Pfizer Inc
235 East 42nd Street
New York, NY 10017
www.pfizer.com

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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. Our **Healthcare Law Compliance Guide (commonly known as the White Guide)** provides an overview of the laws, regulations, Pfizer policies and guidelines that govern our U.S.-based human biopharmaceutical business. It is essential that you familiarize yourself with the White Guide.

Every colleague is accountable for understanding and meeting our company's compliance requirements. We encourage you to bookmark the White Guide as a reference to help ensure that you remain in compliance with all policies and procedures applicable to your work. Do not hesitate to consult with your team attorney if you have any questions or e-mail the White Guide team at WhiteGuide@pfizer.com.

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

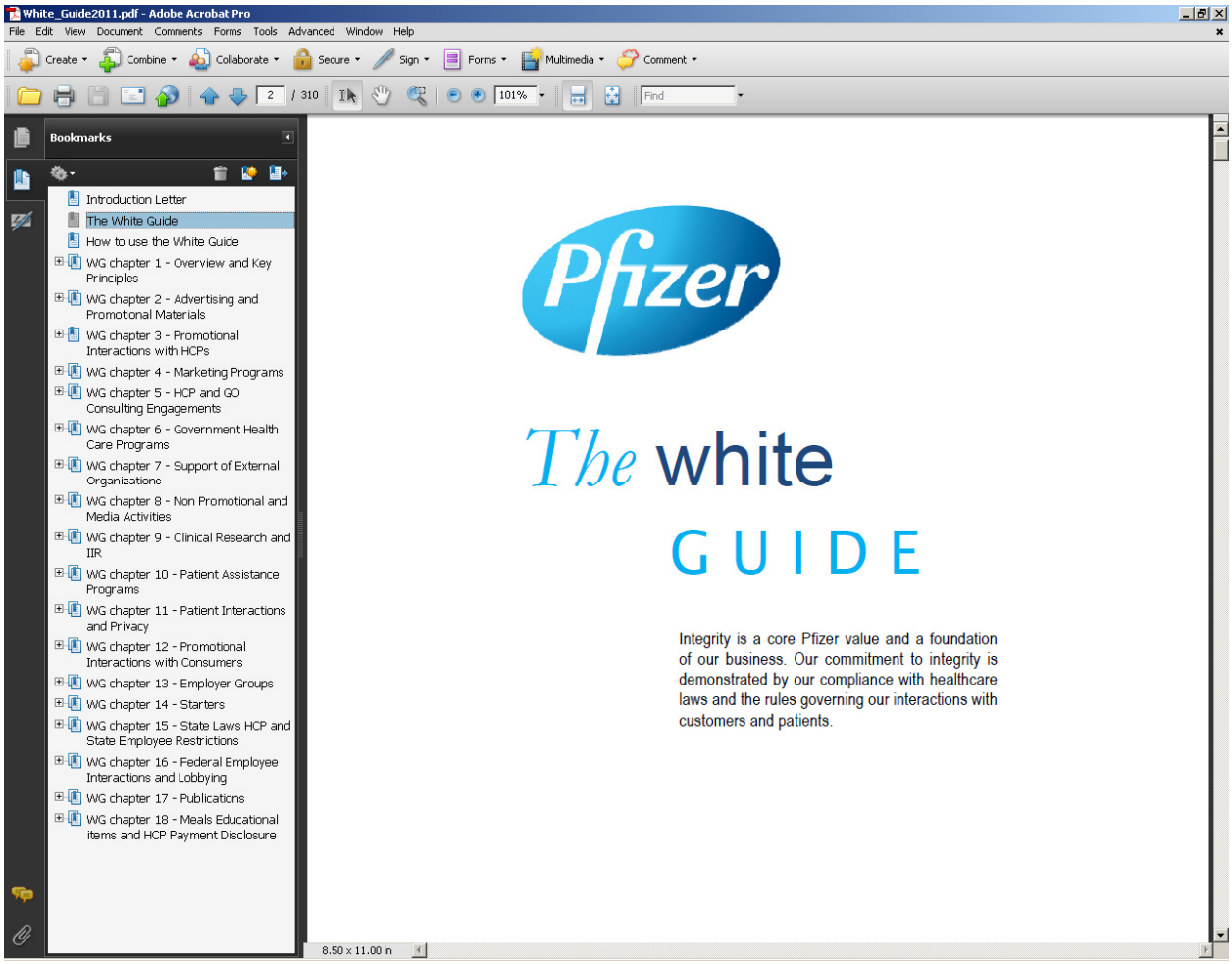
Douglas M. Lankler

Amy W. Schulman

HOW TO USE THE WHITE GUIDE

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

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



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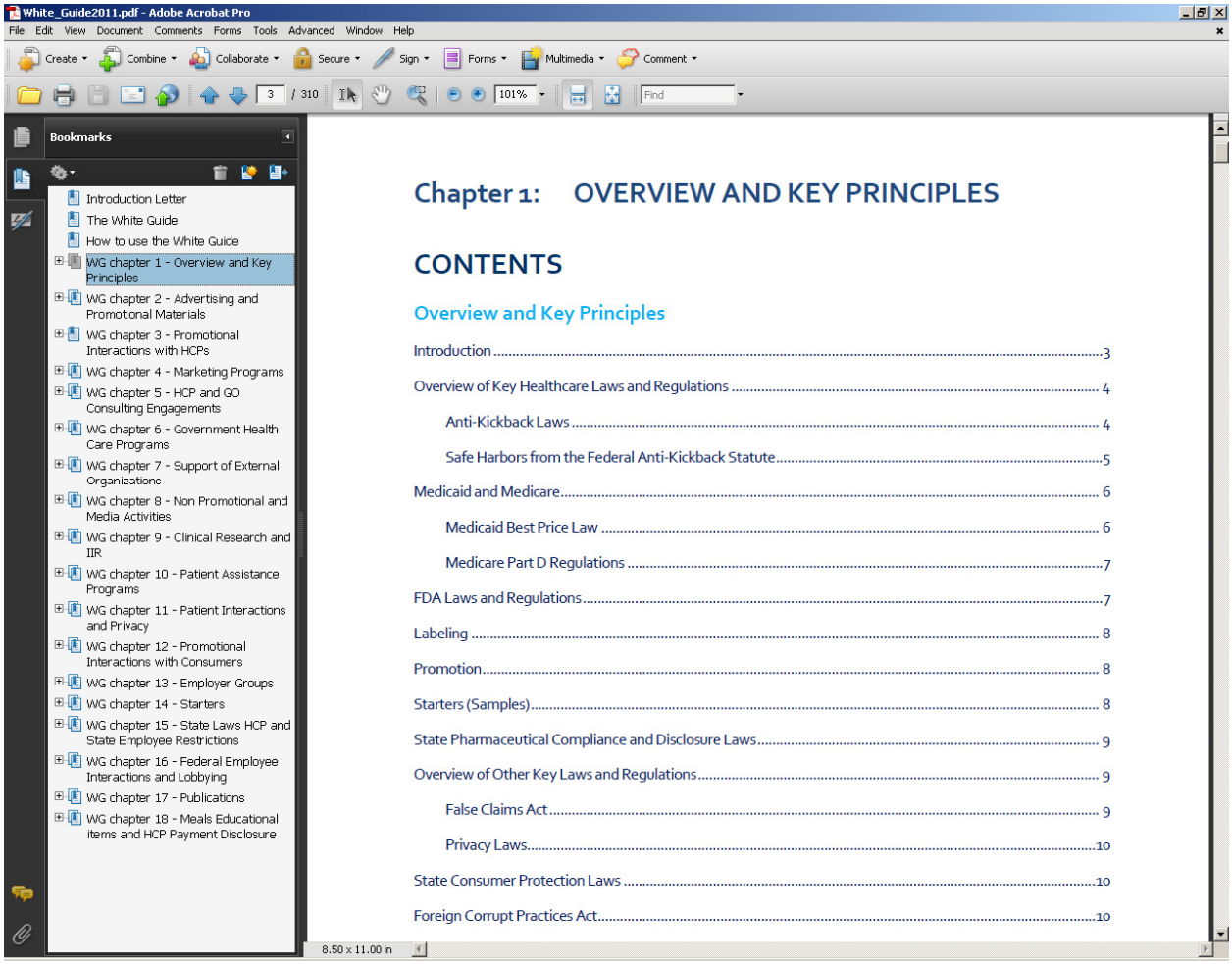

If you have any questions, comments or feedback, please email WhiteGuide@pfizer.com. This will help us continuously improve the **White Guide** to help meet your needs!

Sincerely,

The White Guide Team

The white 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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Overview and Key Principles

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 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 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 pay 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 & 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 Orange Guide Chapter 17: State Gift Restriction and Disclosure Laws, Orange Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure, White Guide Chapter 15: State Laws: HCPs and State Employee Restrictions, and White Guide Chapter 18: 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 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 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-US 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/Compliance/Pages/Home.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 Guidance for the Implementation of the Updated PhRMA DTC Principles. These Principles guide the industry's use of 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 & 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 email 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: ADVERTISING AND PROMOTIONAL MATERIALS

CONTENTS

Advertising and Promotional Materials

Chapter 2: ADVERTISING AND PROMOTIONAL MATERIALS

Introduction

A fundamental basis for our interactions with healthcare professionals (HCPs) and consumers is to promote our products and provide information about the disease states they treat. Pfizer has **five core principles** that must be followed to create FDA-compliant promotional materials and ensure that the information we provide is appropriate. The principles apply to all promotional claims, which include any statement about a Pfizer drug related to effectiveness, safety, dosing, drug class or other topic. They are:

- All claims must be consistent with product labeling;
- All claims must be supported by substantial evidence;
- All claims must be truthful and not misleading;
- All claims must appropriately balance the benefits of the product with its risks; and
- All promotional materials must be approved through Review Committee (RC).

These principles are set forth in detail in REG 08, Pfizer's Policy on Preparing Reviewing and Approving Promotional Activities and/or Materials.

This Chapter summarizes Pfizer policy regarding the development, review and approval of advertising and promotional materials for the human biopharmaceutical business. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination.

Key Points to Ensure Compliance

- Pfizer has five core principles that must be followed to ensure that the information we provide is FDA-compliant and appropriate. The principles apply to all promotional claims, which include any statement about a Pfizer drug related to effectiveness, safety, dosing, drug class or other topic. They are:
  - All claims must be consistent with product labeling;
  - All claims must be truthful and not misleading;
  - All claims must be supported by substantial evidence;
  - All claims must appropriately balance the benefits of the product with its risks; and
  - All promotional materials must be approved through Review Committee.
- Both promotional labeling and advertising for a drug must include a fair balance between efficacy and safety information and must not be false or misleading in any respect.
- Like other forms of promotion, Direct-to-Consumer (DTC) communications must comply with FDA regulations and Pfizer's five core principles as well as PhRMA's Guiding Principles. DTC communications should educate patients and consumers and encourage them to seek guidance from healthcare professionals.
- Like other forms of promotion, FDA governs Pfizer's use of the internet and social media to promote its products. Websites that contain product information must comply with all the laws, regulations, and principles that govern promotional materials made for traditional print media.

