to attend the event, can materials intended for HCPs be put out on the table for display along with the approved consumer materials?
- A. No. You should only place approved consumer materials on the table for display. However, you may have the approved HCP materials available to access and provide to an HCP if one approaches your exhibit to speak with you.

Exhibits at Health Screenings

Colleagues may interact with consumers at exhibit booths located at health fairs, patient advocacy events or health screenings. Screenings promote the early detection of diseases and offer patients a meaningful opportunity to treat a disease or condition. Colleagues who are present during any patient interactions must clearly identify themselves as Pfizer employees. Wear a Pfizer name tag at all times.

Only Corporate and Government Customer (CGC) Colleagues are permitted to fund health screenings. Please see Orange Guide Chapter 13: Health Screenings for further information.

Interactions

When interacting with consumers, you must adhere to the following guidelines:

- **Limit your discussion to the information contained in RC-approved materials.**
- **Present the risks and benefits of Pfizer products in a fair and balanced way.** This can be accomplished by providing both the approved indications and consumer directed safety information found in your approved consumer materials.
- **Do not compare a Pfizer product with competitor products, unless that specific information is contained in the approved consumer materials.** If a consumer asks you to compare the Pfizer product with a competing product, refer the consumer to his or her healthcare provider for that information.
- **Do not discuss off-label use of a Pfizer product.** If a consumer asks you about off-label use, refer the consumer to his or her healthcare provider for that information.

- **Do not provide medical advice to consumers, regardless of your professional training or position within Pfizer.** If a consumer asks you for advice or a recommendation as to treatment options, refer the consumer to his or her healthcare provider for such treatment.
- **Do not encourage consumers to switch their medication to a Pfizer product.** If asked by a consumer whether they should switch products, refer the consumer to his or her healthcare provider to discuss the topic.
- **Follow Pfizer's policies on the reporting of adverse events.** If a consumer shares information about an adverse event, you must report it within one business day by phone (800-438-1985) to the Safety and Risk Management group (SRM). If the consumer will provide it to you, forward his or her name and contact information along with the event to SRM. Refrain from engaging in a detailed discussion with a consumer about an adverse event he or she has experienced. Simply report to SRM a general description of the event and contact information for the consumer if you are able to obtain it. For further information about handling suspected adverse events, visit the PfieldNet Compliance page at <http://PfieldNet.pfizer.com/Compliance> and select "Handling Reports of Suspected Adverse Events," listed under Stay In Compliance.

Educational Presentations to Consumer Audiences

Pfizer Contracted Speaker as Presenter

A speaker program for consumer audiences, just like a speaker program for HCPs, is a promotional activity controlled by Pfizer at which an HCP presents an RC-approved slide deck intended for consumers. As with speaker programs for HCPs, Pfizer is responsible for the conduct and the content of its promotional speaker programs to consumers and, therefore, colleagues must adhere strictly to Pfizer policies regarding consumer presentations and EZSpeak procedures to set up the speaker program. An HCP speaker must not use the Pfizer program as an opportunity to promote their medical services or practice, or recruit new patients.

Content

Before you hold a speaker program for consumers, review with your speaker these important policies regarding the content of your planned program:

- Speakers must use only RC-approved consumer slide decks, and these slide decks must be used in their entirety. Slides cannot be deleted or created and inserted by the speaker under any circumstance.
- If the speaker is presenting an unbranded consumer slide deck, the speaker cannot present information about Pfizer products unless responding to an unsolicited question about the on-label use of a Pfizer product.
- The speaker must remain on-label when providing information about a Pfizer product, even when presented with an unsolicited question from the audience about an off-label use of the product. Consumers are not trained medical professionals; therefore, the dialogue between an HCP speaker and consumer is not considered scientific exchange. The speaker should explain that the product is not indicated for the use which has been asked about, and the speaker should refer the consumer to his or her healthcare provider for further information. In an instance where the speaker does not appropriately respond to the audience question, the Sales Colleague is obligated to make a corrective statement and refer the consumer to his or her healthcare provider.
- The speaker cannot provide specific medical advice to a consumer attendee, even when the individual requests it. The speaker must refer the consumer to his or her healthcare provider for this advice.
- No discussion of competitor products is permitted at branded or unbranded talks unless specifically contained in the RC-approved consumer materials or slide kit.
- As with speaker programs for HCPs, speaker programs for consumer audiences must be a minimum of 45 minutes, inclusive of Q&A, for venue programs, and a minimum of 30 minutes for in-office programs.

Content of Consumer Slide Decks



- Q. If I organize a consumer program with a Pfizer-approved speaker, can the speaker include his own slides?
- A. No. The speaker must stay on-label and strictly follow the content of the approved consumer slide deck to ensure that there is fair balance between a product's benefits and risks. Slides cannot be deleted, created or added by the speaker regardless of whether they are disease state or product-specific slides. Finally, a speaker may not give medical advice. If a consumer asks for medical advice, the speaker must refer the consumer to his or her healthcare provider.

Attendees

The guidelines which you must follow related to consumer attendees are somewhat different than what you are familiar with for HCPs in attendance at speaker programs. In addition to the guidelines below, be sure to follow any specific guidelines provided by the product team.

- **You must make a good faith effort to broadly advertise a consumer speaker program** which you've decided to hold, such that it will likely result in an audience of at least 5 consumers. It is not permissible to hire a speaker to address a group of their patients, or patients of a health system or practice for whom they work.
- **A roster must be completed for consumer programs held, but these rosters should not include the names of consumer attendees.** The total number of consumer attendees should be added in the Consumer Attendance field in EZSpeak. If HCPs are in attendance, the names of the HCPs must be included in the EZSpeak roster. As with speaker programs held for HCPs, the representative and speaker must confirm electronically in EZSpeak that the program was held and that speaking services were provided.

When taking attendance at a program that includes both consumer and HCP attendees, record the total number of consumer attendees and collect the names and other information ordinarily required of HCP attendees. If you are distributing invitations for this type of mixed audience, only consumer directed invitations should be used (available from your Meeting Planner).

Presentations to a Mixed HCP and Consumer Audience

- Q. If I organize a speaker program where both HCPs and consumers may be present, does the speaker have to use a Pfizer slide kit approved for a consumer audience?
- A. Yes. Pfizer must comply with existing FDA requirements and the PhRMA Code Direct-to-Consumer Advertising Principles when interacting with consumers. Therefore, where both consumers and HCPs are expected at the program, the speaker must use an RC-approved consumer slide kit to ensure that information on our products, particularly safety information, is presented in a way that consumers can understand. In addition, any HCPs attending the presentation are subject to Pfizer's HCP Payment Disclosure policy.

Speaker Non-Compliance

- Q. What do I do if a speaker does not conduct a program in compliance with Pfizer's policies?
- A. You must promptly and courteously provide clarification to the audience on any inaccurate or inappropriate information. This should be done immediately after the speaker has presented and prior to the Q&A. In addition, if a speaker does not conduct a consumer program in compliance with Pfizer's policies, you must coach the speaker on the appropriate conduct of a Pfizer consumer program and report the violation electronically upon closing out the program in EZSpeak. Once you have done this, your manager will receive an e-mail notification regarding the violation.

Meals

Providing a modest meal at an educational speaker program is permissible. However, the cost of food, beverage, tax and tip may *not exceed \$25/per attendee*. No entertainment or recreation may be provided. Where there is a mixed HCP and consumer audience, the meal limit remains \$25 per attendee, for both HCP and consumer attendees.

Meals may never be provided: (1) to solicit business; or (2) in a manner that might suggest that the recipient was being bribed or improperly influenced.

Other Program Guidelines

Colleagues are not permitted to conduct a consumer program unless a brand team's RC or the CGC RC expressly allows it.

Adverse Events

Follow Pfizer's policies on the reporting of adverse events. If a consumer shares information about an adverse event at an educational speaker program, you must report it within one business day by **phone (800-438-1985)** to the Safety and Risk Management group (SRM). If the consumer will provide it to you, forward his or her name and contact information along with the event to SRM. Refrain from engaging in a detailed discussion with a consumer about an adverse event he or she has experienced. Simply report to SRM a general description of the event and contact information for the consumer if you are able to obtain it. For further information about handling suspected adverse events, visit the PfieldNet Compliance page at <http://PfieldNet.pfizer.com/Compliance> and select "Handling Reports of Suspected Adverse Events," listed under Stay In Compliance.

Providing Copies of Materials



- Q. Can I hand out copies of the consumer slide deck to consumers in attendance at my consumer program?
- A. No, you may not hand out copies of the consumer slide deck unless you have received clear guidance from the appropriate RC that this is permissible. However, you may hand out appropriate approved DTC materials.

Employees as Consumers

Employers are increasingly making decisions regarding the access their employees have to medicine. As a result, colleagues may have an interest in calling on employers to present information about Pfizer products relevant to the employer in making these decisions.

Employers often request that Pfizer interact directly with their employees in the interest of providing health education. These employees are consumers and it is important that Pfizer treat them as such. Accordingly, Pfizer must ensure that it applies the same principles set forth in this Chapter to its interactions with employees.



Providing Materials for Non-Pfizer Consumer Events

There are also situations in which colleagues may provide RC-approved consumer materials to third parties such as HCPs or patient groups for use in their patient education efforts. Colleagues can provide RC-approved consumer materials for use at patient education programs which are organized and conducted by third parties. Slide decks should not be shared unless the relevant RC has specifically authorized dissemination of the slide deck in this manner. You cannot offer any speaker payment or other financial support for the non-Pfizer programs, including, but not limited to, providing food or equipment for these non-Pfizer programs.

Consumer Privacy

Pfizer recognizes the importance of safeguarding the confidentiality of Personal Information (PI), including Sensitive Personal Information (SPI). SPI is health-related information that, in combination with certain identifiers, such as name, birth date or social security number, can be used to identify a specific individual. As a colleague, you must not seek SPI about consumers when you are interacting with them. In the event you encounter SPI in the course of interacting with a consumer, do not disclose or use such information for any purpose or in any manner that would compromise the confidentiality of such SPI. For a detailed discussion of privacy issues, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.

Other Consumer Interactions

Consumer interactions which are not described in this Field Guide as being permissible are not appropriate for you to engage in. Before engaging in any consumer interaction other than those discussed here please confer with your manager or Regional Attorney.



FOR MORE INFORMATION

- For more information on handling suspected adverse events, visit the PfieldNet Compliance Page at <http://PfieldNet.pfizer.com/Compliance> and select “Handling Reports of Suspected Adverse Events,” listed under Stay in Compliance.
- For more information about Pfizer’s policies and procedures for conducting speaker programs for consumers, please refer to EZSpeak.
- Questions may be referred to your manager or Regional Attorney.



Chapter 17: STATE LAWS: HCP AND STATE EMPLOYEE RESTRICTIONS

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Chapter 17: STATE LAWS: HCP AND STATE EMPLOYEE RESTRICTIONS

States are increasingly enacting laws and regulations that impact our business and restrict our activities, including your interactions with healthcare professionals (HCPs) and state employees. Many of these state laws are more restrictive than the Pfizer policies set forth elsewhere in this Guide.

It is important that all colleagues understand all applicable state laws and policies– and **not only the ones applicable to the state where you work, because several state laws apply regardless of where an interaction occurs.** Activities that violate these laws may result in criminal and civil penalties for you and Pfizer.

This Chapter is relevant to all colleagues who interact with HCPs licensed in the states discussed in this Chapter and with state employees. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination.