Core Compliance Principles for Professional or Consumer Promotional Materials

Pre-Approval Communication

Prior to approval, FDA permits only two types of advertisements for drugs: "**Disease-state**" advertising and "**Coming Soon**" advertising. "Disease-state" advertising may announce that a drug company is conducting research in a particular therapeutic area to develop a new drug, but the name of the investigational drug must not be mentioned. "Coming Soon" advertising announces the name of the

product that will be available soon without any information (written, verbal or graphic) relating to the therapeutic area, safety, efficacy or intended use of the drug. "Coming Soon" advertisements are permissible only if the drug is not expected to have a boxed warning. For a particular product, Pfizer can choose only one of these two types of advertising during the pre-approval time period. Companies are not permitted to use both types simultaneously or to alternate between these approaches during the pre-approval process. Other than these two types of advertising, no promotion may be conducted for a product prior to its approval.

Pre-Approval Communication

Q. When can I meet with customers to begin discussing a new product or new indication?

A. Pfizer is not permitted to promote a new product or indication prior to receiving FDA approval. This means that Pfizer is not permitted to claim that a product is safe or efficacious until after FDA approval. In limited circumstances it may be appropriate to discuss an unapproved product or indication with a customer as part of a non-promotional interaction (e.g., advisory board or scientific exchange). All colleagues must receive appropriate approvals before proactively discussing any unapproved product or indication with a customer. See REG 08 and White Guide Chapter 8: Non-Promotional Communications and Media Activities for more information.

Post-Approval Communications

Core Principle #1: All Claims Must Be Consistent with Product Labeling

Pfizer, like all pharmaceutical companies, is permitted to promote only FDA-approved uses of its products. All promotional statements made about a Pfizer drug must be consistent with the information contained in the product's labeling. Uses that remain under investigation or that are under FDA review, but have not been approved, are considered off-label and claims about such uses cannot be made in promotion.

Core Principle #2: All Claims Must Be Supported by Substantial Evidence

Under FDA regulations, a drug is considered "**misbranded**" if its labeling or advertising contain claims that are not supported by **substantial evidence**. Substantial evidence generally requires two

randomized, double-blind, placebo-controlled clinical trials. This is generally referred to as **two "adequate and well controlled"** clinical trials. In most cases, any statement that would impact an HCP's decision to prescribe a Pfizer product, or not prescribe a competing product, should be considered a claim that needs to be supported by substantial evidence. Moreover, consistent with core principle #1, such a claim must be consistent with the approved labeling. Additionally, RC teams should consider all FDA feedback when determining the appropriateness of a specific claim.

The following chart sets out examples of typical claims and the generally accepted evidence that is required to support the claim being made in approved materials:

Type of Claim	Example	Generally Accepted Supporting Evidence
Efficacy or Safety Claim	"Product X has been shown to reduce blood pressure by 30% in most adult patients"	2 adequate and well controlled clinical trials
Comparative Claim: Comparing any attribute of the Pfizer product with a competing product	"In two studies, Product X reduced high blood pressure better than Competing Product Y"	2 adequate and well controlled clinical trials comparing Product X and Competing Product Y head-to-head using comparable dosage regimens or, in limited circumstances, 1 large, well-controlled head-to-head study
Superiority Claim: Claiming an attribute of the Pfizer product is better or superior to a competing product	"For the highest reduction in blood pressure, use Product X"	2 adequate and well controlled clinical trials comparing Product X to all competing products head-to-head using comparable, approved dosage regimens or a single, large, well-controlled head-to-head study using comparable, approved dosage regimens

Type of Claim	Example	Generally Accepted Supporting Evidence
Healthcare Economic or Pharmacoeconomic Claim: Claiming use of a Pfizer product results in lower healthcare costs	"Over the course of treatment, Product X reduces hospital costs by Y%"	For claims made to formulary committees that are directly related to the product's indication, competent and reliable scientific evidence
Quality of Life Claim: Claiming use of a Pfizer product improves one's overall quality of life or an aspect of one's life	"Patients on Product X showed increased enjoyment from daily activities"	2 adequate and well-controlled clinical trials using an appropriate FDA-agreed upon validated QoL instrument

In addition, as a general rule, all product claims must have **clinical and statistical significance**. Any exceptions to this rule must be carefully reviewed to ensure the claim does not inappropriately imply greater efficacy or fewer risks than otherwise established by scientific or medical evidence. It is also always important to ensure that each claim is only as strong as the evidence that supports it. In other words, each product claim must be narrowly tailored to match the findings of the data.

For a more complete listing of types of claims and the required evidence to support them, please see REG 08.

Superlative Claims

Q. Is it ever appropriate to use superlatives like "best" or "safest"?

A. It is almost never appropriate to use unqualified superlatives such as "best" or "safest" since such claims can rarely if ever be supported by substantial evidence. For example, to establish that a product is the best or safest requires head-to-head trials against all existing therapies. Only if a claim can be substantiated (e.g., "most prescribed") can it form the basis for a product claim.

Core Principle #3: All Claims Must Be Truthful and Not Misleading

Promotional materials **must not be false or misleading**. Accordingly, all Pfizer promotional materials must accurately and truthfully present all material information, which includes the product's important risk and safety information. Materials are false and misleading when they make a claim that is not supported by appropriate data.

Promotional material may be false or misleading if, for example, the material:

- Promotes the drug for an unapproved use or indication;
- Overstates the product's efficacy or claims it is effective in a broader range of conditions or patients than has been demonstrated by substantial evidence;
- Uses favorable data derived from patients treated with dosages different from that recommended in the approved labeling;
- Minimizes the product's safety risks;
- Suggests that a drug is safer or more effective than another drug when the claim has not been demonstrated by substantial evidence;
- Contains or relies on outdated or selective ("cherry-picked") clinical data;
- Inaccurately reflects the methodology used to conduct the clinical study;
- Provides favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions;
- Uses the concept of statistical significance to support a claim that has not been demonstrated to have clinical significance or validity, or fails to reveal the range of variations around the quoted average results;
- Uses statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study, or to suggest scientific validity and rigor for data from studies, the design or protocol of which are not amendable to formal statistical evaluations;
- Presents information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does; or

- Uses statistics on numbers of patients, or counts of favorable results or side effects derived from pooling data from various insignificant or dissimilar studies, in a way that suggests that such statistics are valid even if they are not.

Visual Representations

Q. A brand team wants to include photographs of families (children and parents) in their promotional materials. Are there any concerns with doing this?

A. Visual representations, artwork and graphics must be taken into consideration when determining whether the material is false and misleading. Visuals, like the text in an advertisement, make claims about the product and must be consistent with the product's labeling. For example, if a product is indicated for adults, including pictures of children in the advertising could lead viewers to mistakenly believe that the product is indicated for use in children. Accordingly, all visuals must be reviewed to ensure they are not misleading in light of the product's indication or any claim made about the product.

Core Principle #4: All Claims Must Appropriately Balance the Benefits of the Product with Its Risks

To be truthful and not misleading, all sales and advertising materials must present a "**fair balance**" of the promoted product's benefits and risks. This means that significant risk and safety information must be presented together with efficacy claims.

As a general rule, promotional materials are judged in their entirety to determine whether the advertised products are portrayed with fair balance. However, an individual spread, or set of paired pages, must still be evaluated together to ensure that it is accurate, fair and balanced. To be appropriately balanced, the prominence (based on the typeset, font size, color, use of white space, etc.) of efficacy claims must be "reasonably comparable" to the presentation of information related to warnings, side effects, contraindications and other important safety information.

Fair Balance

Q. Can promotional materials for a product claim that the product is "safe"?

A. No. The word "safe" should not be used without qualification since all products have risks. A product may, however, be described as having a "proven safety profile" where the claim can be substantiated by medical evidence. Appropriate safety information, such as warnings and contraindications, must also always be provided to balance the statement.

Core Principle #5: All Promotional Materials Must Be Approved through Review Committee

All materials intended to promote our product(s) for use in the United States, including disease awareness and pre-launch materials prepared in anticipation of FDA approval and all materials required to be filed under FDA's First Use or pre-clearance policies, must be approved through RC. For more information on the RC Process, see the RC SOP US REG-08-01.

The Review Committee tab on the internal OpSource website includes RC training materials and other helpful documents.

Pfizer product teams have initiated an "**In-Context Training**" platform to provide specific guidance particular to select promotional pieces, such as visual aids and clinical reprints, outlining the boundaries of what representatives "can and cannot say" about a product based on the content of the piece. For more information regarding what types of pieces must include in-context training and how it should be provided, consult the brand's team attorney.

Requirements of Promotional Labeling and Advertising

The Division of Drug Marketing and Communications (DDMAC) of FDA regulates two categories of promotional materials which have slightly different requirements: **promotional labeling** and **advertisements**. DDMAC uses the term "promotional labeling" to apply to a broad array of materials used in marketing a product, including, for example, "brochures, mailing pieces, detailing pieces, file cards, bulletins, price lists, catalogs, letters, films, sound recordings, exhibits, literature and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug."

In contrast to labeling, FDA regulations define "advertising" to include the following: advertisements in published journals, magazines, other periodicals, newspapers, and advertisements broadcast through media such as radio and television.

Both promotional labeling and advertising for a drug must include a **fair balance** between efficacy and risk information and must not be false or misleading in any respect. Except for **Reminder Advertisements and Reminder Labeling** as well as certain types of **Help Seeking Advertisements that do not discuss any particular medicine**, promotional labeling and advertisements must also typically include:

- Proprietary Name & Established (Generic) Name
- Quantitative amounts of active ingredients in combination products;
- Name of the company or its agent (co-promote) responsible for marketing the product;
- Approved indication(s) for use;
- Dosage form and dosage(s);
- Succinct statement of the contraindications, precautions and side effects; and
- Appropriate labeling: 1) Full prescribing information including patient package insert for promotional materials; 2) appropriate brief summary for print advertisements.

Additional requirements apply to advertisements in certain media or directed to certain audiences:

- Professional print advertisements must include the **Brief Summary**.
- Consumer print advertisements must include the **Important Facts Brief Summary**, the PPI or the Medication Guide, as determined by the RC.
- Broadcast advertisements (television and radio) must include the **major statement** and ensure **adequate provision** of the full prescribing information.

In addition, the full prescribing information – both the Package Insert (PI) and the Patient Package Insert (PPI) or Medication Guide, as appropriate – must accompany all promotional labeling. This requirement applies to both professional and consumer labeling.

These concepts are explained in the tables on the following pages.

- **Proprietary (brand) Name & Established (Generic) Name** is required on all promotional labeling and advertising. The established (generic) name must be included at the most prominent proprietary (brand) mention. On any page of an advertisement in which the proprietary name or designation is not featured but is used in the running text, the established name shall be used at least once in the running text. There must be no intervening matter between the brand and generic name. The established name must be used in type at least half as large as the type used for the most prominent presentation of the established name. For example, in a logo, the established name must be included and the type used must be at least half the size of the type used for the brand name.

- **Brief Summary** includes information about side effects, contraindications, warnings and precautions, information about effectiveness, and information in the package insert under headings such as cautions, special considerations and important notes. The Brief Summary typically excludes the pharmacokinetics, pharmacology, and dosage information from the package insert.
- **Important Facts Brief Summary** is a consumer-friendly version of the Brief Summary that is generally derived from the PPI and is used in consumer print DTC advertisements in lieu of the professional Brief Summary.
- **Major Statement** conveys all of a drug's most important risk information in consumer-friendly language during a broadcast advertisement.
- **Adequate Provision** is applicable in the context of broadcast advertisements. The term refers to providing the audience with a reasonably convenient way to obtain the drug's package insert. One acceptable approach to disseminating the product's approved labeling is described below. This approach includes all of the following components:
    - Providing a toll-free telephone number in the advertisement for consumers to call to request the package insert or to have the labeling read to them over the phone;
    - Providing an internet web page (URL) address where the package insert can be viewed;
    - Identifying at least one publication that has a concurrent print advertisement that provides more detailed safety information, along with a toll-free telephone number and address for further consumer access to full package labeling; OR making package inserts available (when the advertising campaign has a relatively limited audience reach) at publicly accessible sites (e.g., pharmacies, doctors' offices, grocery stores, public libraries); and
    - Disclosing that HCPs may provide additional product information.

- **Reminder Advertisements and Reminder Labeling** are short promotional pieces that contain a drug's brand name and established (generic) name and may contain dosage form and strength, as well as pricing information. A reminder cannot mention or imply the drug's indication, effectiveness, safety, use or dosing regimen. Nor can a reminder make any suggestion about the drug's uses. The inclusion of such information would transform a reminder into a full advertisement or promotional labeling. Because reminders call attention to the name of the drug product but do not include indications or dosage recommendations, they are not required to carry the package insert or brief summary or meet the fair balance requirements that apply to full promotional pieces. **Under FDA regulations, reminders cannot be used for products that carry a boxed warning**.
- **Help Seeking Advertisements** are communications disseminated to consumers or HCPs that discuss a particular disease or health condition, but do not mention any Pfizer drug or make any representation or suggestion concerning a particular Pfizer drug.

FDA Submission of Promotional Materials

Q. When do promotional materials need to be sent to DDMAC?

A. All promotional materials for Pfizer drugs must be sent to DDMAC before or at the time that Pfizer first uses the materials. DDMAC does not have to physically review the materials prior to first use. A company may choose to seek "prior review" of materials if it chooses to receive comments prior to their first use. This is typically done prior to the launch of a new product so that the company can receive guidance from DDMAC regarding how much safety information to include and how to maintain fair balance when particular claims are made. Moreover, pursuant to the PhRMA DTC Guiding Principles, Pfizer has committed to seek "prior review" of new television broadcast ads.

Promotional materials for biologics are sent to the Advertising & Labeling Branch of the Center for Biologics Evaluation and Research.

Direct-To-Consumer and Internet Advertising

Direct-To-Consumer Advertising

Pfizer has adopted PhRMA Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines. These principles, which were revised in March 2009, support the use of DTC advertising to communicate information about medical problems and potential treatments so that patients can make informed choices. Like all promotion, DTC communications must comply with FDA regulations and Pfizer's five core principles:

- All claims must be consistent with product labeling;
- All claims must be truthful and not misleading;
- All claims must be supported by substantial evidence;
- All claims must appropriately balance the benefits of the product with its risks; and
- All promotional materials must be approved through RC.

In addition to the five core principles, PhRMA's Guiding DTC Principles serve to ensure that DTC communications educate patients and consumers and encourage them to seek guidance from their healthcare professionals. Pfizer has adopted the Guidance for the Implementation of the Updated PhRMA DTC Principles. All Pfizer DTC materials must be consistent with this guidance. In the event of any inconsistency, the Pfizer guidance takes priority over the PhRMA Principles.

Pfizer has also agreed to abide by additional terms governing its DTC television advertising that require Pfizer to:

- Submit all new DTC television advertising campaigns for any Pfizer product to FDA pre-review;
- Wait a reasonable time (not less than 45 days) until Pfizer receives a response from FDA prior to running the advertising campaign; and
- If Pfizer receives a response within 45 days, modify such advertising consistent with any written comments from FDA, when received.

If FDA does not provide Pfizer with a response within the 45 day waiting period, Pfizer may run the television advertising campaign but it must provide written notice and a copy of the advertising to certain state Attorneys General. Pfizer must also notify DDMAC that it is proceeding to run the television campaign.

In addition, following the initial approval of any product indicated for pain relief, Pfizer shall delay DTC television advertising if FDA recommends a delay in writing to Pfizer. Pfizer must delay the advertising for as long as recommended by FDA, but in no event shall that delay be longer than 18 months from approval. If Pfizer decides to run the television advertising contrary to FDA's recommendation after the expiration of the 18-month waiting period, Pfizer must provide written notice and a copy of the advertising to certain state Attorneys General.

FDA Submission of Promotional Materials

Q. The PhRMA Guiding Principles for DTC Communications do not specify a time that companies need to wait after submitting television advertising to FDA for review. Why are we required to wait 45 days?

A. As part of Pfizer's settlement with several state Attorneys General, Pfizer agreed to undertake additional obligations with respect to its television advertising. One of those obligations was to submit all television advertising to FDA for review and wait at least 45 days for comments. Pfizer is obligated to modify its advertising consistent with any written comments it receives. Pfizer also agreed to delay, if requested by FDA, for up to 18 months any television advertising following the approval of a product indicated for pain relief.

Patient Testimonials

Q. Are there specific guidelines for using patient testimonials?

A. Like all other advertising and promotion, testimonials must follow the core principles outlined above. Any testimonial used by Pfizer must be consistent with the product label and must include fair balance. Testimonials must not include any claims that Pfizer could not make directly. Moreover, in accordance with our agreement with state Attorneys General, Pfizer cannot disseminate in a promotional context any patient testimonial relating to a Pfizer product that does not clearly and conspicuously disclose what the generally expected performance would be in the depicted circumstances or clearly and conspicuously disclose the limited applicability of the experience described by the patient testimonial to what consumers may generally expect to achieve. Please refer to the Guidance for the Implementation of the Updated PhRMA DTC Principles.

Internet Promotion

Like other forms of promotion, FDA governs Pfizer's use of the internet and social media to promote its products. This includes PfizerPro and product websites, as well as banner and other internet advertisements such as sponsored search (or search-engine marketing).

Websites that contain product information must comply with the laws, regulations and principles that govern promotional materials made for traditional print media. This means that any discussions of the product's uses or indications must adhere to FDA-approved labeling. The website must appropriately balance any claims of efficacy with the relevant risk information and the risk information should be presented in a similar fashion to the efficacy information. For example, if the efficacy presentation is active, then the risk information should likewise have an active element. In addition, the website must contain links to the product's package insert. Detailed information on the requirements of internet promotion, including on YouTube and Facebook, can be found on OpSource under the "Review Committee" tab.

FOR MORE INFORMATION

- Refer any questions to your team's Regulatory Affairs or Legal colleague
- REG 08, Pfizer's Policy on Preparing Reviewing and Approving Promotional Activities and/or Materials
- RC SOP US REG-08-01
- PhRMA Guiding Principles on Direct to Consumer Advertising about Prescription Medicines
- Pfizer's Guidance for the Implementation of the Updated PhRMA DTC Principles
- OpSource internal website (for internet/digital media guidance)

Chapter 3: PROMOTIONAL INTERACTIONS WITH HEALTHCARE PROFESSIONALS

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Promotional Interactions with Healthcare Professionals

Chapter 3: PROMOTIONAL INTERACTIONS WITH HEALTHCARE PROFESSIONALS

Introduction

Pfizer Sales Colleagues are primarily responsible for promoting our products to HCPs. However, non-Sales colleagues, including Marketing and Medical Colleagues, may also interact with HCPs in various promotional settings such as congresses, conventions, symposia programs, and "ride-a-longs" with Sales representatives. There may be other interactions with HCPs that will be considered promotional depending on the content and context of the interaction. The "Four Core Compliance Principles" are applicable to any Pfizer colleague engaged in a promotional interaction with an HCP and are reviewed in this Chapter. Additional guidance for RMRS and similar field-based Medical colleagues can be found in the Governance for Field-Based Medical Activities Guide (the Green Guide). Additional guidance for MOS colleagues can be found in the Governance of Medical Outcomes Specialists' Activities Guide (the Purple Guide). For a more detailed discussion on the policies applicable to Sales Colleagues, see Orange Guide Chapter 2 : Detailing to HCPs.

This Chapter summarizes Pfizer policies regarding promotional interactions with healthcare professionals and is relevant to non-Sales colleagues who engage in promotional interactions as part of their roles and responsibilities. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination.

Key Points to Ensure Compliance

- Use only Pfizer Review Committee (RC) approved materials with HCPs.
- All promotional statements must be on-label (consistent with the product's package insert) and based upon approved information. All inquiries about off-label information or unapproved clinical data must be referred to Pfizer's Medical Information Department (800-438-1985).
- Do not discuss new products or indications before they are FDA approved.
- Always give a fair and balanced presentation of the benefits and risks of any Pfizer product.
- Never engage in any actual or perceived quid pro quo.

Four Core Compliance Principles for Successful Product Promotion

Your interactions with physicians and other HCPs must always be based on providing accurate scientific information. Pfizer has Four Core Compliance Principles that protect you and the Company when you are presenting to HCPs:

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

Use Only RC-Approved Materials and Selling Statements

Each Pfizer product has a multi-disciplinary **Pfizer Review Committee (RC)** that reviews and approves all sales and marketing materials for the product. Any written materials that you use in a promotional interaction, whether a marketing visual aid, a clinical reprint, or anything else, must be approved by the relevant product RC. You may not alter RC-approved materials in any way. In addition, "DO NOT DETAIL" pieces or background materials must not be shared with HCPs. For more information on the

review and approval of promotional materials, see White Guide Chapter 2: Advertising and Promotional Materials.

It is critical that you only make promotional 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.

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 individual disciplinary action.

Stay On-Label and Discuss only Approved Products and Indications

All promotional statements about a drug must be consistent with the product's labeling and must be based on information contained in RC-approved materials. **Off-label promotion** is taken extremely seriously by Pfizer and the government. In fact, Pfizer is obligated under our CIA to proactively report any instance of off-label promotion to the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services.

Examples of on-label and impermissible off-label claims are provided in the table on the following page.

Detailing and Sales Materials: On-label vs. Off-label Claims	
On-label Claims	**Off-label Claims**
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
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 inconsistent with the information in the package insert *E.g.*, Toviaz 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

Prior to FDA approval of a product or the approval of a new indication for the product, any claim that the product is efficacious and safe for such use by the manufacturer (or its representatives) is illegal. **Pre-approval promotion** can jeopardize the approval of a new product/indication and may result in severe penalties. Therefore, you may only discuss approved products and indications in accordance with approved promotional materials. No matter how tempting or robust the scientific evidence, you cannot discuss any product or indication with customers until it is approved by FDA.

Additionally, you can only make **comparative claims** (comparing an attribute of a Pfizer product to an attribute of another product) when there are Pfizer RC-approved promotional materials that expressly make such claims and you follow all relevant directions provided in applicable Implementation Guides. 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.

If an HCP asks you an **unsolicited question** about new products or indications or asks for information outside of, or inconsistent with, the product's approved labeling or Pfizer RC-approved materials, the question must be referred to Pfizer's **Medical Information Department (800-438-1985)**. Note that Sales Colleagues enabled to use the iCUE tablet are required to facilitate HCP Medical Inquiry submissions using that tool.

Pfizer colleagues are not permitted to solicit or otherwise prompt HCPs to ask questions about off-label uses of a product in any promotional interaction. Questions submitted to Pfizer's Medical Information Department must be unsolicited.

Provide an Accurate and Balanced Presentation

All promotional materials, selling statements, and presentations on Pfizer products must be truthful and not misleading, supported by substantial scientific evidence, and 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.