If you have any questions about state healthcare compliance laws and HCP-related restrictions:

- Consult the State Healthcare Law tab on either the PfieldNet Compliance page
- Or <http://opsource.pfizer.com/Pages/Home.aspx>
- Send questions to statehealthcarelawcompliance@pfizer.com
- Consult your team attorney

If you have any questions about state employee gift restrictions:

- Consult with the appropriate Government Relations Director (GRD)
- Consult your team attorney

Summary of Key State HCP-related Healthcare Compliance Laws

State	Important Provisions of the State Law	Key Points to Ensure Compliance
<p>California</p>	<p>Companies shall adopt a comprehensive compliance program which sets specific dollar limits on gifts, promotional materials and activities.</p>	<p>Accurately and completely record all expenditures on HCPs.</p> <p>Monitor expenditures per HCP and coordinate with your colleagues to ensure compliance with Pfizer’s annual limit of \$3,500 per CA HCP.</p>
<p>Connecticut</p>	<p>The Connecticut Compliance Program Law requires companies to adopt a marketing code of conduct – the PhRMA Code is acceptable.</p>	<p>No specific requirements other than follow all Pfizer policies and procedures and the PhRMA Code.</p>
<p>District of Columbia</p>	<p>All representatives must secure a license to legally detail in person in D.C.</p> <p>Companies must report certain marketing costs.</p> <p>Members of the D.C. Medication Advisory Committee must not receive gifts, including meals or remuneration, for speaking or consulting.</p>	<p>Anyone who “details” in D.C. must obtain a detailer license from the D.C. Board of Pharmacy, renew it every even numbered year and attend required Continuing Education courses.</p> <p>Accurately and completely record all HCP expenditures.</p> <p>Do not provide any gift to any member of the Medication Advisory Committee, no matter how nominal the value.</p>



State	Important Provisions of the State Law	Key Points to Ensure Compliance
Massachusetts	<p>No meals (including snacks in non-convention settings) with MA-licensed HCPs except in the office or hospital setting that are accompanied by an informational presentation (limited exception for HCPs under bona fide service contracts with Pfizer).</p> <p>Pfizer must give HCPs the opportunity to withhold prescriber data.</p> <p>Pfizer must report certain HCP expenditures to MA.</p>	<p>Do not invite MA HCPs to out-of-office speaker programs that provide meals (even if the program is conducted outside of MA).</p> <p>Do not provide MA HCPs with out-of-office meals or snacks (except snacks in a convention setting).</p> <p>Accurately and completely record all expenditures on HCPs.</p> <p>If you are unsure whether an HCP has a MA license, check the MA HCP Lookup List which is available on the "State Healthcare Law Compliance" tab on http://OpSource.Pfizer.com or under the Compliance tab on PfieldNet. You can also check iCUE, which flags most (but not all) MA HCPs.</p> <p>You must make a good faith effort to determine whether an HCP is licensed in MA.</p>



State	Important Provisions of the State Law	Key Points to Ensure Compliance
Minnesota	<p>Gifts to practitioners are prohibited.</p> <p>Pfizer policy prohibits HCP meals to MN practitioners, including nominal meals and snacks.</p> <p>Pfizer policy prohibits providing text books, journal subscriptions, online subscription services (e.g., Epocrates), and anatomical models, to MN practitioners.</p> <p>Pfizer policy also prohibits engaging MN practitioners as paid consultants, except for the following type of projects:</p> <ul style="list-style-type: none">• R&D, clinical, or development-related projects• Outcomes Research or medical publication-related projects• Speaking and Speaker training <p>Pfizer must report permissible non-gift expenditures that exceed \$100/year.</p>	<p>Do not invite MN practitioners to any speaker programs that provide meals (even if the program is conducted outside of MN).</p> <p>Unless an exception applies, do not provide MN practitioners with meals or snacks.</p> <p>Do not provide MN practitioners text books, journal subscriptions, online subscription services (e.g., Epocrates, including trial memberships), or anatomical models.</p> <p>Do not engage MN HCPs as commercial consultants.</p> <p>If you are unsure of whether an HCP has a MN license, you can check the HCP License List which is available on the "State Healthcare Law Compliance" tab on OpSource.Pfizer.com. Also, iCUE flags most (but not all) HCPs with MN licenses.</p> <p>You must make a good faith effort to determine whether an HCP is licensed in MN.</p> <p>Accurately and completely record all practitioner expenditures.</p>



State	Important Provisions of the State Law	Key Points to Ensure Compliance
Nevada	Nevada Marketing Code of Conduct requires companies to adopt a marketing code of conduct – the PhRMA Code is acceptable.	No specific guidance, other than to follow all Pfizer policies and procedures.



State	Important Provisions of the State Law	Key Points to Ensure Compliance
<p>Vermont</p>	<p>Vermont bans all HCP meals, including in-office meals and meals of nominal value (there is a limited exception for: (i) bona fide service contracts and (ii) refreshments or other snacks at a booth at a convention/congress).</p> <p>Vermont also bans paid market research surveys involving VT licensed HCPs. The restriction applies whether the survey is conducted directly by Pfizer or through an independent third party survey research organization.</p> <p>Pfizer must report certain HCP expenditures, as well as samples, coupons and vouchers, to VT.</p> <p>Price Disclosure Forms must be provided to HCPs when detailing and posted on Pfizer’s website.</p>	<p>Do not invite VT HCPs to any speaker programs that provide meals or snacks (even if the program is conducted outside of VT).</p> <p>Do not provide VT HCPs with meals or snacks (except refreshments or snacks in a convention setting).</p> <p>Do not engage VT HCPs as part of any paid marketing research surveys.</p> <p>Accurately and completely record all HCP expenditures, as well as samples, coupons, and vouchers provided to VT licensed HCPs.</p> <p>If you are unsure of whether an HCP has a VT license, you can check the HCP License List which is available on the “State Healthcare Law Compliance” tab on http://OpSource.Pfizer.com or under the Compliance tab on PfieldNet.</p> <p>Also, iCUE flags most (but not all) VT HCPs.</p> <p>You must make a good faith effort to determine whether an HCP is licensed in VT.</p> <p>Provide VT Price Disclosure Forms to HCPs as appropriate (available on PfieldNet).</p>



State	Important Provisions of the State Law	Key Points to Ensure Compliance
West Virginia	Certain HCP and advertising expenditures must be disclosed.	No specific guidance, other than to accurately and completely record all expenditures on HCPs, state patient advocacy groups, and pharmacies.

Summary of Key State Employee Gift Laws

Almost all states have restrictions on interactions with state employees (including HCPs employed by state institutions). Consult the appropriate Government Relations Director (GRD) for the state employee restrictions in your state. A summary of the most significant state restrictions is provided below.

State	Important Provisions of the State Law	Key Points to Ensure Compliance
Colorado	State employees may not receive anything of value worth more than \$50 from a company (as a whole, not by employee).	Accurately and completely record all expenditures on state employees. Monitor spend per state employee and coordinate with your colleagues to ensure we are not spending beyond the \$50 annual limit.
Louisiana	State employees are prohibited from performing certain compensated services for pharmaceutical companies. State employees have a \$50 cap on food, drinks, and refreshments provided during a single event.	Before considering engaging a state employee to perform a compensated service, consult with your manager. Before providing a meal or refreshments to state employees, coordinate with your colleagues to ensure the employee is not receiving value greater than \$50 during the event.



State	Important Provisions of the State Law	Key Points to Ensure Compliance
New York	State and local employees are prohibited from receiving gifts.	Do not provide meals or educational items to state or local employees. However, state and local employees may receive food items of nominal value as long as they are not part of a meal.

Key Points to Ensure Compliance

- Understand the laws and policies of the states in which you work and the states where the HCPs with whom you interact hold licenses.
- Before providing a meal or educational item to an HCP, know where the HCP is licensed and follow any applicable state restrictions. For example, regardless of where the interaction takes place, significant restrictions apply to HCPs with active VT, MA and MN licenses. These restrictions apply to both Sales and non-Sales colleagues.
- Conduct your activities in accordance with the relevant state laws described in this Chapter, as well as general Pfizer policy found in this guide.
- Be aware of and abide by all spending limits and restrictions in your state.
- Follow and complete all process steps required to track and report expenditures.
- Remember that federal government employees, such as those working for the VA or DoD, must follow federal gift restrictions which include restrictions on meals. For further information on these restrictions, see the chapter on Federal Employee Interactions and Lobbying.
- Almost all states impose restrictions on what may be provided to state and local employees (including HCPs employed by state institutions). You can direct any specific questions on state laws that are not addressed in this Guide to the relevant Regional Attorney or to statehealthcarelawcompliance@pfizer.com. For information about state employee restrictions, consult with your Government Relations Director.

California

The Law: The California Drug Marketing Practices Law

The California Drug Marketing Practices Law requires that each pharmaceutical company:

- Establish, at a minimum, a comprehensive compliance program that complies with the requirements set forth in the OIG's Compliance Program Guidance for Pharmaceutical Manufacturers and PhRMA's Code on Interactions with Health Care Professionals;
- Set an annual aggregate limit for spending on meals, promotional items, and other activities provided to covered HCPs; and
- Declare annually, on its public website, that it is in compliance with the OIG Guidance, PhRMA Code, its own corporate compliance program, and the annual limit it has set.

Definition of Healthcare Professional

Covered HCPs include any CA-licensed prescriber of human drugs, medical student, or member of a formulary committee. Non-prescribing pharmacists, nurses, and office staff, who are not medical students or formulary committee members, are not included in the annual aggregate limit on spending to covered HCPs.

How the Law Impacts Pfizer Colleague Activities

Pfizer has set its annual aggregate limit on covered promotional expenditures at \$3,500 per covered California HCP. This limit does not apply to CA-licensed HCPs practicing in other states.

The value of the following items must be included when calculating the annual aggregate limit:

- PhRMA Code compliant meals, including all food and beverage in and outside a medical office or hospital, in connection with any promotional activity; and
- Pfizer Review Committee (RC) approved educational items with a retail value equal to or greater than \$25.



The value of the following items are not included when calculating the annual aggregate limit:

- Starters;
- Fair market value payments for services, such as speaking and consulting payments;
- RC-approved promotional literature such as clinical reprints and slim jims;
- Independent educational grants (financial support for continuing education forums);
- Financial support for educational scholarships; and
- Pfizer RC-approved educational items with retail value of less than \$25.

All colleagues who engage in activities in California should be aware that their expenditures which meet the criteria above will be included when calculating the annual aggregate limit. Colleagues must ensure that their records on these expenditures are accurate and complete.

The State of California can impose significant penalties on Pfizer for failure to comply with this law. If you have any questions concerning the California Pharmaceutical Sales and Marketing Disclosure Law, please contact the Regional Attorney with responsibility for California.

Colorado

The Law: Restrictions on Gifts to State Employees

Colorado law prohibits any state employee from soliciting, accepting, or receiving, directly or indirectly, any gift or other item of value (including meals), regardless of form (e.g., money, service loan, travel, entertainment, hospitality, or promise) worth more than \$50 in any calendar year.

As with any other customer, colleagues may not provide any type of gift, regardless of value, to a Colorado state employee if the gift is intended or expected to influence or reward that employee in the performance of any activity related to his or her official duties.

Definition of Healthcare Professional State Employee under the law

A Colorado state employee includes any HCP employed, *either full-time or part-time*, by the State of Colorado, any community healthcare providers employed by a Colorado county or municipal government, and any physicians employed at the University of Colorado Health Sciences Center.

How the Law Impacts Pfizer Colleague Activities

Collectively, Pfizer colleagues are prohibited from providing gifts, including meals, which have a total value over \$50 to a Colorado state employee in any calendar year. This means that colleagues must coordinate to ensure that no employee of the State of Colorado receives more than \$50 in items and meals from Pfizer as a company during any calendar year. (The \$50 annual limit is not per Pfizer colleague.) Pfizer RC-approved educational items of more than nominal value (e.g., anatomical models) may not be provided to Colorado state employees who are healthcare providers, even though they are RC-approved items. This limitation applies to **all Pfizer colleagues** who interact with employees of the State of Colorado, not just Pfizer Sales Colleagues who work in the state.

The following items are exceptions to the annual \$50 limit for Colorado state employees:

- Meals provided in connection with an educational presentation (e.g., speaker program) that is widely attended by non-state employees;
- PhRMA Code compliant food and beverage snack items of nominal value (e.g., doughnuts and non-alcoholic beverages such as soft drinks and coffee) which are not part of a meal;
- RC-approved educational items of nominal intrinsic value; and
- Fair market value payments for an employee's provision of services, such as speaking or consulting services.

Helpful Point

- If you are not sure whether an HCP is employed by the State of Colorado or just affiliated with a state institution, you must confirm his or her relationship with the state prior to providing any meals or items of more than nominal value to the HCP. If the HCP receives regular compensation directly from a state institution, he or she is likely considered a state employee and is therefore subject to the restrictions discussed in this section.

If you have any questions, please contact the Regional Attorney with responsibility for Colorado.

Connecticut

The Law: Connecticut Compliance Program Law

- Requires pharmaceutical, biological, and medical device companies to adopt and implement a marketing code that is at least as restrictive as the PhRMA Code and a comprehensive compliance program.
- Connecticut Department of Consumer Protection has authority to investigate alleged violations of the code-adoption requirement and alleged failures to conduct any training program or regular audit for compliance with the adopted code. Violations of the provisions would subject a company to a civil penalty of not more than \$5,000.