FDA requires such "**fair balance**" of a product's benefits and risks and it is necessary to provide this information so that the HCP can make an informed treatment decision. The more robust the efficacy statements, the more risk information needs to be provided in order to balance the information. This means providing the relevant contraindications, warnings, precautions, side effects or other material information, such as relevant clinical trial exclusion criteria, that are necessary for a prescriber to make an informed decision about whether to prescribe the product. Balanced presentations demonstrate Pfizer's commitment to improving patient care and are required under the law.

Never Engage in Actual or Perceived Quid Pro Quo

Quid pro quo is Latin for "this for that." Never offer or appear to offer any remuneration or item of value in exchange for prescribing or formulary acceptance. The decision of an HCP 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 prescriber.

Key Point Regarding Meals, Educational Items and Other Transfers of Value to HCPs

On occasion, in the course of promotional and other interactions such as consultant meetings and conventions, Pfizer colleagues may have a bona fide reason to provide a meal or other item of value to an HCP. **All colleagues (including HQ/Marketing Colleagues) are required to comply with Pfizer policies and laws (including state law restrictions) regarding when, how and who may provide meals, educational items, or other items of value to HCPs**. Please see White Guide Chapter 5: HCP and Government Official Consulting Engagements; White Guide Chapter 18: Meals, Educational Items and HCP Payment Disclosure; and White Guide Chapter 15: State Laws: HCP and Government Employee Restrictions.

Under no circumstances can you ever tie giving something of value – even something of nominal value – to directly or indirectly influence an HCP's prescribing or recommendation of a product. Doing so puts both you and Pfizer at substantial legal risk.

FOR MORE INFORMATION

- Refer any questions to your Regulatory Affairs or Legal team colleague
- Orange Guide Chapter 2: Detailing to HCPs
- Green Guide: Governance for Field-Based Medical Activities (for RMRS Colleagues)
- Purple Guide: Governance of Medical Outcomes Specialists' Activities
- White Guide Chapter 18: Meals, Educational Items and HCP Payment Disclosure
- White Guide Chapter 15: State Laws: HCP and Government Employee Restrictions

Chapter 4: MARKETING PROGRAMS

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Marketing Programs

Chapter 4: MARKETING PROGRAMS

Introduction

The general term "marketing programs" is used is this Chapter to describe activities that promote Pfizer products by providing HCPs or consumers with educational, scientific, and clinical information consistent with FDA regulations. Marketing programs include speaker programs, symposia, congress and convention exhibits and displays, and any other activities designed to promote Pfizer or its products. Thus, Pfizer marketing programs, including those executed by an advertising agency or other vendor working on Pfizer's behalf, must adhere to FDA and other rules governing promotion and must be approved by the brand Review Committee (RC). Although they cannot be used to promote products, this Chapter also includes information about "quality programs." For more information on the development of promotional materials used as a part of a marketing program, see White Guide Chapter 2: Advertising and Promotional Materials.

This Chapter is relevant to all Pfizer Marketing colleagues and other colleagues who are responsible for developing and executing speaker programs and other marketing initiatives. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination.

Key Points to Ensure Compliance

- Pfizer marketing programs, including those executed by an advertising agency or other vendor working on Pfizer's behalf, must adhere to FDA and other rules governing promotion and must be approved by the relevant Review Committee.
- The main objective of all speaker programs should be to provide scientific and educational information consistent with FDA guidelines in order to increase the awareness and appropriate utilization of Pfizer products.
- Pfizer policy requires that Speakers engage attendees for a minimum of 45 minutes, inclusive of Q&A, or a minimum of 30 minutes for programs with attendees in an in-office setting. Marketing must be mindful of these requirements when developing content in order to ensure that an sufficient amount of content is provided to support program duration requirements.

Key Points to Ensure Compliance (cont'd)

- Speakers may only be selected based on their expertise, credentials and ability to communicate with the target audience.
- Prior to providing any speaking services, all speakers must have a signed agreement with Pfizer which documents the fair market value rate to be paid.
- Prior to engaging in any speaker program, all new speakers are required to complete training on: (1) the brand's core product or topic slide kit (as applicable); and (2) Pfizer compliance policies.
- Pfizer's HCP Payment Disclosure Policy applies to all speaker and consulting fees, travel expenses, meals and other items of value provided in connection with speaker programs. The disclosure policy applies to all U.S. HCPs who can prescribe medicines, including physicians, nurse practitioners and physician assistants. Until further notice, for speaker programs conducted using EZSpeak, Pfizer's disclosure policy will allocate the costs of meals among all attendees, regardless of actual consumption.
- At many 3rd party meetings and conventions, Pfizer may pay for space or for an opportunity to promote its products (or in some cases to promote Pfizer) and must not pay more than fair market value.
- Marketing Teams must follow the Legal Guidelines for Pfizer External Web Sites and Other Internet Activity in developing internet-related content.
- Co-pay, rebate, and other similar programs offered by U.S. teams (including brand teams and non-brand teams, such as the U.S. Trade Group) must be developed and implemented in accordance with Pfizer's policy on Free Trial Vouchers, Co-Pay Relief and Similar Consumer Programs, New Limitations Regarding Free Trial Voucher Programs, and related guidance and FAQs.

Speaker Programs

A speaker program is a promotional activity controlled by Pfizer in which a speaker (typically an external HCP) presents educational information on products, disease states or other healthcare topics, consistent with FDA regulations, to a group of invited HCPs or consumers. Even though an external HCP is engaged to speak, Pfizer is responsible for the conduct and content at promotional speaker programs, since the FDA considers HCP speakers to be representatives of Pfizer. This section focuses on speaker programs for HCPs. For more information on speaker programs for consumers, see White Guide Chapter 12: Promotional Interactions with Consumers.

Sales and Marketing can both plan speaker programs, although the programs are almost always executed by Sales. All speaker program content must be reviewed and approved by the relevant RC (e.g., the product RC if the program is product-related). Marketing, with input from Medical, is responsible for developing the content and strategy around both types of programs and is also responsible for the implementation of Marketing programs. Similarly, Sales is responsible for the implementation and execution of Sales programs. Even when Pfizer hires a third-party vendor to assist with the development or facilitation of a program or series of programs, Pfizer remains responsible for the content and message.

Speaker Programs

Q. If a Pfizer Sales Colleague initiates a promotional speaker program, what responsibilities does he or she have?

A. Generally speaking, the Sales Colleague chooses the venue and presentation topic (from the list of approved topics in EZSpeak), and contacts the speaker. The Sales Colleague must review Pfizer's Promotional Speaker Policy and the speaker's slide deck with the speaker prior to the event to ensure that the speaker understands that he/she must present in accordance with the product's approved labeling and is using an approved slide deck that does not contain any unapproved slides. The Sales Colleague must monitor the program and must identify any potential compliance violations committed by the speaker during the EZSpeak close-out process. For more information on Sales Colleague responsibilities in conducting a speaker program, see Chapter 9 of the Orange Guide.

Content Development

Prior to creating a new speaker program initiative, Marketing should have a clear understanding of its business objectives and goals. The objective of all speaker program initiatives may only be to provide scientific and educational information consistent with FDA guidelines in order to increase the awareness and appropriate utilization of Pfizer products. **It is against the law and Pfizer policy to design a speaker program strategy around influencing speakers.** Examples of legitimate business objectives are:

- An initiative to address underutilization of a Pfizer product within its therapeutic class.
- Education for HCPs about a new product, indication, label change, and/or new safety or efficacy data.

If there is no identifiable legitimate business need for the initiative – for example, in cases in which the information is already well known and understood by the target audience – then it may not be appropriate to develop and implement or continue with an initiative. Indeed, if HCPs generally are already familiar with the information proposed to be presented, then the likelihood of generating appropriate audiences for programs decreases and the risk of non-compliance increases. Thus, Marketing, with input from Medical, is responsible for identifying the legitimate business objectives and goals for a proposed speaker program and developing the content in accordance with the identified objectives.

The content for all promotional speaker programs must be developed in accordance with Pfizer policies on advertising and promotion. For more information on content development, see White Guide Chapter 2: Advertising and Promotional Materials. Speakers must use Pfizer approved slide kits when speaking to HCPs on behalf of Pfizer. **Pfizer policy requires that speakers engage attendees for a minimum of 45 minutes, inclusive of Q&A, or a minimum of 30 minutes for programs with attendees in an in-office setting. Marketing must be mindful of these requirements when developing content in order to ensure that a sufficient amount of content is provided to support program duration requirements.**

Pfizer policy prohibits the speaker from creating or inserting his or her own slides (including introductory, speaker bio, case study or disease state slides). The speaker must use only Pfizer RC-approved slides during a speaker program. In limited circumstances, a speaker may present slides that

are not contained in the approved speaker kit so long as RC approval of the slides is received prior to the speaker program. All slides for which a speaker seeks RC approval must be consistent with product labeling, accurate and truthful, supported by substantiated and scientifically-sound data, and appropriately balanced with information on both benefits and risks.

Speaker Recruitment & Contracting

The **Pfizer Speaker Operations Team (SOT)** maintains a list of "active" Pfizer speakers. These are speakers that: (1) have a signed contract with Pfizer; (2) have completed compliance training; (3) have completed training on a core product or topic slide kit (either live or online) as applicable; and (4) are below the Pfizer annual promotional speaker payment cap. An HCP's promotional speaking agreement with Pfizer is valid for one year and is automatically renewed.

The two main requirements in the speaker recruitment process are: (1) a determination of the number of speakers reasonably required to execute the number of expected speaker programs (in order to determine if new speakers need to be recruited for the initiative in addition to speakers already trained and active); and (2) an identification of the qualifications and expertise of the speakers necessary to execute the initiative.

Speakers may only be selected based on their expertise, credentials and ability to communicate with the target audience. Brand Teams, along with input from Medical if requested, must review nominees against these criteria and work with the SOT to submit the nominations through EZSpeak. In addition to MDs, speakers may be nurses, pharmacists, or any other person with the requisite subject matter expertise and credibility to speak on a particular topic. For more information on speaker recruitment, see Speaker Operations Team Standard Operating Procedure, SOT SOP1-08.

Prior to providing any speaking services, all speakers must have a signed agreement in place with Pfizer which documents the **fair market value (FMV)** payment rate. In determining an individual HCP's FMV payment rate, the speaker's specialty, credentials and expertise must be considered. For more guidance and details on how to determine FMV rates for speaker programs, consult the Speaker Operations Team.

Only speakers may be paid in connection with speaker programs; attendees may not be compensated in any manner. All speaker payments must be made by Pfizer and not by a third-party vendor.

Speakers may also be reimbursed for reasonable expenses associated with speaking at the program, such as out-of-pocket lodging, transportation or parking costs. As set forth in the speaking agreement, if a speaker is required to travel farther than 50 miles and/or 2 or more hours one way by car from the speaker's residence, the speaker is paid a higher pre-determined "travel program" fee.

Speaker Training

All Pfizer brands that execute speaker programs create **Core Product and/or Topic Training Slide Kits** that cover the key aspects of the product or topic, including prescribing information. These slide kits are used to train speakers on the product or disease state. Prior to engaging in any speaking engagements, all new speakers are required to complete training on: (1) the brand's Core Product or Topic Training Slide Kit, as applicable; and (2) Pfizer's compliance requirements. Depending on availability and the needs of the brand team, a speaker may complete training either online via the Speaker Resource Center, via webex, offline (i.e., paper-based) or live in-person. In limited instances, offline training may be conducted by the Regional Medical and Research Specialist for speakers who cannot complete training online. For more information on speaker training see Speaker Operations Team Standard Operating Procedure, SOT SOP1-08.