District of Columbia

The Law: Prescription Drug Marketing Costs Disclosure Law

The District of Columbia (D.C.) Prescription Drug Marketing Costs Disclosure Law requires Pfizer to report all marketing costs for prescription drugs to the D.C. Department of Health, including the value, nature, purpose and recipient of all expenses associated with advertising, marketing, and direct promotion to D.C. residents through radio, television, magazine, newspaper, direct mail and telephone.

Specifically, costs associated with the following activities are required to be reported:

- Direct-to-consumer advertisements targeting D.C. residents;
- Educational or informational programs, materials, or seminars provided to healthcare professionals, pharmacies, clinics, health plans and other healthcare providers;
- Remuneration for promoting or participating in educational or informational sessions;
- Food, entertainment, gifts, and anything else provided to HCPs valued at more than \$25 or provided for less than market value;
- All expenses associated with HCP trips and travel;
- Starters (unless they are for distribution to patients at no charge); and
- The aggregate cost of all employees and contractors engaging in drug advertising and promotion in D.C.

The following marketing expenses do not have to be reported:

- Expenses of \$25 or less;
- Compensation for bona fide clinical trial activities; and
- Scholarships and expenses for attending educational, scientific, or policy conferences if attendee is selected by the sponsoring organization.

Definition of Healthcare Professional

The law applies to expenditures provided to persons and entities who are licensed to provide healthcare in D.C., including healthcare professionals and persons employed by them who work in D.C., licensed insurance carriers, health plans and benefit managers, pharmacies, hospitals, nursing facilities, clinics and other entities licensed to provide health care in D.C.

How the Law Impacts Pfizer Colleague Activities

All colleagues who engage in activities in D.C. should be aware that expenditures which meet the criteria above will be reported to the D.C. Department of Health. Colleagues must take special care to

ensure that their reporting of attendees is accurate and complete. The District of Columbia can impose significant penalties on Pfizer for failure to comply with this law.

The Law: SafeRx Amendment Act of 2008

The SafeRx Amendment Act of 2008 (“SafeRx”) requires licensure for any colleague or speaker who communicates with a licensed HCP located in D.C. for the purpose of promoting a pharmaceutical product. SafeRx also prohibits offering a gift or remuneration of any kind to a member of the D.C. medication advisory committee.

Gifts to D.C. Medication Advisory Committee Prohibited

SafeRx gift prohibitions apply to D.C. Medication Advisory Committee (DCMAC) members. Do not provide a gift or remuneration to any DCMAC member.

Colleagues must not give the following items to any DCMAC member (even if RC-approved):

- Speaking and consulting fees;
- Food or beverage, whether inside or outside the office, or in connection with a promotional program or otherwise; and
- Educational items (e.g., textbooks, stethoscopes and anatomical models).

However, colleagues may provide starters to DCMAC members who are licensed physicians engaged in the practice of medicine and who intend to distribute them free of charge to patients.

For a list of DCMAC members, please consult the Department of Health Care Finance FAQ at http://hpla.doh.dc.gov/hpla/frames.asp?doc=/hpla/lib/hpla/pharmacy/faq_pharmaceutical_detailers.pdf (Question 27).

How the Law Impacts Pfizer Colleague Activities

Colleagues who detail HCPs in D.C. must complete and submit a license application to the D.C. Board of Pharmacy. You must have a valid pharmaceutical detailer license before calling on an HCP in D.C. Pfizer speakers must be licensed as well, and Sales Colleagues should not hold speaker programs in



D.C. unless the speaker has a SafeRx license. It is your responsibility to apply for your license, and application costs will be reimbursed by Pfizer.

The license application materials are available online at the [District of Columbia Board of Pharmacy website](#). The license application requires submission of an affidavit to abide by a Code of Ethics, which prohibits, along with other requirements: (1) sending messages of disappointment for failing to prescribe certain medications; and (2) continuing to make sales calls after the healthcare professional has requested in writing not to receive further calls.

The following materials are necessary to complete the application:

- A completed, signed DC application form;
- Two (2) recent passport photos (2x2);
- One (1) clear copy of a U.S. government-issued photo ID;
- Social Security Number or a Sworn Affidavit;
- Name Change Documents (Marriage Certificate, Divorce Decree or Court Order) if applicable;
- Official certificate of graduation in a sealed envelope or notarized Waiver of Educational Requirements form;
- Notarized Affidavit to Abide by Code of Ethics form;
- A criminal background check; and
- \$175 for the Application and License Fee in the form of a check, money order or certified check payable to the D.C. Treasurer, which you should submit for reimbursement in GCE.

Impacted colleagues will need to renew their license each even numbered year prior to the end of February. Colleagues should plan to submit their application by December 31st of the preceding year to allow adequate time for review and processing of your application prior to the deadline. As part of the license renewal application, you will need to attest that you have completed a minimum of 15 hours of continuing education during the two year period preceding the date the license expires. You must register for a "SafeRx Pharmaceutical Detail Licensing CE Program" through P2L. Once registered, you will receive a list of CMR training courses that are approved for CE under the SafeRx Pharmaceutical



Detail Licensing Program. It can take up to two months to complete each course offered, and Pfizer will pay directly for home study courses taken with the CMR SafeRx Pharmaceutical Detail Licensing CE Program. If you have completed a CMR Certification or CMR Flex course post receipt of your pharmaceutical detailer's license, you should contact CMR at (800) 328 – 2615 or program@cmrinstitute.org to determine if you already received renewal credit.

The District of Columbia can impose significant penalties on Pfizer for failure to comply with this law, which may include a fine of up to \$10,000 as well as penalties and sanctions, for failure to comply. If you have any questions concerning the D.C. Prescription Drug Marketing Costs Disclosure Law or SafeRx please contact the Regional Attorney with responsibility for the District of Columbia.

Louisiana

The Law: Code of Governmental Ethics

The Louisiana Code of Governmental Ethics prohibits HCPs who are “public servants” from performing certain compensated services for Pfizer, such as receiving fees for speaking services or reimbursement for associated expenses. In addition, Louisiana imposes a \$50 cap on food, drink, or refreshment provided to a public servant for a single event. The amount should be calculated by dividing the total cost of the food by the total number of persons (including non-public servants) at the event.

Definition of "Public Servant"

“Public servants” are either public employees or elected officials. They include persons who are employees at any of the following institutions:

- Louisiana State University (LSU) and affiliated hospitals and clinics;
- Charity hospitals and other state hospitals;
- Medicaid P&T Committee members;
- State prisons; and
- State rural health clinics.

How the Law Impacts Pfizer Colleague Activities

Louisiana public servant cannot be engaged as promotional speakers for Pfizer.

The Louisiana Board of Ethics has stated, however, that a public employee can serve as a consultant (e.g., at a marketing advisory board) as long as the consultant services are related to his or her academic discipline or area of expertise and prior approval has been granted. For example, at LSU, the LSU chief administrative officer would need to approve such a consultancy. Further, if a public servant is involved in research with Pfizer, he or she can in most circumstances receive reimbursement for travel expenses for a Pfizer-sponsored clinical trial. Lastly, the Code of Governmental Ethics and Board of Ethics' rulings do not prohibit a public servant from speaking at a conference where Pfizer has provided an independent educational grant since Pfizer does not control the selection of the speaker or the content of the presentation, and the expenses at such an event would be paid by the conference organizer directly.

Helpful Point

- If you are not sure whether a potential speaker is a Louisiana public servant, you must confirm their status prior to engaging the person as a speaker. If the person receives regular compensation directly from one of the institutions above, they are probably a "public servant" and would be prohibited from receiving compensation from Pfizer for speaking.

The cap on meal expenditures at any program where Pfizer is providing a meal and where there is at least one public servant present is \$50. The law applies to any event where Pfizer is providing food or drink, and where a public servant is present, including speaker programs, advisory board meetings and speaker training meetings. It would not, however, apply to an event funded through an independent educational grant, where Pfizer provides financial support for the event and the grant recipient provides the meal.

The State of Louisiana can impose significant penalties on Pfizer and individual Pfizer employees for failure to comply with the law.

If you have any questions concerning the Louisiana laws discussed here, please contact the Regional Attorney with responsibility for Louisiana.

Massachusetts

The Law: Pharmaceutical and Medical Device Manufacturer Conduct Law (Massachusetts Marketing Code of Conduct)

The Massachusetts Marketing Code of Conduct significantly restricts Pfizer's ability to provide meals and other items of value to HCPs licensed in MA. The law also requires Pfizer to disclose payments and items provided to "Covered Recipients" (further defined below) that have a value of \$50 or more. These laws are more restrictive than the PhRMA Code. They apply to all colleagues and extend to interactions with Massachusetts HCPs that occur outside of Massachusetts.

In summary, the law requires Pfizer to:

- Adopt the Massachusetts Marketing Code of Conduct;
- Establish a compliance program and conduct annual training;
- Disclose annually certain financial interactions between Pfizer and Covered Recipients; and
- Provide Massachusetts HCPs the opportunity to withhold their prescriber data from use by sales and marketing.

Failure to comply with any provision of the law can subject Pfizer to a penalty of \$5,000 per violation.

Definition of Healthcare Professional

The Massachusetts definition of a healthcare professional (HCP) is broad. It includes any person who prescribes prescription drugs and is licensed to provide healthcare in Massachusetts, including a partnership or corporation comprised of such persons. Examples include:

- Physicians
- Physician Assistants
- Certified nurse midwife
- Psychiatric nurse mental health specialists



- Nurse Practitioners
- Employees and agents of such persons (e.g., nurses, office staff, etc.)

HCP does not include hospitals, nursing homes, pharmacists, health benefit plan administrators, healthcare professionals not licensed in Massachusetts, and other entities if they are not agents, employees, etc. of a MA-licensed HCP. (However, such entities *are* considered Covered Recipients for MA disclosure, as described below.)

How the Law Impacts Your Activities

All colleagues (regardless of division, business unit, or role) who engage in activities with Massachusetts HCPs, regardless of where the HCP practices or where the interaction occurs, should be aware that Massachusetts laws restrict Pfizer's ability to provide meals and other items of value to Massachusetts HCPs. In addition, certain expenditures have to be reported, so all colleagues must ensure that their records on these expenditures are accurate and complete.

You must make a good faith effort to determine whether an HCP is licensed in Massachusetts. To help you determine whether an HCP holds a MA license, you should check the **HCP License List** available on [Opsource](#) under the State Healthcare Law Compliance tab. Sales Colleagues can also access this information on [PfieldNet](#) under the Compliance Tab or by looking up the HCP in their iCUE tablet.

Meals

The Massachusetts Marketing Code of Conduct is more restrictive than the PhRMA Code with respect to the provision of meals to HCPs.

- Meals must be "on-site". In other words, meals are only permissible during informational presentations in an HCP office or in-hospital setting (a cafeteria located within a hospital would generally qualify as a hospital setting). Meals must be modest and occasional.
- The restriction applies to all colleagues – not only Sales and Marketing.
- All types of food and beverages (including nominal ones such as coffee, drinks, etc.) are limited to in-office or in-hospital settings during promotional presentations.



- The restriction also applies to interactions with Massachusetts HCPs that occur outside of Massachusetts.
- There is a limited exception for meals provided as compensation to Massachusetts HCPs who are consulting pursuant to a bona fide contract with Pfizer. In addition, refreshments such as coffee and snacks provided by Pfizer at a booth at a convention/congress are also permissible.

Other Prohibited Items of Value and Activities

Generally, educational items may be provided to Massachusetts HCPs as long as they are RC-approved.

Colleagues are prohibited from making expenditures on behalf of any Massachusetts HCP for:

- Entertainment or recreational items of any value;
- Grants, scholarships, subsidies or educational items offered with the intent to encourage or modify prescribing behavior; or
- Residents, fellows and HCPs to attend educational conferences (where funding comes directly from Pfizer and Pfizer chooses the recipient).

In addition, Pfizer may only provide CME support (through the MEG process and standards) to conference organizers that meet ACCME standards or equivalent standards. Pfizer may not, however, provide funding directly to support meals for HCPs or compensate HCPs for attending CME events.



Helpful Points

- Colleagues must not invite MA HCPs to Pfizer speaker programs that provide food unless the program occurs in an HCP's office or a hospital setting (even if the program is conducted outside of Massachusetts).
- Do not provide MA HCPs with any meal or snacks outside an office or hospital setting. Remember that any food provided in an office or hospital setting must be part of an informational presentation.
- There is an exception for meals provided as compensation under valid consulting agreements and for refreshments provided in a convention/congress booth.
- Colleagues must make a good faith effort to determine whether an HCP is licensed in MA before inviting an HCP to a speaker program and can consult [PfieldNet](#) for a list of MA HCPs or iCUE for assistance.
- The meal and gift restrictions apply even when a MA HCP is located in another state.