Program Execution

All speaker programs must be executed according to the requirements outlined in Orange Guide Chapter 9: Speaker Programs for HCPs.

Promotional Opportunities at 3rd Party Meetings and Conventions

Pfizer brand teams are often provided the opportunity to promote Pfizer products by paying for promotional opportunities at 3rd party meetings and conventions. Common promotional opportunities include, but are not limited to:

- Symposia programs/Product Theaters
- Exhibit/Booth Display Space
- Advertisement Space In Conference Brochure
- Online Acknowledgement

- Supporter's Board Acknowledgement
- Meeting Registrations
- Delegate bag inserts

Financial support in exchange for these opportunities can occur at a variety of venues and programs, but the key principle is that Pfizer is paying for the space or opportunity to promote its products (or in some cases to promote Pfizer) and must not pay more than fair market value for the opportunity.

There are several factors to consider when making a determination about fair market value with respect to promotional opportunities. Examples include the following:

- The opportunity to promote Pfizer or a Pfizer product to a particular population of HCPs or consumers;
- The opportunity for Pfizer colleagues to interact with conference attendees;
- The length of time given to Pfizer to exhibit and display;
- The physical location of the table or booth in relation to those attending an event; and
- The extent of the internet traffic associated with the conference organizer's website.

In addition, Pfizer must be sure that other companies providing financial support in exchange for promotional opportunities are charged the same amount for the same type of opportunity. Often, the event brochure lists the levels of support opportunities available and describes the space and services that are available at each level. This type of brochure should accompany the request for financial support whenever possible because it helps to validate the fair market value of the opportunity. Follow the procedures outlined in the SOP covering Funding Requests for Not-for-Profit Organizations to facilitate funding for promotional opportunities at 3rd party meetings and conventions. All promotional materials used at a marketing program, such as exhibit panels, professional advertising, or consumer materials, must be approved by the appropriate product RC.

Symposia Programs

Pfizer defines symposia as Pfizer-initiated and/or controlled live events held in conjunction with a congress or convention. (Note that external organizations may use the term "symposia" for other types

of events, however the preceding definition is used for purposes of Pfizer policy.) The content is typically customized for the event by a Pfizer-paid faculty speaker, and is subject to RC approval. Attendees are not paid and are not asked to provide formal feedback.

Symposia may be **open-door**, at which any congress/convention participant may attend, or **closed-door**, invitation-only events, at which attendance is controlled. Open-door symposia take place at third-party events such as congresses or conventions, and are managed by the Healthcare Association Management (HCAM) group. Closed-door symposia may coincide with, but typically do not take place at, third-party events such as congresses or conventions, and are managed by the Compliant Meetings & Controls (CMC) group.

There are three types of symposia:

- **Promotional Symposia** (also commonly known as "product theaters") are programs where product-specific information is provided consistent with the product label;
- **Non-promotional Symposia** are symposia where no promotional content or product-specific information is mentioned; the intent is to promote unbranded disease awareness; and
- **Scientific-exchange Symposia** are symposia where non-promotional scientific or medical information about an unapproved product is presented (e.g., a pipeline product). Marketing colleagues are not permitted to execute these programs and thus they are not discussed in this Chapter.

Initiating Symposia Programs

The HCAM and Marketing teams are responsible for determining the annual Pfizer congresses and convention open-door symposia plan. Any symposium, however, can be proposed, initiated and conducted by any appropriately trained Pfizer colleague (Project Owner) responsible for the project management of symposia. The Project Owner must document the need for a symposium on a Business Rationale Form and follow the rest of the steps outlined in the HCP Engagements Job Aid (also known as the "One Process" Job Aid). For more information on engaging consultants, see White Guide Chapter 5: HCP and Government Official Consulting Engagements.

Except for scientific-exchange symposia, fees paid to speakers at symposia are included in, and subject to, Pfizer's annual speaking fee cap (also applicable to traditional speaker programs). Colleagues wishing to engage a speaker for a symposium event should first check the speaker's cap status on the Speaker Cap Report available on OpSource.

Content Development

The content of a symposium, which includes any promotional materials that will be presented or handed out at the event, must be RC-approved. For more information on content development, see White Guide Chapter 2: Advertising and Promotional Materials. The Project Owner and the vendor are responsible for informing the symposium's faculty of Pfizer's content requirements and processes. For symposia managed with the support of HCAM, the HCAM Manager is responsible for ensuring that all speakers have received compliance training.

Invitations, Logistics, and Meals

The Project Owner and the HCAM Manager or CMC Manager (as applicable) are responsible for logistics related to the program. Travel and lodging expenses may be provided for Pfizer speakers but not for attendees. Modest meals and refreshments may be provided where appropriate. These and any other items of value conferred are subject to disclosure in accordance with Pfizer's HCP Payment Disclosure Policy, and may also be subject to disclosure or further restrictions in accordance with applicable state law. **HCP attendees who are licensed to practice in Massachusetts, Minnesota, or Vermont must not be provided a meal by Pfizer at these programs (although coffee or other light snacks at the convention/congress booth are permissible for MA and VT HCPs)**. For additional information, see White Guide Chapter 15 on State Laws: HCP and Government Employee Restrictions, and White Guide Chapter 18: Meals, Educational Items and HCP Payment Disclosure.

Exhibit/Display & Other Advertising Opportunities

Funding for an exhibit or display or other promotional opportunity at a congress or convention must not be greater than the fair market value of the opportunity. Likewise, brand teams cannot bypass the Medical Education Group (MEG) grant process by funding a promotional opportunity when the funding request is really for non-promotional aspects of a program. Promotional and non-promotional funding

must always be separated, easily identifiable, and able to be tracked for auditing purposes. In addition, if the opportunity involves the distribution or provision of any items to conference attendees, brand teams may only fund opportunities involving PhRMA Code compliant educational items.

The process for funding sponsorship opportunities is outlined in the SOP covering Funding Requests for Not-for-Profit Organizations, which is described in more detail in White Guide Chapter 7: Support of External Organizations. Applicable FCPA due diligence must also be conducted for sponsorships involving non-U.S. third-party congresses, conventions and open-door symposia. Also, all requests from managed care customers, regardless of amount, must be reviewed and approved by the Managed Care Review Committee (MCRC) before the date of the event and before Pfizer may pay for the exhibit/display or undertake any activities associated with the exhibit or display opportunity.

External Websites and Other Internet-Related Activities

Like other forms of promotion, the FDA governs Pfizer's use of the internet to promote its products. This includes the PfizerPro, and product websites, as well as banner and other internet advertisements. For more information, see White Guide Chapter 2: Advertising and Promotional Materials.

Co-pay Relief Programs

Pfizer is committed to encouraging patients to talk to their doctors about available treatment options and to helping patients better afford Pfizer medications. An example of this commitment is the distribution of co-pay coupons, co-pay cards, savings cards and other similar offerings to consumers relating to Pfizer medications, all of which are subject to RC approval.

Even though such programs are designed to benefit patients, if not carefully developed and implemented, they are subject to a number of significant legal risks (such as federal and state kickback laws, consumer protection laws, the "best price" Medicaid drug rebate statute, state contract law and state pharmacy laws). Co-pay, rebate, and other similar programs offered by U.S. teams (including brand teams and non-brand teams, such as the U.S. Trade Group) must therefore be structured and implemented in accordance with the Policy on Free Trial Vouchers, Co-Pay Relief and Similar Consumer Programs, along with the New Limitations Regarding Free Trial Voucher Programs dated July 25, 2011 and related FAQs.

Quality Programs

Quality programs refer to RC-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, HMOs, VA and DoD and pharmacy benefit managers. Quality programs focus on addressing the overall quality of healthcare rather than promoting Pfizer products.

Under Pfizer standards, quality programs can be used to support the following objectives:

- Enhance Pfizer's corporate image, visibility, name recognition and general goodwill;
- Enhance the quality of patient care or clinical research;
- Offer free information of broad and general application to the target audience; and/or
- Provide scientifically sound information

Quality programs improve patient care by providing customers with information about, for example, quality accreditation standards, HCPs' patient interaction skills, and management of medical conditions. A listing of current Pfizer quality programs can be found at mmweb.pfizer.com.

Quality programs must never be offered in exchange for increased prescribing or improved formulary status. Although customers may alter prescribing habits based on information provided at a quality program, Pfizer employees must never require these changes as a condition of the program.

Pfizer's quality programs **may never be offered 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; and/or
- Offer an implied discount on the price of Pfizer products

Every quality program must receive approval from the relevant RC before it is made available to the public.

Commercial E-mail

The **CAN-SPAM Act of 2003** establishes an opt-out framework for commercial e-mail and pre-empts state commercial e-mail statutes. The Act is enforced by the FTC, state Attorneys General, and Internet Service Providers (ISPs).

All commercial e-mail must include the following:

- A clear and conspicuous notice that the consumer can opt out of receiving future e-mails.
- An Internet-based mechanism for opting out, such as a reply e-mail address or a link to a website. This mechanism must remain in effect for at least 30 days after the commercial e-mail is sent and an opt-out request must be honored within 10 business days of receipt. Brand teams are not allowed to share or sell an e-mail address of someone who has opted out.
- A clear and conspicuous identification that the e-mail is an advertisement. The Act does not require specific language, so Marketers may choose how to describe the e-mail as an advertisement. Commercial e-mail sent to a consumer who has specifically opted-in to receive commercial e-mail from the Marketer does not need to be identified as an advertisement.
- The sender's physical postal address. The Direct Marketing Association requires that the address be a street address.

There is an exception from these requirements for transactional e-mails (such as an e-mail that confirms a purchase or provides an account balance). A transactional e-mail may contain advertising as long as the *primary purpose* of the e-mail is transactional, not promotional.

The Act prohibits false or misleading information in the "From" and "Subject" lines of commercial e-mail and transactional e-mail. The "Subject" line should accurately reflect the content of the e-mail and the "From" line should accurately indicate who is responsible for sending the e-mail. This requirement raises some difficult questions with respect to referral e-mails, such as in a promotion where people may authorize the sending of an e-mail to their friends and colleagues but the actual party sending the e-mail is the sponsor of the promotion. Consult with your team attorney if your program involves referral e-mails.

The Act also prohibits falsifying header information, harvesting e-mail addresses, opening multiple e-mail accounts using false information and using open relays to transmit commercial e-mail. It pre-empts state commercial e-mail laws, but does not pre-empt state fraud and trespass laws that can be applied to commercial e-mail. This means advertisers no longer need to include "ADV:" in the subject line, as some states had once required, but states can still sue advertisers for fraudulent commercial e-mail.

Colleagues who are responsible for sending commercial e-mail should coordinate with the multichannel enablement team and their team attorney to ensure compliance with all applicable laws and regulations.

FOR MORE INFORMATION

- For speaker programs consult the Speaker Operations Team and for conventions/ congresses/symposia the HCAM team
- Pfizer's Promotional Speaker Policy
- Orange Guide Chapter 9: Speaker Programs for HCPs
- Policy on Free Trial Vouchers, Co-Pay Relief and Similar Consumer Programs and related FAQs
- New Limitations Regarding Free Trial Voucher Programs
- The HCP Engagements Job Aid (also known as the "One Process" Job Aid)
- White Guide Chapter 2: Advertising and Promotional Materials
- White Guide Chapter 7: Support of External Organizations
- White Guide Chapter 15: State Laws: HCP and State Employee Restrictions
- White Guide Chapter 18: Meals, Educational Items and HCP Payment Disclosure
- Refer any other questions to your Regulatory Affairs or Legal team colleague

Chapter 5: HCP AND GOVERNMENT OFFICIAL CONSULTING ENGAGEMENTS

CONTENTS

HCP and Government Official Consulting Engagements

Chapter 5: HCP AND GOVERNMENT OFFICIAL CONSULTING ENGAGEMENTS

Introduction

Pfizer enters into consulting arrangements with HCPs for a range of services including business counseling, Pfizer colleague training, external-HCP education and training, clinical program design, post-launch regulatory compliance assistance, and marketing program development, among others. For U.S.-based Business Unit and Medical Colleagues, the HCP Engagements SOP is applicable to most HCP or non-U.S. Government Official (GO) consulting engagements, except for Marketing and Sales speaker programs, clinical services, and others activities subject to other policies (see Scope section of the SOP for more information).

(Note, in particular, that HCP engagements in support of Pfizer's Research and Development activities are subject to the policies and procedures set forth in Worldwide Research & Development (WRD) SOP 201: WRD Anti-Corruption, GPIHP and External Funding Controls. While all of Pfizer's HCP engagement policies reflect the same core principles, the requirements and controls detailed in this Chapter relate only to the HCP Engagements SOP applicable to the aforementioned U.S.-based BU and Medical Colleagues. For further information regarding R&D HCP engagements, please consult WRD SOP 201 or WRD Legal.)

Pfizer may provide compensation to consultants in amounts constituting fair market value, as well as reimbursement for reasonable expenses associated with consulting activities. However, since these interactions potentially implicate federal and state anti-kickback laws and other U.S. and international anti-corruption laws, it is important for Pfizer colleagues to establish that a proposed consulting relationship is bona fide prior to engaging the consultant, among other requirements. A consulting arrangement is permissible as long as:

- There is a legitimate business need for the services;
- The consultant(s) is selected based on his or her expertise and knowledge and not to gain access or to influence prescribing habits;

- The number of consultants selected is supported objectively and appropriate to the business need;
- A written contract is executed that specifies the nature of the services and the basis of payment for those services;
- The term of the agreement is for at least one year (unless a shorter term is otherwise approved by Legal);
- The services are provided as outlined in the written contract; and
- Any compensation does not exceed fair market value.

Consultants must provide an actual service. For example, passive activities such as time spent merely receiving a marketing presentation are not considered bona fide services and are not compensable. You must select consultants who possess knowledge or expertise relevant to the project or engagement, and never solely because they are "high-prescribers." Consulting fee amounts must not be determined in a manner that takes account of the past, present, or future volume or value of business generated by consultants for Pfizer. The written consulting agreement should clarify that there is no connection between the compensation provided and the prescribing of Pfizer products.

In sum, your objective in entering into a consulting arrangement with an HCP 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.

The Pfizer Global Policy on Interactions with Healthcare Professionals (GPIHP) governs relationships with HCPs, including interactions with physicians, nurses, pharmacists and others who administer, prescribe, purchase or recommend prescription medicines. Further, in addition to the HCP Engagements SOP, the fair market value process is outlined in the HCP Services: U.S. and International Fair Market Value SOP and the process for conducting international meetings is outlined in the Global Procedure for International Meetings. You should consult these SOPs and the HCP Engagements Job Aid to identify the specific steps that are necessary to plan and execute a compliant consulting

engagement. The OpSource website contains job aids, guidelines, and other useful documents necessary to ensure a compliant consulting arrangement.

The Pfizer Compliant Meetings and Controls (CMC) Group is responsible for organizing meetings involving consulting arrangements with HCPs.

This Chapter summarizes certain key Pfizer policies regarding HCP and non-U.S. GO consulting engagements and is relevant to all U.S.-based Pfizer colleagues supporting the human biopharmaceutical business involved in initiating and executing these engagements. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination.

Key Points to Ensure Compliance

- Consult the HCP Engagements Job Aid for the step-by-step process to engage an HCP or non-U.S. GO for consulting services;
- All HCP/GO consulting engagements must:
  - Further a legitimate business need;
  - Have a written contract which specifies the nature and scope of the services and the amount and basis of payment for those services;
  - Involve consultant(s) who are selected based on their expertise and knowledge and not to gain access or to influence prescribing habits;
  - Have a term of agreement for at least one year (unless a shorter term is approved by Legal);
- Not involve a payment in excess of fair market value and must be based on a centrally managed pre-set rate structure.
- Additionally, Pfizer colleagues must ensure that:
  - The consultant's qualifications meet the identified business need; the consultant does not appear on the FDA Debarment List, the OIG Watchlist, the General Services Administration Excluded Parties Listing System (or any international equivalent to the foregoing); and the consultant has been further screened for restrictions applicable to Data Monitoring Committee members supporting Pfizer trials, State discipline and FDA Warning Letters, and Pfizer's policy on consulting engagements with Minnesota-licensed prescribers;
  - The output/work product of a consulting engagement is collected and retained, and it is documented how such output/work product was used to aid the business;
  - The output/work product is assessed for consistency with what was identified in the BRF, a consultant assessment form and the consulting agreement; and
- The Compliant Meetings and Controls Group oversees the organization of meetings involving HCP consultants.

Impact of the 2009 CIA

On August 29, 2009, Pfizer Inc. entered into a Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS). The CIA requires the implementation and maintenance of certain compliance controls and the provision of regular reports to the government. Requirements related to Pfizer's consultant engagements reflect many of the processes and controls that Pfizer had already implemented prior to the CIA, with a few additional and enhanced measures. The following summarizes the CIA's requirements related to HCP consulting engagements:

- **Annual Consultant Needs Assessment:** On an annual basis, BU Compliance Counsel, Product Attorneys and their respective brand teams will develop Annual Consultant Needs Assessments (ACNAs) relating to each product in accordance with each brand's operating plan. Each ACNA must identify the estimated number, expenses associated with, and the business rationale for various consultant engagements and activities to occur during the year in the U.S. in connection with government-reimbursed products.
- **Business Rationale Requirements:** Prior to each engagement, Pfizer must ensure that a Business Rationale Form (BRF) is completed that describes the justification for retention of a consultant. The BRF must identify the business need for the information to be provided by the consultant and, in conjunction with a consultant assessment form, must provide specific details about the consultant arrangement, including qualifications of the consultant(s) to be engaged, the scope of services to be provided, and the expected work product/information to be generated from the engagement. The relevant team attorney will review the BRF for consistency with Pfizer policy and with the relevant ACNA and will document explanations for any variance.
- **Contract Requirements:** Pfizer must execute written agreements with consultants it engages. The agreement must describe the scope of work to be performed as well as the consultant fees to be paid. Fees must be based on a centrally managed pre-set rate structure that is determined based on fair market value. The agreement must also describe the compliance obligations of the consultant. Finally, consultants must be required to disclose their consultant relationship with Pfizer and to adhere to the disclosure

requirements of any healthcare institution, medical committee, or other medical or scientific organization with which the consultants are affiliated.

- **Work Product:** Work product created as a result of a consultant engagement must be collected, retained, and assessed to verify consistency with what the consultant was engaged to provide/do, as set forth in the Business Rationale Form. This assessment and verification must be documented in an **Engagement End Document** (EED).

Requirements for a Bona Fide Consulting Arrangement

The step-by-step process for engaging HCP consultants is outlined in the HCP Engagements SOP. The following section provides a high level overview of the key compliance requirements pertaining to this process.

Legitimate Need for Services

Because of the inherent kickback risk that HCP consulting arrangements pose, Pfizer colleagues must complete a Business Rationale Form to demonstrate that there is **a legitimate need** for a proposed consultant services. This involves:

- Identifying the business need to retain the consultant(s), e.g., the gap in knowledge, understanding or expertise that the consultant(s) will be able to provide;
- Identifying the necessary and substantive services that the consultant(s) will provide; and
- Describing how the output or deliverable of the proposed arrangement will benefit Pfizer.

The relevant team attorney must review all BRFs associated with any consulting engagements prior to the retention of consultants. The relevant team attorney will review the BRFs for consistency with Pfizer policy and with the relevant Annual Consultant Needs Assessment, and will document any variance from the ACNA.

Legitimate Need

Q. A Marketing team would like to organize a series of four advisory board meetings with various specialties to gain a better understanding how its pain medication is used in different clinical settings. The team would like to engage 20 HCPs for each meeting and intends to use the information to improve and tailor the promotional message for each specialty. Is this an acceptable initiative?

A. Maybe. It is permissible to engage consultants to gain a better understanding of how a promotional strategy or campaign is being received by HCPs. However, it is important that such initiatives involve the minimum number of HCPs necessary to meet the business objectives of the team. Here, it is not clear whether it is necessary to hold four separate advisory board meetings involving a total number of 80 HCPs. Depending on the nature of the information sought, it may indeed be necessary and appropriate, but it is also possible that a smaller number of consultants would be able to provide the same information. The Marketing team must provide specific details in the Business Rationale Form explaining why this approach is necessary.

Consultant Qualifications

It is essential that Pfizer colleagues explain how the **qualifications of the proposed consultant(s) meet the identified business need**. It is not acceptable to select an HCP because he or she is a "high prescriber." Though a consultant's experience with a particular class of drugs may be taken into consideration in determining whether he or she is qualified to provide the requested services, prescribing habits may not be the basis for selection. The following must be addressed in the Business Rationale Form:

- The number of consultants necessary for the project or meeting must be supported objectively;
- The qualifications of the consultants meet the identified business need.

Project Managers should work with a Pfizer Medical Colleague to define the required qualifications and specifications for consultant selection.

Consultant Screening Requirements

Pfizer colleagues must screen prospective consultants against the following lists before proceeding with any engagement, and are required to certify that these screening have been conducted.

- **FDA Debarment List:** The FDA maintains a list of individual and entities that have been debarred for engaging in criminal conduct with respect to the development or approval of new drugs. Individuals appearing on the FDA Debarment List may not be engaged as consultants or speakers for Pfizer.
- **OIG Watchlist:** The HHS OIG may exclude individuals and entities from Federally-funded healthcare programs that have committed criminal and other offenses. The OIG maintains a List of Excluded Individuals and Entities (LEIE) and may impose penalties on companies that engage them. Individuals appearing on the OIG list may not be engaged as consultants or speakers for Pfizer.
- **EPLS Watchlist:** The General Services Administration (GSA) maintains an Excluded Parties Listing System (EPLS) which identifies individuals and entities excluded by the U.S. Government from receiving Federal contracts and subcontracts and from certain types of Federal assistance. Individuals appearing on the EPLS list may not be engaged as consultants or speakers for Pfizer.
- **State Discipline and FDA Warning Letter Screening:** Pfizer actively screens its HCP speakers and consultants for disciplinary actions by state medical boards, FDA warning letters, and other misconduct. Individuals appearing on the list may not be engaged as consultants or speakers for Pfizer. (In rare cases, exceptions may be granted by the BU Chief Counsel or BU Compliance Counsel.)
- **DMC Member List:** Per Clinical Trial DST SOP CT 22: Use of Data Monitoring Committees and Conduct of Interim Analysis, a current member of an active Data Monitoring Committee (DMC) for a Pfizer trial may not be engaged in certain financial relationships with Pfizer. Individuals appearing on this list that are members of an active DMC for a Pfizer trial may not be engaged as consultants, advisors or speakers for Pfizer. (In rare cases, and in accordance with SOP CT22, exceptions may be granted by R&D Legal and the Chief Medical Officer. For additional information regarding permissible activities of DMC members,

please consult CT22 and White Guide Chapter 9: Clinical Research and Investigator-Initiated Research.)