Disclosure

Pfizer must track and report annually all expenditures made to Covered Recipients for sales and marketing activities in excess of \$50 (per transaction). The definition of "Covered Recipients" is broader than the definition of HCPs and includes hospitals, nursing homes, pharmacists and health benefit administrators. Therefore, even though pharmacists are not prohibited from receiving meals (because they are not included in the definition of HCP), they are subject to the disclosure requirements since they are considered Covered Recipients, so certain payments to pharmacists must be disclosed. The only expenditures that do not need to be disclosed are those associated with rebates and discounts, genuine research, clinical trials, demonstration units, and starters. That data will be made publicly available on the state's website.

Non-patient Identified Prescriber Data

Before using non-patient-identified prescriber data, Pfizer must give Massachusetts HCPs the opportunity to request that their prescriber data be withheld from Sales and Marketing and not be used



for marketing purposes. The Commercial Operations group within Pfizer is responsible for ensuring that any prescriber data provided by Pfizer to Sales representatives complies with state law.

Minnesota

The Law: Gift Restriction Law

Minnesota prohibits Pfizer from offering or giving any gift of value to a Minnesota healthcare practitioner. The definition of “gift” includes anything or service that is given and received for less than fair market value unless it is specifically permitted under the statute. The restrictions apply to all colleagues (not only Sales) and extend to interactions with Minnesota practitioners that occur outside of Minnesota.

The following are not considered “gifts” under the statute and may be given to Minnesota practitioners:

- Free drug samples for free distribution to patients;
- Payment to sponsor a medical conference, professional meeting, or other educational program, provided no payment is made directly to a practitioner;
- Reasonable fees and expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting;
- Compensation at fair market value in connection with a genuine research project;
- Certain publications and educational materials, including most (but not all) RC-approved educational materials (e.g., Pfizer-created branded and unbranded promotional materials, reprints, literature, and other printed materials); and
- Salaries or other benefits paid to employees.

Educational Items

Educational reference items which provide general medical or drug information are not considered to be “publications and educational materials” and may not be provided. Examples of prohibited items include text-books, journal subscriptions, online subscription services (such as trial memberships for



Epocrates) and anatomical models. If you are unsure about whether an RC-approved item can be provided to a Minnesota practitioner, check with your manager or Regional Attorney.

Meals

As of May 31, 2010, Pfizer prohibits all colleagues from providing meals to Minnesota practitioners, subject to a very limited exception for meals provided as a reasonable expense to practitioners who serve on the faculty at a Pfizer professional or educational conference or meeting who are receiving compensation for services pursuant to a contract with Pfizer.

A modest meal is not considered a “gift” under the law if provided as a reasonable expense to a practitioner serving on the faculty at a professional educational conference or meeting. Where a Minnesota practitioner is serving as a speaker at a Pfizer promotional program, for example, his or her meal does not constitute a gift and may be provided. All meals must, however, comply with all Pfizer policies on providing meals to HCPs, including the policy that meals should be modest and not exceed \$135 in value.

Companies are required to submit annual reports to the Minnesota Board of Pharmacy of non-gift payments to practitioners, such as consulting fees, speaking honoraria, and related expenses, if the payments total \$100 or more per year per practitioner.

Consulting Engagements with MN HCPs

Effective September 1, 2011, Pfizer policy prohibits engaging MN licensed practitioners as consultants except with respect to the following types of projects:

- R&D, clinical or development related projects
- Outcomes Research
- Medical publications
- Speaking and speaker training

Engaging MN practitioners as consultants for any other purposes is prohibited without prior Legal approval.

Definition of Practitioner

A “healthcare practitioner” is essentially *anyone who is able to prescribe a prescription drug in Minnesota* regardless of whether the practitioner actively prescribes. Physicians, nurse practitioners, physician assistants, dentists, optometrists and veterinarians are all included in the definition of practitioner in Minnesota. Pharmacists, however, are not included in the definition of practitioner and are therefore not covered by the law.

You should treat any Minnesota healthcare practitioner as if they are subject to the Minnesota gift law *regardless of the state in which the practitioner works or where the practitioner is geographically located*. For example, if a Minnesota-based practitioner is attending a speaker program in another state, the Minnesota state gift law still applies. If a physician who lives and practices in Florida is dual licensed in Minnesota, the Minnesota gift law is deemed to apply. Therefore, meals cannot be provided to any Minnesota-licensed practitioner, regardless of his or her location.

How the Law Impacts Your Activities

All colleagues are prohibited from providing meals to Minnesota-licensed practitioners, unless the meal is provided as a reasonable expense to a practitioner in connection with serving on the faculty at a Pfizer professional or educational conference or meeting, or performing bona fide services under one of the permitted consulting engagements, and who is receiving compensation for services pursuant to a contract with Pfizer. These types of meals are not considered a “gift” under the state statute. Similarly, gifts (as defined above) to practitioners are also prohibited.

You must make a good faith effort to determine whether a practitioner is licensed in Minnesota. To help you determine whether a practitioner holds a Minnesota license, you can check the HCP Lookup List available on [Opsource](#) under the State Healthcare Law Compliance tab. Sales Colleagues can also access this information on [PfieldNet](#) under the Compliance Tab or by looking up the HCP on their iCUE tablet.

Minnesota can impose significant penalties on Pfizer as well as criminal misdemeanor penalties for failure to comply with this law. If you have any questions concerning the Minnesota Gift Law, please contact the Regional Attorney with responsibility for Minnesota.

Helpful Points

- Colleagues must not offer or give any gift of value to a Minnesota HCP, including educational items.
- Colleagues must not provide meals to Minnesota HCPs.
- There is an exception for meals provided as a reasonable expense to a practitioner in connection with serving on the faculty at a Pfizer professional or educational conference or meeting, or performing bona fide services under one of the permitted consulting engagements, and who is receiving compensation for services pursuant to a contract with Pfizer, and for snacks provided at a booth at a conference or seminar.
- Colleagues must not engage Minnesota HCPs as consultants, except under the limited circumstances detailed in this Chapter.
- You are required to make a good faith effort to determine whether an HCP is licensed in Minnesota before providing a gift or a meal to the HCP. You can consult [PfieldNet](#) or [Opsource](#) for a list of Minnesota HCPs.
- The meal and gift restrictions apply even when a Minnesota HCP is located in another state.

Nevada

The Law: Nevada Marketing Code of Conduct

The Nevada Marketing Code of Conduct requires all manufacturers and wholesalers who sell or market a drug in Nevada to:

- Adopt a written marketing code of conduct (the current PhRMA Code is acceptable);
- Adopt a training program to provide regular training to appropriate employees on the marketing code of conduct;
- Conduct annual audits to monitor compliance with the marketing code of conduct;
- Adopt policies and procedures for investigating instances of noncompliance with the marketing code of conduct;

- Identify a compliance officer responsible for the marketing code of conduct; and
- Submit certain information annually to the Nevada State Board of Pharmacy (including the marketing code of conduct, description of the training program; description of the investigation policies; contact information for the Compliance Officer; and certification of the company's annual audit and compliance with its marketing code of conduct).

New York

The Law: Restrictions on Gifts to State and Local Officers and Employees

New York prohibits all NY elected officials, state officers and employees, state legislators, state legislative employees, municipal officers and municipal employees from receiving (directly or indirectly) any gift. "Gift" includes anything of value given in any form, including any money, service, loan, travel, entertainment, hospitality, or promise, unless an exception applies. Colleagues may not provide any item to a New York State or local officer or employee if the item is intended or expected to influence or reward the New York State or local officer or employee in the performance of any activity related to his or her official duties.

Definition of Officer or Employee

A New York officer or employee includes any HCP employed, either full-time or part-time, by any New York State or county hospital, New York State Medicaid Board or any other New York State or county agency.

How the Law Impacts Pfizer Colleague Activities

Pfizer colleagues may not provide any gift, including meals, to a New York State officer or employee. Additionally, Pfizer colleagues may not provide gifts, including meals, to any New York local officer or employee. In addition, even PhRMA Code compliant RC-approved educational items such as anatomical models or textbooks may not be provided.



Pfizer colleagues may continue to provide PhRMA-compliant items of food and beverage of nominal value (e.g., doughnuts, cookies and non-alcoholic beverages such as soft drinks and coffee) which are not part of a meal.

Helpful Point

- If you are not sure whether an HCP is employed by the State of New York or a municipal institution, or is just affiliated with such an institution, you must determine the relationship prior to providing any item of value to the HCP. If the HCP receives regular compensation directly from one of these institutions, he or she is likely a state official and would be governed by the restrictions discussed in this section.

If you have any questions, please contact the Regional Attorney with responsibility for New York.

Vermont

The Law: The Prescribed Products Law

The Vermont Prescribed Products Law significantly restricts Pfizer’s ability to provide meals and other items of value to Vermont healthcare providers (HCPs). These laws are more restrictive than the PhRMA Code. They apply to all colleagues and extend to interactions with Vermont HCPs occurring outside of the State of Vermont. Pfizer is required to disclose these expenditures to the State of Vermont.

Pfizer has an obligation to self-report to the State of Vermont if we inadvertently give a prohibited gift or meal to a Vermont HCP. If you become aware of any such occurrence, you must report it immediately to statehealthcarelawcompliance@pfizer.com.

Definition of Healthcare Provider

Healthcare provider is defined very broadly in Vermont. It includes:

- Any person licensed to prescribe products or authorized to recommend prescribed products (“healthcare professionals”);



- Partnerships and corporations comprised of healthcare professionals;
- Officers, agents and employees of healthcare professionals (e.g., nurses, office staff, etc.); and
- Hospitals, nursing homes, pharmacists, and any other person authorized to dispense or purchase for distribution prescribed products.

Examples of HCPs in Vermont include:

- Physicians
- Nursing Homes
- Nurse Practitioners
- Dentists
- Healthcare professional office staff
- Physician assistants
- Hospitals
- Pharmacists
- Licensed Clinical Social Workers and psychologists
- Health plan benefit administrators

How the Law Impacts Your Activities

All colleagues (regardless of division, business unit or role) who engage in activities that involve Vermont HCPs, regardless of where the HCP practices or where the interaction occurs, should be aware that Vermont prohibits Pfizer from providing meals and certain other items of value to Vermont HCPs. In addition, certain expenditures have to be reported, so all colleagues must ensure that their records on these expenditures are accurate and complete.

You must make a good faith effort to determine whether an HCP is licensed in Vermont. To help you determine whether an HCP holds a VT license, you can check the HCP Lookup List available on



[Opsource](#) under the State Healthcare Law Compliance tab. Sales Colleagues can also access this information on [PfieldNet](#) under the Compliance Tab or by looking up the HCP in their iCUE tablet.

Meals

All meals to Vermont HCPs are banned. This prohibition includes the provision of coffee and donuts, or other food items of nominal value, even if these items are for non-prescribing staff in a physician's office. There is a limited exception for meals provided as compensation to Vermont HCPs who are providing services pursuant to a bona fide contract with Pfizer. In addition, refreshments such as coffee and snacks provided by Pfizer at a booth at a convention/congress are also permissible.

Gift Ban

In addition to the prohibition on meals, colleagues cannot provide Vermont HCPs with any item of value unless the item is explicitly allowed under the law.

The following items are allowed under Vermont law:

- Starters;
- Peer-reviewed academic, scientific, or clinical articles or journals that have been RC-approved;
- Articles, journals and other educational items;
- Certain conference sponsorships;
- Rebates and discounts;
- Clinical trials; and
- Compensation at fair market value for bona fide consulting services, including research and product development meetings.

Marketing Research

In June 2011, the Attorney General in the state of Vermont updated its Guide to the Prescribed Products Gift Ban and Disclosure Law by adding new restrictions in connection with VT-licensed HCPs participation in paid marketing research surveys (including blinded surveys).

Effective July 1, 2011 paid market research surveys involving VT-licensed HCPs are now banned. The restriction applies whether the survey is conducted directly by Pfizer or through an independent third party survey research organization.