- **Minnesota-Licensed Prescribers:** Per Pfizer policy, Minnesota-licensed prescribers may only be engaged as consultants in connection with (1) R&D, clinical, or development-related projects, (2) Outcomes Research or medical publication-related projects, and (3) speaking and speaker training. (In rare cases, exceptions may be granted by the relevant BU Chief Counsel or BU Compliance Counsel.) For more information on Minnesota law, see White Guide Chapter 15: State Laws: HCP and State Employee Restrictions.

Fair Market Value Compensation

Pfizer may only provide compensation that **does not exceed fair market value** for the services and in a manner that does not account for the volume or value of business generated by the consultant for Pfizer. Utilize the U.S. FMV or International FMV Rate Calculators to determine appropriate fees, which then must be reflected in the written agreement. Pfizer must pay all U.S.-based consultants directly for their consulting services (this does not apply to blinded market research).

Zero Fee Engagements

Q. I would like to discuss a new marketing initiative with an HCP and she does not wish to be paid anything for the meeting, including no travel expenses. Do I still need to treat this as a consultant engagement, subject to the various required controls (e.g., BRF, contract, etc.)?

A. Maybe. If an HCP interaction will be merely exploratory to a business relationship and no compensation of any kind will be provided, it probably does not constitute a consultant engagement triggering the controls described in this Chapter. However, where the activities are such that compensation would normally be provided *but for* an HCP's request not to be compensated, and/or if Pfizer will cover or reimburse an HCP's travel expenses (e.g., hotel; airfare; taxi), the interaction should be processed as a formal consultant engagement. For example, if an HCP will be a member of a committee, advisory board, or other Pfizer-assembled consultant group; will represent, speak for or act on behalf of Pfizer to an external audience; will produce tangible work product (e.g., a report; slides) for Pfizer; or will participate in the development or exchange of sensitive Pfizer commercial or scientific information, the interaction should be treated as a consultant engagement even if no compensation will be provided. For further guidance, consult your team attorney.

Consulting Engagements with Non-HCPs

Q. Does the HCP Engagements SOP and the requirements in this Chapter apply to interactions and payments to patients or other U.S. based non-healthcare professionals?

A. These requirements do not apply to interactions involving only U.S.-based non-HCPs. However, it is important for colleagues to understand that the definition of "HCP" in the HCP Engagements SOP is written broadly, and includes categories of individuals that may influence prescribing behaviors without necessarily being prescribers themselves. For a list of specialties and categories considered to be HCPs for purposes of these requirements, consult Appendix B to the HCP Services: U.S. and International Fair Market Value SOP. Further, these requirements apply to interactions with any non-U.S. Government Officials.

Output / Deliverable

The Business Rationale Form must indicate how you intend to collect and use the output of the consulting arrangement. Pfizer colleagues must also maintain documentation that the services were actually provided as required by the consulting agreement. The Project Manager is responsible for ensuring the retention of the work product generated from the engagements and for completing an **Engagement End Document** which:

- Describes the information or work product (advice, slides, meeting minutes, agendas) collected from or generated by the consultants;
- Provides recommendations/incorporation of the information learned or advice obtained from the consultant;
- Specifies where the work product from the engagement will be retained; and
- Assesses whether the work product is consistent with what was identified in the BRF/consultant assessment form and required under the consulting agreement. If there are inconsistencies, they must be noted and explained in the Engagement End Document.

Written Agreement

Pfizer colleagues must execute a **written consulting agreement** prior to the services being provided. The written agreement must:

- Include a detailed description of the services that the consultant will provide including the project deliverables or other appropriate milestones;
- Specify the fee and that payment is contingent on full participation in a meeting and/or completion of any written work product or other deliverables;
- State why the consultant was selected (i.e., why his/her expertise is needed);
- Indicate that the consulting fee was not determined in a manner which accounts for the past, present, or future volume or value of business generated by the consultant for Pfizer;
- Specify that only reasonable, documented expenses may be reimbursed;
- Describe the compliance obligations of the consultant;
- Contain consultant's consent to Pfizer disclosure of payments and other items of value provided in connection with the engagement, in accordance with Pfizer's HCP Payment Disclosure Policy and applicable law;
- Require consultants to disclose their relationship with Pfizer and to adhere to the disclosure requirements of any healthcare institution, medical committee, or other medical or scientific organization with which the consultants are affiliated;
- Contain consultant's representation that he/she has not been, and is not, subject to government discipline or criminal sanction unknown to Pfizer; and
- Include specific FCPA contract language if an International HCP or GO is involved.

HCP Consultant Engagements with Employer Institutions

Q. An HCP that I wish to engage as a consultant has advised me that her employer-Institution requires that her consulting fees be paid to the Institution, not her. Is this OK?

A. Yes. In these cases, the Consulting Agreement should generally be between Pfizer and the Institution (or other employer entity) directly, with the HCP identified in the contract as the Institution employee performing the services. Although Pfizer contracts with and provides payment to the Institution and not the HCPs who provide the service, all of the consulting arrangement compliance principles outlined in this Chapter apply. Further, for purposes of Pfizer's HCP Payment Disclosure policy, the Institution will be identified as the payee and the individual will be identified as the associated HCP in Pfizer's report. Contact HCPQuestions@pfizer.com if you have questions about a particular arrangement.

Meeting Venue

The venue for any consultant meeting, including a speaker training, must be conducive to the business purpose of the meeting, commercially reasonable, and not susceptible to characterization by third parties as "resort-like" or "lavish." Pfizer colleagues must utilize the Pfizer Compliant Meetings and Controls Group to organize meetings involving HCP consultants.

Reimbursement of Expenses

Consultants may be reimbursed for reasonable business travel (e.g., coach airfare for flights lasting less than 5 hours) and lodging expenses incurred in connection with the consulting services. Consultants may not be reimbursed for extended or non-business-related stays at a hotel prior to or after the meeting, or for travel or additional lodging costs for spouses or other guests.

Types of Consulting Arrangements

All Pfizer consulting arrangements must adhere to the guidelines outlined above. Certain Pfizer consulting arrangements, however, entail specific compliance risks which are addressed below.

Advisory Board Meeting

Advisory board meetings pose a particular risk because they can involve large numbers of HCPs and potentially entail discussion of off-label information about Pfizer products. (If off-label information is presented at an advisory board meeting, it must bear a direct relationship to the purpose of the meeting. For additional information, see White Guide Chapter 8: Non-Promotional Communications and Media Activities.) The primary purpose of an advisory board meeting **must be to gain expert feedback or advice** on commercial or clinical/medical topics, and not to provide a forum for product promotion. Pfizer colleagues should ensure that advisory board participants clearly understand that they are being retained to provide a service and not merely to passively receive promotional presentations. An advisory board meeting cannot be designed to:

- Influence the invited consultants or to change their prescribing preferences;
- Provide physicians with an opportunity to meet and mingle with their peers; or
- Have physicians merely listen to new information about Pfizer products.

Input from Sales Colleagues

Q. A Brand team is planning an advisory board meeting to solicit feedback to learn about a disease state related to a pending new indication for the product. Can the Brand team seek assistance from Sales to identify possible advisory board consultants?

A. Yes. Sales can be a valuable resource in assisting Brand teams with the identification of HCP experts. Sales may suggest possible consultants based on specific criteria provided by the Brand team that would meet the needs for the advisory board. Sales colleagues, however, may not be involved with any communications with HCPs regarding the proposed advisory board, e.g., offer an invitation to participate.

If the meeting involves an international HCP(s), Pfizer colleagues must also complete the FCPA GO Approval Form and obtain iMAS approval.

Live Speaker Training Meeting

Prior to conducting any speaking engagements, all Pfizer promotional speakers are required to complete training on (1) the brand's core product training slide kit; and (2) Pfizer's compliance

requirements. Depending on the circumstances of the speaker program initiative, a speaker may complete training either online via the Speaker Resource Exchange or webex, offline (i.e., paper-based) or live in-person. Speaker training activities are treated as consulting arrangements.

If your speaker program initiative requires speakers to be trained, you should consult with your Brand RC to determine whether a live training program is appropriate. In many cases, a training method other than a live meeting may be sufficient. If a healthcare professional is compensated for participating in speaker training, the speaker must be contractually required to provide speaking services for a minimum of 2 programs on the product(s) trained within 12 months of participation in the training. For more information on speaker recruitment, contracting, and training, consult White Guide Chapter 4: Marketing Programs, and Orange Guide Chapter 9: Speaker Programs for HCPs.

Investigator Meetings

For information regarding HCP consultant meetings and engagements related to clinical research and development projects, including the conduct of clinical trials, see White Guide Chapter 9: Clinical Research and Investigator Initiated Research (IIR).

Focus Groups and Market Research

The Market Research and Global Market Analytics team (Market Analytics) conducts market research for a number of purposes, including helping to gain a better understanding of customer needs, to assess how Pfizer and competitor products are perceived and used in clinical practice, and to develop and test promotional messages. Pfizer colleagues should generally execute any market research activities through the Market Analytics team. All market research activities must be conducted in accordance with the CASRO Code of Standards and Ethics for Survey Research.

Market research initiatives involve randomly selected HCPs (or those selected on the basis of objective criteria) to obtain representative information via a "focus group" meeting or a telephone or online survey. In order to prevent Pfizer from learning the identity of individual market research respondents and to protect respondent-identifiable information, the final set of respondents are generally a randomly selected or screened subset of a larger sampling universe, and outside vendors are typically utilized to conduct the research. No detailing or other dissemination of promotional information is

permitted, except for the legitimate purpose of testing a particular promotional message or strategy. Compensation up to fair market value may be provided.

Mentorships and Preceptorships

Mentorship programs are individual, observational teaching sessions with an HCP that take place at the HCP's office or a hospital. Field representatives may participate in a mentorship program through the appropriate Field-based process, provided that the HCP is not compensated.

A preceptorship is a training program provided by university and teaching hospitals for Pfizer colleagues covering a therapeutic area or the clinical use of a Pfizer product(s) in professional practice. Although Pfizer provides payment to the institution and not the HCPs who provide the service, all of the consulting arrangement compliance principles outlined above apply to preceptorship programs.

Like all consulting engagements, HCP mentors and preceptorship institutions must be selected based on their expertise and qualifications. These programs may not be used as selling opportunities, or offered to influence the prescribing practices of a particular physician. For information on the privacy considerations of these activities, see Chapter 11: Privacy: Protecting Personal Information.

Retaining Government Employees as Speakers or Consultants

Non-U.S. Government Officials

The Foreign Corrupt Practices Act (FCPA) is a U.S. law that prohibits corrupt or improper payments to non-U.S. government officials (GOs). 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 an improper advantage. The statute broadly covers "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" is very broad and includes any officer or employee of a foreign government (any department, agency or instrumentality) or public international organization. Due to public funding of many health systems outside the U.S., many non-U.S. HCPs could fall within this definition. HCPs at government-owned hospitals, for example, may qualify as government officials under the FCPA. If you intend to engage a non-U.S. HCP as a consultant or enter into any other interaction in which a payment or other benefit (monetary or non-monetary) may be

given to the individual, you must follow the Pfizer FCPA procedures outlined in the HCP Engagements SOP.