Helpful Points

- Vermont bans all meals with VT HCPs (regardless of where the meal takes place) except as noted below.
- Snacks of nominal value (e.g., coffee, drinks, cookies, etc.) are also prohibited, except when provided at a booth at a convention/congress.
- You must not invite VT HCPs to Pfizer speaker programs at which food is provided even if the program is conducted outside of Vermont.
- There is an exception for meals provided as compensation for services performed under a bona fide consulting contract.
- You are required to make a good faith effort to determine whether an HCP is licensed in VT before inviting an HCP to a speaker program. You can consult [PfieldNet](#) or [Opsource](#) for a list of VT HCPs or by looking up th HCP in the iCUE tablet.
- The meal and gift restrictions apply even when a VT HCP is located in another state.

Disclosure

Most allowable expenditures to Vermont HCPs, or other institutions covered by the law (e.g., Vermont academic institutions), must be disclosed, regardless of the amount.

Effective January 2011, Pfizer amended its policies and began tracking the distribution of samples, coupons and vouchers. The first disclosure report is due by April 2012. Vermont's law defines "sample"

as a unit of a prescription drug, biological product or medical device that is not intended to be sold and is intended to promote the sale of the drug, product or device, including starter packs and coupons or vouchers that allow any individual to receive a prescribed product for free or at a discounted price.

Items exempt from disclosure are:

- Refreshments and other snacks provided at a booth at a convention/congress
- Rebates and discounts
- Royalties and licensing fees for patent rights
- Labels on prescribed products
- Reasonable expenses related to the interview by a manufacturer in connection with a bona fide employment opportunity
- Prescribed products distributed free of charge or at a discounted price pursuant to a Pfizer Patient Assistance Program

The Law: Vermont Price Disclosure Law

The Vermont Price Disclosure Law requires that, when marketing directly to Vermont authorized prescribers, Pfizer disclose the Average Wholesale Price (AWP) “per pill” of each drug marketed, as well as the prices of other drugs in the same therapeutic class. Two types of disclosure are required:

- **Long Form Disclosure:** Disclosure of price-related information posted on Pfizer’s website; and
- **Short Form Disclosure:** Written disclosure of price information which must be provided to the prescriber at the point of specific detailing or promotional activity (whether in person, by mail, by telephone or electronically). This short form is available at http://www-stg2.pfizer.com/vtprescribers/mn_shortforms.jsp.



The following table identifies which forms are required in connection with typical promotional activities.

Promotional Activity	Action Required
Face-to-face meeting with prescribers (detailing, dinner or lunch programs, exhibit booths, professional conferences) in Vermont	Provide short form to each prescriber for each product promoted or detailed
Mailing to prescribers	Include short form with mailing for each product promoted
Telephone calls	Inform Vermont prescriber that short form will be mailed; mail short form for each product promoted to business address within 24 hours
E-mails or electronic communications	Include short form for each product promoted as an attachment or as conspicuous and separate section of the e-mail

Marketing activities which do not require price disclosure in Vermont include placement of advertisements and marketing to state or private payers as well as hospitals.

Vermont can impose significant penalties on Pfizer for failure to comply with this law. If you have any questions, please contact the Regional Attorney with responsibility for Vermont.

West Virginia

The Law: Advertising Expense Reporting Law

West Virginia law requires pharmaceutical manufacturers that employ, direct or utilize marketing representatives in West Virginia to report the following:

- The total amount spent for advertising and direct promotion of prescription drugs to consumers, prescribers, pharmacies, and patient support or advocacy groups within West Virginia;
- Gifts, grants or payments of any kind – including meals, transportation/lodging, patient and practice-related items, branded promotional items, honoraria, and consulting fees – in any amount exceeding \$100 paid directly or indirectly to a West Virginia prescriber per year in the aggregate; and
- All DTC advertisements in West Virginia and total expenditures that pertain to West Virginia residents.

The following are exempt from reporting:

- Starters;
- Reasonable compensation and reimbursement of expenses for bona fide clinical trials; and
- Scholarships or support for medical students, residents and fellows to attend educational, scientific, or policy conference (if recipient is selected to attend by conference sponsor).

Definition of Healthcare Professional under the Law

The law impacts licensed prescribers in West Virginia, which includes the following professionals:

- Medical Doctors
- Advanced Nurse Practitioners
- Physician Assistants
- Optometrists



- Osteopaths
- Podiatrists
- Dentists
- Registered Nurses

How the Law Impacts Your Activities

All colleagues who engage in activities with West Virginia prescribers should be aware that their expenditures on HCPs will be reported and ensure that their reporting of attendees at programs is accurate and complete.

The State of West Virginia can impose significant penalties on Pfizer for failure to comply with this law. If you have any questions, please contact the Regional Attorney with responsibility for West Virginia.

FOR MORE INFORMATION

- Refer any questions to the Regional Attorney with responsibility for the relevant state.



Chapter 18: MEALS, EDUCATIONAL ITEMS, AND HCP PAYMENT DISCLOSURE

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Chapter 18: MEALS, EDUCATIONAL ITEMS, AND HCP PAYMENT DISCLOSURE

Introduction

The Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals (PhRMA Code), updated in January 2009, provides that occasional meals may be offered to U.S. healthcare professionals (HCPs) in connection with informational presentations and discussions, so long as the meal is modest as judged by local standards and occurs in a venue and manner conducive to informational communication that provides scientific or educational value. The PhRMA Code also restricts who may provide out-of-office meals to U.S. HCPs. In addition, it allows colleagues to give occasional approved educational items to U.S. HCPs if the items are valued at \$100 or less.

Meanwhile, in early 2009, Pfizer committed to publicly disclose payments and the value of meals, reimbursable travel expenses and educational items that it provides to U.S. licensed prescribers, beginning in 2010. Pfizer also committed to disclose all payments to U.S. institutions in connection with clinical research, along with the names of the associated principal investigators. These disclosure commitments were subsequently included and expanded as part of Pfizer's 2009 Corporate Integrity Agreement with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services. Soon, all pharmaceutical manufacturers operating in the U.S. will be required to report and disclose payments and other transfers of value to U.S. physicians and U.S. teaching hospitals in accordance with the transparency provisions of the Patient Protection and Affordable Care Act (PPACA). HCP payment disclosure is just one of the many ways Pfizer is working to maintain our commitment to increased transparency and public candor.

This Chapter concerns the provision of payments, meals, educational items or anything of value to U.S. prescribers or U.S. institutions. Also certain state laws that restrict or require the disclosure of payments and other items provided to U.S. HCPs are described in the State Laws: HCP and State Employee Restrictions Chapter. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination.



Key Points to Ensure Compliance

- Unless further restricted by state law, food and beverages provided by any Pfizer colleague to HCPs must be modest by local standards. In no event may the cost spent on food and beverages exceed \$135 per attendee, including tax and tip.
- When providing a modest meal in connection with product promotion, the meal must never serve as the primary focus of the interaction – it should be incidental to the dissemination of approved information and must comply with the PhRMA Code.
- It is improper for colleagues to provide “take out” meals to HCPs or their staff members.
- The PhRMA Code prohibits Sales representatives and colleagues who supervise one or more Sales representative from hosting any out-of-office meal for HCPs (outside of speaker programs). Senior Sales Colleagues (above District Manager) and non-Sales Colleagues (including Marketing) are not subject to this restriction and may host restaurant or other meals, as long as there is a “legitimate business purpose” for hosting the meal.
- The PhRMA Code prohibits non-educational items from being offered to U.S. HCPs or members of their staff. Accordingly, only Pfizer Review Committee-approved (“RC-approved”) educational items may be provided to HCPs and their staff.
- Pfizer’s payment disclosure policy applies to payments, meals, snacks, reimbursable travel expenses and approved educational items provided to U.S. licensed prescribers, including physicians, nurse practitioners and physician assistants. Pfizer also discloses payments to U.S. institutions in connection with clinical research, along with the names of corresponding principal investigators.
- Pfizer’s disclosures are posted on the Pfizer public website at http://www.pfizer.com/responsibility/working_with_hcp/working_with_hcp.jsp.
- For meals provided in connection with an informational presentation or consultant meeting, the disclosable value is calculated by taking the total cost of the meal and dividing it by the number of attendees.



Key Points to Ensure Compliance

- Until further notice, the cost of meals provided at speaker programs are allocated among all attendees, regardless of actual consumption (i.e., U.S. prescribers who are present at a speaker program where a meal is provided can not “opt out” of having a proportionate value of the meal allocated to them).
- Colleagues must ensure that they correctly record information necessary to identify a prescriber and payments or items of value conferred in the applicable finance and payment system(s), for accurate attribution of compensation or other value for disclosure purposes.
- Except for meals provided at speaker programs, a U.S. prescriber may “opt-out” of being offered meals, snacks or educational items by contacting PTI@Pfizer.com. (“Opt-out” prescribers may also “opt back in” by contacting the mailbox.) Colleagues that interact with HCPs are responsible for checking the “opt-out” list maintained on OpSource and PfieldNet.
- If a U.S. prescriber has “opted-out” but still accepts payments, meals or other disclosable items of value from Pfizer, the prescriber will be subject to disclosure accordingly.
- There are also certain state laws that limit and/or require the disclosure of payments and other items provided to HCPs. These laws are described in the State Laws: HCP and State Employee Restrictions Chapter. Additional information is also available on OpSource.Pfizer.com under the “State Healthcare Law Compliance” tab and on PfieldNet under the “Compliance” tab.
- In-scope payments or other exchanges of value provided to U.S. licensed prescribers and U.S. institutions through approved third party entities, such as Contract Research Organizations (CROs) and Contract Sales Organizations (CSOs), remain subject to disclosure.

Meals to HCPs

General Rules and Restrictions

Pfizer policy and the PhRMA Code permit colleagues to **provide meals to U.S. HCPs on occasion in appropriate circumstances** – such as meals in connection with informational presentations or discussions providing scientific or educational value – so long as the meal is modest as judged by local

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standards, occurs in a venue and manner conducive to informational communication (recreational and entertainment venues are prohibited), and never serves as the primary focus of the interaction. In addition, under Pfizer policy, **meals to U.S. HCPs cannot exceed \$135 per attendee (including the cost of food, beverage, tax and tip)**. Further, providing excessive or solely alcoholic beverages to HCPs is prohibited, as it is not conducive to providing scientific or educational information or other business purposes, and is presumed recreational.

As further described in this Chapter, the PhRMA Code restrictions on out-of-office meals apply only to field Sales representatives and their immediate managers. Accordingly, if and when certain Pfizer colleagues are permitted to provide meals to HCPs varies based on each colleague’s role and/or seniority. The table below provides a high-level summary:

	Host restaurant meals?	Host in-office meals?	Host in-hospital meals?	Host speaker programs?	Host meals at conventions?
PHR, TSR, IHR and any other Sales Representative	No	Yes	Yes	Yes	No
Account Manager, DE, CAD, ADM (only if such Colleague does not directly supervise Sales Representatives)	Only for HCPs who do not regularly treat patients	Yes	Yes	Yes	Only for HCPs who do not regularly treat patients
District Manager	No	Yes	Yes	Yes	No
Regional Manager, State Director, Regional Presidents	Yes	Yes	Yes	Yes	Yes
HQ Marketing/Medical	Yes	Yes	Yes	Yes	Yes



Furthermore, several states and the VA/DoD also impose meal limitations and reporting requirements that are stricter than the PhRMA Code and/or Pfizer's HCP Payment Disclosure policy. For instance, with very limited exceptions (such as meals provided in connection with certain HCP services), no meals (in- or out-of-office) may be provided to physicians licensed to practice in Vermont or Minnesota, and no out-of-office meals may be provided to physicians licensed to practice in Massachusetts. Before providing any meals or other items of value to HCPs, colleagues should refer to the Chapters on State Laws: HCP and State Employee Restrictions and Federal Employee Interactions and Lobbying. To determine whether an HCP is licensed in Massachusetts, Minnesota or Vermont, Sales representatives should consult the physician profile on their iCUE tablet, and other colleagues should consult the HCP License List at <http://hcplookup.pfizer.com/Pages/search.aspx>. Additional information on State law restrictions and other tools are available on PfieldNet under the Compliance tab and on Opsource.Pfizer.com under the "State Healthcare Law Compliance" tab.

Meals Provided by Field Sales Colleagues and Their Managers

Under the PhRMA Code, any meals provided to U.S. HCPs by Sales representatives and their immediate managers in connection with informational presentations must be limited to in-office and in-hospital settings. The only time a representative or his/her immediate manager may provide a restaurant meal to an HCP is at a Pfizer speaker program where an approved speaker (generally a paid external HCP) is presenting RC-approved educational information about Pfizer product(s), disease state(s) or other healthcare topic(s), where the content is controlled by Pfizer. Sales representatives and their managers are prohibited from providing out-of-office meals to HCPs in all other circumstances. Presentations made by a Pfizer employee (such as an Account Manager) who is not specifically authorized to conduct a promotional presentation to HCPs do not constitute a speaker program. It is also impermissible to pay for a meal at an activity which does not consist of Pfizer controlled content, such as at an independent continuing medical education program. (For more information about speaker programs, see the Orange Guide Chapter 9: Speaker Programs for HCPs and White Guide Chapter 4: Marketing Programs.)

It is inappropriate for a Sales representative to include an HCP's spouse or other guest in any Pfizer-provided meal unless the spouse or guest is an appropriate HCP or office staff member themselves, who is otherwise permitted to attend the meal. It is never appropriate for a Sales representative to offer "take-out" meals or meals to be eaten without the representative present.

PhRMA Code “Meals” Defined



- Q. What is considered a “meal” under the PhRMA Code?
- A. Anything more than nominal food or beverage items is considered a meal and, thus, may not be provided by Sales Representatives outside of an office or hospital setting unless in connection with a speaker program.
- Q. Does taking an HCP out for a cup of coffee constitute a meal?
- A. No. In accordance with the PhRMA Code, food or beverage items of nominal value – such as coffee, other non-alcoholic beverages, pastries or snacks – are not considered to constitute a meal. Pfizer policy permits a Sales representative to make an educational presentation to an HCP out of the HCP’s office or hospital (such as in a coffee shop near the HCP’s office) over such nominal food or non-alcoholic beverage, unless further restricted by state law or other laws or policies. In all cases, however, the value of any food or beverages, *regardless of amount*, provided to a U.S. licensed physician is subject to public disclosure by Pfizer, and the Pfizer colleague must appropriately record the expense as described in this Chapter.

Sales Colleagues Providing a Meal to Office Staff



- Q. If a Sales representative is bringing lunch to a medical office for HCPs to eat during a product discussion, can the representative also provide lunch to non-HCPs (e.g., office staff) in attendance?
- A. Yes, the PhRMA Code provides that when Sales representatives conduct an in-office business meal (“lunch and learn”) or program it is permissible to provide the meal to members of an HCP’s staff who attend the presentation.
- Q. Can a Sales representative provide a lunch to members of a medical office’s staff who do not attend the informational presentation?
- A. No. A Sales representative cannot provide a meal to any individuals (including HCPs and office staff) who do not attend the representative’s informational presentation. “Take-out” meals are prohibited.
- Q. A large medical clinic will only accept appointments from Sales representatives who agree to bring lunch to the clinic. They have offered to schedule a regular lunch appointment for a representative on the first and third Wednesday of each month. Can the representative accept this offer?
- A. No. Under the PhRMA Code, meals may only be provided to HCPs on an occasional basis. Such a recurring lunch appointment would be improper.

Providing in-Hospital Meals



- Q. What qualifies as an appropriate “in-hospital” meal? Can a Sales representative host a meal at a hospital food court or a cafeteria within the hospital complex?
- A. An in-hospital meal takes place in offices, conference rooms or hospital locations that are considered part of the hospital complex. Sales Representatives may provide a meal at a hospital food court or cafeteria on hospital grounds in conjunction with an informational presentation if it is considered part of the hospital complex.

Providing Meals to Pharmacists



- Q. Do the same rules apply to pharmacists and pharmacy technicians?
- A. Yes. While the PhRMA Code does not define “healthcare professional,” Pfizer policy requires colleagues to treat pharmacists as HCPs and to treat pharmacy techs as office staff.

Colleagues Permitted to Host Non-Speaker Program Restaurant Meals



- Q. The PhRMA Code states that meals (except for speaker programs) offered in connection with presentations by Sales representatives and their immediate managers should be limited to in-office or in-hospital settings. Does that mean that all colleagues who meet with customers are prohibited from providing these types of presentations in restaurants?
- A. No. The following senior Sales Colleagues may host HCP restaurant meals: Regional Managers, State Directors, and Regional Presidents. The following colleagues may host restaurant business meals for non-HCPs and HCP customers who do not treat patients: Account Managers, Directors, Employers, Customer Alliance Directors, and Alliance Development Managers. The following colleagues are prohibited from providing restaurant meals to HCPs outside of speaker programs: Healthcare Representatives, Therapeutic Specialty Representatives, District Managers, Clinical Specialists, and all other Sales Colleagues who either call on HCPs or who supervise colleagues who call on HCPs. Non-Sales colleagues, such as Marketing, are permitted to provide restaurant meals if there is a “legitimate business purpose” for hosting the meal.

Sales Representatives Attending Non-Speaker Program Restaurant Meals

- Q. May a Sales representative or District Manager attend a restaurant meal with a customer that is hosted by an appropriate colleague?
- A. Yes. Representatives and DMs may attend meals that are hosted by an appropriate colleague (e.g., restaurant meals hosted by RMs and SDs at conventions or congresses).
- Q. May a Sales representative or District Manager attend a restaurant meal with an HCP if the parties each agree to pay their own way?
- A. No. The spirit of the PhRMA Code is to help address perceived and real conflicts of interest. Continuing to provide information in restaurants, even if we are not paying the bill, does not help to address these perceptions.

Meals Provided by Senior Sales Colleagues and Headquarters Colleagues

While all colleagues are subject to the general rules and restrictions set forth at the beginning of this section, the PhRMA Code restriction on restaurant meals is not applicable to senior Sales Colleagues above District Manager level or non-Sales Colleagues. These colleagues, including Marketing, may provide modest food or beverages to HCPs in restaurants or other appropriate venues (such as Pfizer's offices) as long as there is a "legitimate business reason" for hosting the meal. (While Sales representatives and their immediate managers may attend meals hosted by such colleagues, they should not use them as a means to conduct activities or events that they cannot host on their own.)

In order to determine whether the "legitimate business reason" requirement is satisfied, these colleagues should determine whether the proposed interaction and meal is consistent with their role and responsibilities and whether the interaction helps them satisfy (in a legitimate way) their goals and objectives. The central focus must be the business interaction, with the meal being incidental to that primary purpose. At all times, colleagues must exercise sound judgment and discretion when providing meals in conjunction with a business interaction. Any questions about whether a meal can be provided to an HCP should be directed to the relevant team attorney.

Legitimate Business Reason

- Q. Pfizer is hosting a promotional booth staffed by Marketing Colleagues at a medical conference. Can a Marketing Colleague take a group of physicians out to a restaurant meal to discuss new Pfizer RC-approved data on a Pfizer product?
- A. Yes. This would be considered a “legitimate business purpose” since it is certainly permissible for Marketing Colleagues to discuss RC-approved content with HCPs so long as they adhere to the Four Core Compliance Principles. Marketing colleagues may continue to provide a modest meal incidental to the discussion (unless restricted by state law). For more information, see Chapter on State Laws: HCP and State Employee Restrictions..

Educational Items to HCPs

In accordance with the PhRMA Code and Pfizer policy, RC-approved educational items valued at less than \$100 may be provided on occasion to HCPs or members of their staff. [Non-educational items](#) are prohibited from being offered, even if the items are practice-related and of minimal value (such as pens, pads, mugs, etc.). If you have a question about whether a specific educational item is still approved to provide to HCPs, consult the relevant product Legal or Regulatory Affairs colleague, or submit your question to PharmaCode@pfizer.com.

Further, like meals, several states and the VA/DoD also impose limitations on educational items (and other items of value) that may be provided to HCPs that are more strict than the PhRMA Code and/or Pfizer’s HCP Payment Disclosure policy. For instance, to ensure compliance with Minnesota state law, Pfizer policy prohibits colleagues from providing educational items to physicians licensed to practice in that state. Before providing educational items to HCPs, colleagues should refer to the Chapters on State Laws: HCP and State Employee Restrictions and Federal Employee Interactions and Lobbying. For further information, and to determine whether an HCP is licensed in Minnesota, consult the HCP License List and other references available on OpSource.Pfizer.com under the “State Healthcare Law Compliance” tab and on PfieldNet under the Compliance tab.

Out-of-Pocket Gifts for HCPs



- Q. Can I pay for a gift for an HCP out of my own pocket if I do not expense it?
- A. No. It is not appropriate to purchase personal gifts of any kind for HCPs in the course of doing business, even if you pay out-of-pocket and do not seek reimbursement from Pfizer. The gesture can too easily appear to be an attempt to illegally influence prescribing in violation of anti-kickback laws. Remember that Pfizer Policies of Business Conduct require you to avoid even the appearance of a conflict of interest.

HCP Payment Disclosure Policy

Overview

Pfizer has committed to publicly disclose payments and the value of meals, reimbursable travel expenses and educational items that it provides to U.S. licensed prescribers. That commitment has been memorialized and expanded as part of Pfizer's August 2009 Corporate Integrity Agreement (CIA). On March 31, 2010, Pfizer made its first disclosure of payments, meals and other non-cash items provided to prescribers, covering the period between July 1, 2009 and December 31, 2009. The March 2010 disclosure included payments and non-cash items valued at \$25 or more, and identified prescribers who received an aggregate of \$500 or more during the reporting period.

Pursuant to the CIA, beginning with Pfizer's March 2011 disclosure of data for the entire 2010 calendar year, Pfizer is now reporting all disclosable payments, meals and non-cash items, regardless of value, provided to U.S. licensed prescribers who receive in excess of \$100 during a calendar year. For those who do not pass this annual threshold, only payments and other transfers valued at \$10 or more are disclosed. These de minimus and aggregate threshold rules align with those set forth in the transparency provisions of the federal Patient Protection and Affordable Care Act. Also pursuant to the CIA, after March 2011, Pfizer began issuing its public disclosures on a quarterly basis. The first quarterly disclosure occurred on June 1, 2011, covering the first quarter of 2011.

Pfizer's disclosure policy affects any colleague who provides payments, meals or non-cash items of any value to licensed U.S. prescribers, U.S. clinical investigators or U.S. institutions. Colleagues must be familiar with the policy and must personally and proactively discuss our disclosure policies



with all U.S. prescribers to whom they intend to provide disclosable payments or items of value, to ensure they are aware they will be disclosed.

Stakeholders Affected By Policy

Pfizer's disclosure includes applicable payments and non-cash items given to the following:

- U.S. HCPs who can prescribe medicines, including physicians, nurse practitioners and physician assistants;
- Major institutions involved in clinical trials ongoing as of July 1, 2009; and
- Principal investigators and other entities for clinical trials beginning on or after July 1, 2009.

Items Included in Reporting

Pfizer's disclosures include payments and non-cash items given to U.S. prescribers and U.S. institutions for:

- Meals (including snacks / refreshments of nominal value)
- Business travel expenses
- Educational Items
- Investigator Initiated Research
- Non-interventional/Observational Studies
- Consulting
- Promotional Speaking
- Phase I–IV Clinical Trials
- Outcomes Research Studies

In-scope payments and exchanges of value to U.S. prescribers and institutions processed through approved third-party entities, such as Contract Research Organizations (CROs) or Contract Sales Organizations (CSOs), will be disclosed if Pfizer selects the HCP and pays or reimburses the entity for the payment to the HCP.



Disclosure of Monetary Compensation and Business Travel Expenses

Pfizer may directly or indirectly provide **fair market value compensation** to U.S. HCPs in connection with a number of activities, including consultant services, promotional speaking events, clinical trials and other studies or projects. Pfizer may also compensate HCPs by paying for reasonable travel expenses incurred in connection with these activities, such as airfare, hotel accommodations and ground transportation. All such compensation must correspond to bona fide services provided pursuant to written agreements. See the White Guide Chapter on HCP and Government Official Consulting Engagements and the Clinical Research and Investigator-Initiated Research Chapter for more information on common engagements involving monetary compensation.

Pfizer's disclosures generally reflect the actual sums paid for the HCP's involvement in the activity, whether the funds are provided to the HCP directly or via an approved third-party entity. Disclosable travel expenses reflect either the actual sums expended for a specific HCP's accommodations or, if the activity or event requires attendance of multiple HCPs, may reflect a proportionate allocation of travel expenses.

Disclosure of the Value of Meals

As described in this Chapter, colleagues are permitted to provide occasional meals to U.S. HCPs in appropriate circumstances. Currently, subject to state laws that may also impose meal limitations and reporting requirements that are stricter than the PhRMA Code and/or Pfizer policy, Pfizer's disclosures include all meals provided to U.S.-licensed HCPs who can prescribe medicine, regardless of value. (Although not treated as "meals" under the PhRMA Code, snacks and refreshments of nominal value are categorized as meals for purposes of Pfizer's disclosures. Therefore, Pfizer colleagues must appropriately record any coffee, snacks, or refreshments in their expense reports, as directed in this Chapter.)

When meals are provided in connection with an informational presentation or other grouping of multiple attendees, the disclosable value is calculated by taking the total cost of the meal and dividing by the number of attendees. While Pfizer's disclosure policy applies only to HCPs who can prescribe medicines (and associated institutions), all appropriate attendees (including administrative staff, non-prescribing HCPs, nurses, physical therapists, etc.) will be included in calculating the per-person value of a meal.

Tracking and Calculating the Disclosable Value of Meals

- Q. I am planning to provide a meal at an informational presentation that will be attended by six U.S. licensed HCPs and four other appropriate attendees (e.g., Pfizer colleagues or appropriate HCP office staff). I intend to spend \$120. How will the meal be disclosed?
- A. The total value of the meal will be divided by the total number of people who actually attend your meeting. Therefore, if all ten individuals attend, \$12 will be disclosed for each of the U.S. HCPs licensed to prescribe medicine. However, if only eight individuals attend, \$15 will be disclosed for each of the HCPs.
- Q. Do the same disclosure rules apply to meals provided to U.S. HCPs at speaker programs?
- A. Yes. Pfizer's disclosures will include all items of value that are provided in connection with speaker programs (excluding overhead or similar facility expenses). The value of meals will be allocated among all attendees. The value of speaker fees and speaker travel expenses will be allocated to the speaker.
- Q. I am planning for 10 HCPs to attend a speaker program at a restaurant that, as part of its room reservation contract, requires a \$75 meal cost per attendee commitment ($\$75 \times 10 = \750), regardless of actual attendance. If 2 HCPs do not show up, will that increase their allocated meal value ($\$750 / 8 = \93.75)?
- A. No. If a restaurant requires Pfizer to pay a fixed "per person" meal fee based on estimated attendance at a speaker program, that "per person" fee will be allocated to all actual attendees (regardless of actual consumption). In this example, the 8 HCPs would be allocated \$75 each.
- Q. If a U.S. HCP attends a meeting or presentation at which a meal is offered but elects not to consume any food or beverages, can the HCP avoid being allocated a portion of the meal for disclosure?
- A. It depends. If the expenses and HCP attendees will be recorded in a Pfizer system that permits including only those consuming the meal (e.g., GCE), then non-consuming HCPs may not be disclosed. However, if the Pfizer system does not currently allow this distinction (e.g., EZSpeak), then all HCPs will be disclosed regardless of actual consumption.

Disclosure of Snacks and Refreshments Provided at Exhibit Booths



- Q. We are planning to have an exhibit booth at a state physicians' annual convention, at which we intend to make coffee and pastries of nominal value available. Do I need to track and report the snacks/refreshments provided to U.S. physicians visiting the Pfizer booth?
- A. Yes. Although not considered a "meal" for purposes of the PhRMA Code, snacks and refreshments of any value (including nominal value) are categorized as meals for purposes of Pfizer's HCP Payment Disclosure policy. You must ensure that you can accurately record the full name, title, credentials and address of each prescribing HCP that accepts a snack/refreshment, including the value of the items provided.

Disclosure of the Value of Educational Items and Non-Disclosure of Patient Materials

As discussed in this Chapter, under Pfizer's policies and PhRMA Code guidelines, RC-approved educational items valued at less than \$100 may be provided on occasion to U.S. HCPs. The value of these educational items (such as **textbooks** and **anatomical models**) provided to U.S. HCPs are included in Pfizer's public disclosures.

Generally, Pfizer-created branded and unbranded promotional materials, literature and other leave behind written materials are NOT subject to disclosure. Likewise, items that are of value to patients are NOT disclosable but must be tracked for business purposes. These non-disclosed items include:

- Co-pay cards
- Savings cards
- Pill dispensers
- Brochures
- Vouchers
- Prescription stamps
- Pamphlets



Recording Disclosable Payments and Items

Colleagues MUST properly record all payments, meals (including the number and classification of attendees), and all other disclosable items, **regardless of value**, as part of the regular expense reporting process. Colleagues are expected to:

- Obtain **full and complete names for all U.S.-licensed HCPs** receiving payment for, or otherwise participating in, activities involving disclosable items, including attendees at meetings, presentations and speaker programs where meals are provided;
- Ensure that they **accurately record information about payments and non-cash items** given to U.S.-licensed HCPs in the appropriate system (e.g., Pegasus budgets; GCE's "My HCP" category; EZSpeak's "Attendee & Guests" sections; GEMS' Attendee registry);
- Classify budgets and expenses to the **appropriate codes** and ensure **invoices** can be attributed to the HCP through the Pfizer Physician ID Number; and
- Never approve expense reports or invoices that are lacking full names and appropriate expense allocation.

Opting-Out of Receiving Disclosable Items

It is critical that colleagues make sure that the U.S.-licensed HCPs with whom they interact are aware of Pfizer's disclosure policy and the meaning of an "**opt-out.**" If an HCP does not want to have items reported, he or she should not be *offered* – and must not *accept* – payments or other disclosable items from Pfizer. Pfizer maintains a record of HCPs who have "opted out" of receiving disclosable items from Pfizer on [PfieldNet](#) and [OpSource](#).

If an HCP wishes to opt-out of receiving meals, snacks or educational items, the notified colleague must: (1) immediately make Pfizer aware of the opt-out by e-mailing all relevant information to PTI@Pfizer.com; and (2) inform other colleagues who may interact with that HCP so that the HCP's request can be honored. The HCP may also submit questions or an opt-out request directly to PTI@Pfizer.com.

Once an HCP has opted out, Pfizer should not provide – nor should the HCP accept from Pfizer – any payment (e.g., fees) or other disclosable item (e.g., meal, textbook, in-scope educational item). **If an**

HCP does accept a disclosable payment or item of value, that information will appear in Pfizer’s public disclosures regardless of any prior opt-out request. Also, if an HCP attends a speaker program at which a meal is provided, an equal portion of the cost of the meal will be allocated to the HCP regardless of actual consumption or prior opt-out request.

If an HCP who has opted out subsequently chooses to opt back in, the notified colleague or HCP should contact PTI@Pfizer.com.

Understanding the Opt-Out Process



- Q. Can a Sales Colleague provide a meal to an office with multiple HCPs if some HCPs have opted out and others have chosen not to opt-out?
 - A. Generally, yes. However, any HCPs in the office who have opted out must not be provided the meal.
- Q. Can a Sales Colleague provide a meal for office staff if all the HCPs (prescribing and non-prescribing) in an office have opted out?
 - A. No.
- Q. What happens if an HCP who has previously opted out later eats a meal that I provided for other HCPs in the office or at a joint meeting or event?
 - A. You must inform the HCP that any meals consumed will be reported, and you must include the HCP in the list of attendees in the relevant expense system (e.g., GCE) for allocation of an appropriate portion of the meal to the HCP. Pfizer’s duty to report meals that it provides to HCPs is non-negotiable.
- Q. What happens if an HCP who has previously opted out attends a speaker program at which a meal is provided?
 - A. All speaker program attendees will be allocated a portion of the meal regardless of actual consumption and, accordingly, the HCP will be disclosed as having received the meal. Speaker event invitations and attendee sign-in sheets include language advising attendees of this policy.
- Q. I have an HCP that is willing to perform consulting services for zero compensation, including no travel payments. Will this arrangement be subject to disclosure?
 - A. Probably not. In most cases, the HCP must still be required to sign a “zero fee” consultant agreement to memorialize the terms. Please contact HCPQuestions@pfizer.com or your team attorney with any questions.

Public Disclosures

Pfizer’s disclosures separately identify payments and non-cash items provided to each U.S. licensed prescriber or U.S. institution by category, including meals, educational items, business-related travel expenses, professional advising (i.e., consulting fees) and expert-led forums (i.e., speaker fees). The disclosures are posted on Pfizer’s website at http://www.pfizer.com/responsibility/working_with_hcp/working_with_hcp.jsp.

The Disclosure Process



- Q. Will HCPs have the opportunity to review Pfizer’s disclosures before they are posted?
- A. Due to the volume of information that Pfizer discloses, it is not possible to provide HCPs with the opportunity to review their data prior to publication.
- Q. How should I handle complaints by HCPs about Pfizer’s disclosure policy? What if an HCP believes that the information in Pfizer’s disclosures is incorrect?
- A. Pfizer has a dedicated staff to address questions and concerns raised by HCPs. You should send an e-mail to PTI@pfizer.com and copy your manager on the communication. The HCP may also send an e-mail directly to PTI@pfizer.com.

FOR MORE INFORMATION

- For more information about the PhRMA Code, refer to the PhRMA website at http://www.phrma.org/code_on_interactions_with_healthcare_professionals.
- For more information on Pfizer’s meal and educational item guidelines based on the PhRMA Code, including an updated FAQ on the PhRMA Code, refer to the “PhRMA Guidelines” tab at OpSource.Pfizer.com on PfieldNet under the Compliance tab or e-mail PhRMACode@pfizer.com.
- For more information regarding processes for capturing and recording disclosable payments in GCE, refer to the GCE Meal Expense Guidance available on PfieldNet at http://PfieldNet.pfizer.com/workspace/TechnologySupport/Documents/GCE_Meal_Guidance.pdf.
- To determine whether an HCP is licensed in Massachusetts, Minnesota or Vermont, Sales representatives should consult the physician profile on their iCUE tablet, and other



colleagues should consult the HCP License List at <http://hcplookup.pfizer.com/Pages/search.aspx>. Additional information on State law restrictions and other tools are available on PfieldNet under the Compliance tab and on OpSource.Pfizer.com under the "State Healthcare Law Compliance" tab.

- [SOP on Public Disclosure of Payments to U.S. Healthcare Professionals](#).
- For more information on Pfizer's HCP disclosure policy, refer to the "HCP Payment Disclosure" tab at <http://OpSource.Pfizer.com>, or e-mail PTI@Pfizer.com.



Chapter 19: SALES ACTIVITIES: GREENSTONE AND PFIZER INJECTABLES

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Chapter 19: SALES ACTIVITIES: GREENSTONE AND PFIZER INJECTABLES

Introduction

Your sales of Pfizer and Greenstone products to customers, including pharmacies, wholesalers, hospitals, and group purchasing organizations (GPOs), is essential to Pfizer’s success. To fulfill our legal and regulatory responsibilities, it is also vital that your sales activities be conducted according to Pfizer policy and procedures.

This Chapter is applicable to all Greenstone and Pfizer Injectables Colleagues. Non-compliance with these policies puts the Company at risk and can subject Colleagues to disciplinary action up to and including termination.

The term “healthcare professional” (HCP) is defined broadly to include any individual who directly interacts with patients or has a role in patient diagnosis or treatment. It also includes nurses, nurse practitioners, physicians, and dispensing pharmacists. It also may include individuals who do not work directly with patients but have influence over the recommendation, purchase, or prescribing of Pfizer products – such as health plan administrators, Pharmacy & Therapeutics Committee members, and Formulary Committee members who do not see patients. Generally, the term HCP does not include administrative staff such as receptionists, office managers, and case or file managers. It is important to note, however, that the definition of HCP may differ in certain contexts as demonstrated throughout this Field Guide (including, for example, how states define HCPs in the context of applicable state laws). Generics purchasers at wholesale and retail customers are not considered HCPs for the purposes of this Chapter.

Key Points to Ensure Compliance

- Never engage in any actual or perceived quid pro quo. Anything given to or received from a customer must be considered in light of anti-kickback laws as well as Pfizer’s corporate policies.
- Any payment or gift to customers may implicate pricing and discount considerations.
- Ensure that any items you provide to customers are Review Committee-approved and comply with the policies in this Chapter.
- Ensure that all meals, including meals provided in conjunction with any customer or other meeting, adhere to the policies in this Chapter.
- Ensure that the proper process is followed when purchasing exhibit or display space at a conference, trade show, or other event in accordance with this Chapter.

Never Engage in Actual or Perceived Quid Pro Quo

Anti-Kickback Laws

Quid pro quo is Latin for “this for that.” This means offering or appearing to offer any remuneration or item of value in exchange for purchasing, prescribing, dispensing, or formulary acceptance. The decision of an HCP to prescribe, recommend, or dispense a Pfizer product must be based on the best interests of the patient and not on any item of value offered to the prescriber.

This principle governs the relationships between Greenstone and Pfizer Injectables and their customers. Any remuneration from a manufacturer provided to a purchaser that is expressly or impliedly related to the purchase of a Greenstone or Pfizer Injectables product potentially implicates the anti-kickback laws. Providing a donation or any funding, including sponsoring any customer event, also may implicate the anti-kickback laws. This includes charitable contributions if the contribution is given to a customer or a charity affiliated with a customer as well as donations to patient awareness programs run by customers.

Please review the Overview and Key Principles Chapter for more information on the anti-kickback laws.



Pricing Considerations

Any amount of money or items of value given to a customer, no matter how small, may implicate pricing considerations. Any donation, funding or sponsorship to a customer could be considered to be a “discount.” A discount offered to one customer may have to be offered to other customers.

The Robinson-Patman Act prohibits a seller from discriminating among its commercial customers with respect to price, or promotional allowances or services, in certain circumstances. “Price” in this situation means transactional, or net, prices, taking into account discounts, rebates, prompt payment terms, and other factors affecting price.

The government’s increased role as a purchaser of prescription medicines in the past few years has heightened its attention to enforcement of the laws and regulations concerning the Medicaid Drug Rebate Program. Under the law, manufacturers have certain reporting responsibilities and are required to provide the federal government with a rebate for each unit of product paid for by State Medicaid agencies.

Please review the Overview and Key Principles Chapter and Orange Guide Chapter 2: Detailing to HCPs for information on the Medicaid Best Price Law and the False Claims Act, as well as the Corporate Policy on Compliance with Antitrust Laws.

Providing Funding to Customers



- Q. What are the considerations involved in deciding whether I can approve a donation to a pharmacy's patient awareness program? The money would fund the distribution of sunscreen to patients when they fill prescriptions for medications that increase photo-sensitivity.
- A. This request might be considered a discount, which Pfizer or Greenstone might then need to offer to other customers or consider for its government price reporting. Any payment or gift to customers also must be considered in light of potential anti-kickback concerns. Consult with your Legal Counsel about the propriety of making such a donation.
- Q. What if the donation requested would be paid to a foundation or other not-for-profit organization?
- A. Donations to not-for-profit organizations must follow the procedures set out in the Standard Operating Procedure on Funding Requests for Not-for-Profit Organizations. However, if a not-for-profit organization is affiliated with a customer (such as a foundation established by a pharmacy), a donation may raise potential anti-kickback concerns, and you should consult with your Legal Counsel.

When a funding request relates to a not-for-profit organization, please refer to Orange Guide Chapter 3: Support of External Organizations. The Standard Operating Procedure (SOP) on Funding Requests for Not-for-Profit Organizations, available at <http://opsources.pfizer.com>, applies to all funding to not-for-profit organizations.

Giveaway Items

The Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals (PhRMA Code) prohibits non-educational items from being offered to practicing HCPs or members of their staff, even if practice-related and of minimal value (e.g., pens, pads, and mugs). Items of nominal value, such as pens, may be distributed by Greenstone and Pfizer Injectables at booths at trade shows and conferences, provided that Pfizer brands are not being represented at such events. Such items must not, under any circumstances, be distributed in the field (e.g., at hospitals or to practicing pharmacists), nor may these items be made available through the Promos online catalog or other sources accessible by all colleagues.

Providing Give-aways to Customers



- Q. Can we give away Pfizer Injectables pens to our customers in the field or on sales calls?
- A. No. Pfizer Injectables may only give away the pens (and similar reminder items) at the Pfizer Injectables booth or table at meetings and conventions if no Pfizer brand teams nor personnel from other Pfizer Business Units have purchased a booth or table at the same event. There are certain local or regional meetings that Pfizer Injectables will attend and the other Pfizer brand teams will not. It is **OK** for the Pfizer Injectables team to distribute pens at these local or regional meetings when Pfizer Injectables is the sole Pfizer group attending. **Prior to arranging to distribute reminder items at an event**, please contact the convention or meeting organizers to confirm that no other Pfizer teams will be attending or exhibiting.

You must never tie giving something of value – even something of nominal value – to an HCP’s or other recipient’s purchasing, prescribing, dispensing, or recommendation of a product. Doing so exposes both you and Pfizer to substantial legal risk and is strictly prohibited.

Business Meals Provided by Greenstone and Pfizer Injectables Colleagues

Greenstone and Pfizer Injectables Account Managers, excluding the Hospital Surgical Team, may host business meals at restaurants for non-HCP customers and HCPs who hold administrative positions and dedicate very little time, if any, to seeing patients or filling prescriptions. For this purpose, “Account Managers” include persons titled Director - National Accounts, Regional Business Manager, and Territory Representatives. The Pfizer Injectables Hospital Surgical Team shall comply with the business meals guidance provided in Chapter 18: Meals, Educational Items, and HCP Payment Disclosure.

Inclusion of a customer’s spouse or other guest in the meal is not appropriate unless the spouse or guest is an individual who has a legitimate business reason to attend.

Meals must be modest by local standards and cannot exceed an amount of \$135 per attendee — including the cost of food, beverage, tax and tip. A meal should never be the primary focus in speaking with customers. The central focus must be the business discussion, with the meal being incidental to that primary purpose. In addition, providing excessive or solely alcohol beverages is prohibited, considered not conducive to a business discussion, and is presumed recreational.



	Host restaurant meals?	Host in-office meals?	Host in-hospital meals?	Host meals at speaker programs?	Host meals at conventions?
Account Manager Director – National Accounts, Regional Business Manager, and Territory Representatives	Only for non-HCP customers and HCPs who do not regularly treat patients	Yes	Yes	Yes	Only for non-HCP customers and HCPs who do not regularly treat patients

You cannot provide any food or other support in connection with an accredited continuing medical education activity (ACCME, ACPE, or ANCC). Note that “medical education” is not limited to medical education for physicians, but includes education for other HCPs, including pharmacists. Even if you are offered time to promote while providing a meal to attendees at an accredited medical education conference, you must decline the opportunity since providing a meal could be considered inappropriate support for that conference. Any type of financial support for accredited continuing education, including payment for event expenses or meals, must be funded through an independent professional education grant. Requests for these grants should be sent by the requestor through Pfizer’s Medical Education Grants website. For more information, see Orange Guide Chapter 3: Support of External Organizations.

Activities in Connection with Customer and Other Meetings

Customer-sponsored meetings of customers, such as trade shows and member or affiliate meetings, may provide an excellent opportunity to promote Pfizer and Greenstone products to those in attendance.

When deciding whether to conduct legitimate sales activities in connection with such meetings you must evaluate your goals, determine whether your business purpose is appropriate, and exercise good judgment. Conducting a sales activity, such as an exhibit or display, in this circumstance must be based on a legitimate business purpose to present information about Pfizer or Greenstone products and



cannot be based on a desire to support or otherwise fund an independent meeting or entertain customers.

Follow these key principles to ensure that the promotional activities you conduct in conjunction with customer-sponsored meetings are appropriate:

- If a meal is being provided, adhere to all Pfizer policies and processes regarding business and speaker program meals; and
- Make it clear to the customer or organization that Pfizer or Greenstone is funding or participating in specified, permitted activities and will receive specified, permitted tangible benefits.

It is important to remember that if a Pfizer or Greenstone Colleague participates in any way in the content of a non-Pfizer meeting, the entire meeting may be considered a promotional event, in which case it is governed by the same promotional rules that apply to all Pfizer promotional activities.

Exhibits and Displays

Pfizer is often given the opportunity to promote Pfizer and Greenstone products and provide approved information and materials to customers by paying for an exhibit, display table or booth at an event. An exhibit or display opportunity can occur at a variety of venues and programs, but the key principle for you to remember is that Pfizer or Greenstone is paying for the space to promote our products (and in some cases our name) and must not pay more than fair market value for the display opportunity.

Money allocated to fund an exhibit or display at independent educational programs should not be used to fund other aspects of the program (e.g., speaker honoraria, requestor's rental expenses, and food). Likewise, you should never try to bypass the grant approval process by submitting an exhibit or display request when the funding is really going to the non-promotional aspects of a program. Promotional and non-promotional funding must always be separated, easily identifiable and tracked for auditing purposes. The location of the display should also be separate and apart from any independent educational activity.

Exhibit and display requests for the same event that total \$3,500 or more must be approved by your Legal Counsel unless the request requires **Managed Care Review Committee (MCRC)** review. In

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addition to appropriate legal review and approval, your managers must also approve the request before the day of the event. The same criteria apply to all exhibits and displays, regardless of their cost.

Managed Care Review Committee (MCRC): created to review and provide final approval of all proposed non-rebate payments or transfer of funds to managed care customers.

Further, all exhibit and display requests from managed care customers, regardless of amount, must be reviewed and approved through the MCRC before the date of the event and prior to any payment or initiation of activities associated with the payment. For more information on the MCRC, see Chapter 5: Payments to Managed Care Customers.

Key Factors to Consider when Evaluating Fair Market Value

- The opportunity for promotion to large numbers of people or an audience that is difficult to access without the display opportunity;
- The size of the table or booth and the number of colleagues who can work the table or booth;
- The length of time given to Pfizer to engage in promotional discussions with event attendees;
- The physical location of the table or booth in relation to those attending an event;
- Availability of electricity or internet and computer connections; and
- Whether setup and cleanup are included in the exhibit and display fee.

In addition to these factors, you must make sure that if other companies are displaying, all exhibitors are being charged the same amount for the same type of space. It is also acceptable if all exhibitors are being charged the same fee but Pfizer has negotiated to pay a discounted rate.

Often the event brochure will list the cost levels of exhibit and display opportunities and describe the space and services that are being purchased at each level. This type of brochure should accompany your exhibit or display request whenever possible because it helps to validate the fair market value of the exhibit opportunity.



Please refer to the SOP on Exhibits & Displays for the procedure to be followed.

Also refer to the <http://OpSource.pfizer.com> when:

- the space purchased is at an event held by a not-for-profit organization, **and**
- **either:** (a) the request is initiated by someone other than a U.S. Sales Colleague; or (b) a U.S. Sales Colleague purchases a package from a third party not-for-profit organization that includes other benefits (i.e., in addition to the exhibit and display space).

State Laws

State laws on providing meals and other items of value

Note that the rules in certain states may be more restrictive than the PhRMA Code. For example, effective July 2009, the State of Vermont enacted laws which significantly restrict Pfizer's ability to provide meals and other items of value to Vermont HCPs. They apply to all colleagues and extend to interactions occurring with Vermont HCPs in and outside the State of Vermont. Further, the Vermont definition of HCP is much broader than the PhRMA Code definition. The Vermont definition of HCP includes any person licensed to prescribe products or authorized to recommend prescribed products and any person authorized to dispense or purchase for distribution prescribed products. For more information on whether your activities are implicated by state laws, see Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions or contact your Legal Counsel.

State pharmaceutical compliance and disclosure laws

A growing number of states are requiring companies to monitor their annual expenditures relating to marketing activities to comply with annual spending limits and disclosure requirements. Since the passage of Minnesota's marketing disclosure and restriction law in 1993, several other states including California, Nevada, Maine, Massachusetts, Vermont, West Virginia, as well as the District of Columbia, have enacted laws imposing varying spending limitations and disclosure requirements on companies that market prescription products in those states. In addition, some states require price reporting of AMP and Best Price to state government agencies. For more information on whether your activities are

implicated by state pharmaceutical compliance and disclosure laws, see Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions contact your Regional Attorney.

State law example: Vermont law



- Q. Does the law apply to account directors who support our generics business and who deal with buyers at large customers?
- A. Yes. The Vermont restrictions apply to all colleagues interacting with any persons authorized to dispense prescribed products or purchase prescribed products for distribution (as these persons are included in the definition of HCP).

FOR MORE INFORMATION

- For more information on anti-kickback laws, the Medicaid Best Price Law, and the federal False Claims Act, see Chapter 1: Overview and Key Principles.
- For more information on funding requests, see Orange Guide Chapter 3: Support of External Organizations.
- For more information on the PhRMA Code, including FAQs, see the Compliance tab on PfieldNet at <http://pfieldnet.pfizer.com>.
- For more information on whether certain activities implicate state laws, see Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions.
- Questions may be referred to your manager or Legal Counsel.