Non-U.S. Government Official

Q. May I engage an HCP to attend an advisory board if he or she is from a country where HCPs are considered government officials?

A. Maybe. Pfizer's FCPA procedures do not prohibit engaging GOs, but do require additional approvals if the GO is in a position where he/she could potentially influence Pfizer's business (called a "potentially-influencing government official" or "PIGO") to ensure there is no appearance of impropriety about the engagement. The FCPA GO Approval Form in the InterAct system must be completed and this form (together with the FCPA Job Aids) will provide guidance on how to determine if the GO is a PIGO and, if so, will route the form for the required additional approvals. In addition, any engagement must comply with local law. Consult the Country Profile for the HCP's country of residence, notify the consultant's employer if required, obtain iMAS approval, and use the International Consultant Agreement.

U.S. State and Federal Government Officials

Many state and federal government agencies require their employees to obtain prior approval before engaging in consulting activities with outside organizations. Pfizer's standard consulting template includes a clause requiring proposed HCPs consultants who are government employees to warrant that, if necessary, they have obtained any prior approvals required by their relevant government agency and/or ethics officer to provide consulting services and accept fee and expense reimbursements.

Part-time State or Federal Employees

Q. May I engage an HCP that works part-time at a federal government institution to be a consultant?

A. Yes, but HCPs who work part-time for a federal government agency are required to follow the policies of that agency. Every consultant agreement with a government employee, whether employed full- or part-time, will generally include the government employee's representation that he/she has been approved to act by the relevant agency and/or the agency's ethics officer, and specifically state whether the employee may accept a fee as well as expense reimbursement.

Retaining Government Employees in Connection with Their Official Duties

Federal laws, regulations and agency policies generally prohibit federal executive branch employees from receiving anything of value in return for performing outside activities related to the employee's official position. Therefore, there are only limited circumstances in which Pfizer can engage federal employees in connection with their official duties. Also, a government employee may never consult with Pfizer on any matter pending before the employee's government agency, unless the agency wishes the individual to do so as part of his/her official duties. In general, however, a federal employee cleared to work with Pfizer on an official basis may receive expense reimbursement but not a consulting fee.

Retaining Government Employees Outside of Their Official Duties

At times, Pfizer may retain a federal employee to perform services in his/her *individual* capacity outside of his/her official duties. Services that may not relate to an employee's official duties should conform to the following parameters:

- Employee is advising on matters about which he/she is a subject matter expert and is not being engaged because of his/her official position, but rather based on that expertise;
- Employee is not advising in relation to a matter pending before his/her government agency;
- Employee is taking personal time to participate rather than participating during employer/government time (in which case he/she must be acting in an official capacity); and

- Employee is not conveying information that draws on ideas or official data that is not public information.

The rules on the acceptance of a fee in such circumstances are interpreted differently by different agencies. The individual agency that employs the individual must therefore determine whether or not the federal employee can accept a fee from Pfizer. If Pfizer engages a federal employee outside of his/her official duties, the federal employee may not use his or her official title or position to identify himself or herself in connection with the services, including teaching, speaking or writing on behalf of Pfizer or in conjunction with Pfizer colleagues. An employee's title or position may, however, be included as part of his or her general biographical details when teaching, speaking or writing. The employee's title or position may also be used in connection with the publication of an article in a scientific or professional journal; however, a disclaimer must be printed acknowledging that the views expressed in the article do not necessarily represent those of the employee's agency or the United States.

Promotional Speakers

Q. Can a VA employee be a speaker for Pfizer?

A. Yes, with appropriate approvals from the VA entity that employs the speaker, and as long as Pfizer is in compliance with the entity's internal requirements pertaining to their employees. Every consultant agreement with a government employee must include the government employee's representation that he/she has been approved to act by the relevant agency and/or the agency's ethics officer, and specifically state whether the employee may accept a fee as well as expense reimbursement.

NIH Employees

Pfizer may not directly retain an NIH employee for any consulting services without NIH's prior written approval, and may not compensate any NIH employee for teaching, speaking, writing or editing.

National Institutes of Health

Q. Can NIH employees work for Pfizer as consultants, if they have their employer's permission? May we offer them a payment for speaking at a Pfizer event?

A. NIH, as well as most other government agencies, has special conflict of interest rules. Part-time and full-time NIH employees are prohibited from working for or consulting for industry, with or without compensation, unless they have been granted prior written approval by NIH. Therefore, Pfizer may not hire NIH employees as consultants in their personal capacity without NIH's prior written approval.

FOR MORE INFORMATION

- Pfizer Global Policy on Interactions with Healthcare Professionals
- HCP Engagements SOP
- HCP Engagements Job Aid
- HCP Services: U.S. and International Fair Market Value SOP
- Global Procedure for International Meetings
- OpSource
- Corporate Procedure #301: Travel, Entertainment and Other Business-Related Expenses
- White Guide Chapter 4: Marketing Programs
- Orange Guide Chapter 9: Speaker Programs for HCPs
- DST SOP CT 22: Use of Data Monitoring Committees and Conduct of Interim Analysis
- Worldwide Research & Development SOP 201
- Refer any other questions to HCPQuestions@pfizer.com or your team attorney

Chapter 6: GOVERNMENT HEALTHCARE PROGRAMS

CONTENTS

Government Healthcare Programs

Chapter 6: GOVERNMENT HEALTHCARE PROGRAMS

Introduction

Pharmaceutical manufacturers have become increasingly involved with government customers and stakeholders. For example, many federal and state healthcare programs, including **Medicare** and **Medicaid**, purchase or reimburse for the purchase of Pfizer medicines. Prior to the passage of the **Medicare Prescription Drug, Improvement, and Modernization Act (MMA)**, the Medicare program only covered the cost of certain prescription medicines dispensed either in a doctor's office or in a hospital setting. Now, the program provides comprehensive prescription drug coverage for eligible individuals. The government has also historically covered the cost of prescription drugs for low income and disabled patients under Medicaid.

Pharmaceutical manufacturers provide preferred prescription drug pricing to federal customers generally via the **Federal Supply Schedule** and to specific federal purchasers, including the Department of **Veterans Affairs** and the **Department of Defense**, as required by statute. Companies also provide discounts to certain state-supported programs, including **State Pharmaceutical Assistance Programs** and **AIDS Drug Assistance Programs**.

Paying or providing benefits to healthcare providers or beneficiaries to prescribe or utilize products ultimately reimbursed by federal healthcare programs potentially implicates the federal Anti-Kickback Statute and state all-payor laws. Similarly, failure to provide the government with preferential pricing in certain situations may expose a manufacturer to liability under federal and state laws. It is critical that Pfizer remain vigilant of – and responsive to – all relevant federal and state laws that may be implicated while doing business with the government.

This Chapter summarizes key Pfizer policies regarding government healthcare programs. 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

- Pfizer must not link or reference the terms of a commercial rebate agreement with a Medicare Part D agreement, or leverage a commercial arrangement to secure a Medicare Part D agreement.
- Pfizer colleagues must not provide P&T Committee members with "special treatment." In addition, Pfizer colleagues must take special care not to link any financial transaction (other than disclosed rebate or discount arrangements) to formulary decisions or formulary placement of a Pfizer product.
- Pfizer may not provide any substantial assistance in the structuring of a Part D sponsor's "Medication Therapy Management Program" (MTMP). In addition, Pfizer may not provide any substantial resources to, or work with, a Plan D sponsor for the purpose of helping such a customer fulfill its MTMP obligations.
- Generally, if Pfizer provides anything of monetary value to its customers as part of price negotiations, it must be reflected in Pfizer's reported discounts to Medicaid. Under no circumstances may Pfizer conceal information to avoid paying higher Medicaid rebates.

Medicare

Medicare is a federally-funded and administered healthcare program. In general, individuals are eligible for Medicare if they are 65 years or older, under 65 with certain disabilities, or any age with permanent kidney failure. Notably, Medicare does not cover all healthcare services, nor does it pay for the entire cost of the services that it does cover. Additionally, Medicare does not pay program beneficiaries directly under any of these parts; rather Medicare reimburses healthcare providers and professionals for the services and products provided to beneficiaries.

The original Medicare program had two parts: Part A (Hospital Insurance) and Part B (Supplemental Medical Insurance). Medicare Part A helps defray the costs of inpatient care received in a hospital, skilled nursing facility, or hospice. Medicare Part B helps pay for medically-necessary healthcare professional services and other outpatient care not covered under Part A. Part B also covers some preventive services such as screening exams and lab tests to detect, prevent, or manage a medical

condition. Under the original Medicare program, the government reimburses the provider (e.g., a doctor or an institution) for certain drugs used in certain settings as part of payment for the patient's overall care. Medicare beneficiaries may also enroll in the Medicare Advantage (MA) Program, otherwise known as Medicare Part C. MA Plans are managed care Medicare plans that generally provide a wider range of services than those covered under the original Medicare program.

In addition, with the changes introduced by the MMA, individuals covered under Medicare are also eligible for outpatient prescription drug coverage under **Medicare Part D**. Operationally, beneficiaries may obtain prescription drug coverage through Part D stand-alone Prescription Drug Plans (also called PDPs) or through Medicare Advantage-Prescription Drug Plans (also called MA-PD plans) under Part C. Part D enrollees incur cost-sharing obligations (including deductibles and co-payments), although many low income individuals are eligible for subsidies.

Medicare Part D

The **Medicare Prescription Drug Benefit** functions as an insurance program, with private companies providing prescription drug coverage and administering the Part D benefit. The Center of Medicare and Medicaid Services (CMS) oversees the Part D program and contracts with private health insurance companies and Pharmacy Benefit Managers to act as PDP or MA-PDs, respectively, and administer the Part D prescription drug benefit. Because the federal government funds the Part D benefit, CMS regulates these plans closely. In particular, CMS seeks to ensure that the Part D program is not overcharged for prescription drugs and that all prescribing decisions are based on appropriate considerations. Thus, Part D plans must report their costs to the government, and in doing so, must disclose any "direct or indirect remuneration" (including rebates) that they receive from pharmaceutical manufacturers. Accordingly, Pfizer must carefully track all payments to Part D plans in the event that CMS requests verification of cost data provided by a Medicare Part D plan.

A **Managed Care Customer** is a non-governmental entity whose principal business is to manage or provide health benefits, including prescription drug coverage. Such customers include traditional indemnity insurance plans, Health Maintenance Organizations (HMOs), Preferred Provider Organizations (PPOs), and Pharmacy Benefit Managers (PBMs). Because Medicare Part D contracts with private insurance companies to implement the drug benefit program, many of Pfizer's Managed Care Customers administer prescription benefit coverage for both Medicare Part D beneficiaries as well

as non-Medicare (commercial) beneficiaries. In so doing, these Managed Care Customers frequently negotiate discounts with pharmaceutical manufacturers on behalf of both governmental and commercial plans.

The government has expressed concern that Managed Care Customers may use access to Medicare Part D enrollees as leverage in negotiations with pharmaceutical companies in order to obtain preferential terms under their commercial agreements. This practice is known as "swapping." Here are some examples of possible swapping scenarios:

- A pharmaceutical manufacturer and a Managed Care Customer have a commercial agreement that provides the Managed Care Customer with an average 10% rebate on all products. The parties enter into negotiations on new commercial and Part D agreements. In exchange for the Managed Care Customer 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 is the swap and may be considered an improper reward to the Managed Care Customer for providing the pharmaceutical company with access to the Managed Care Customer's Part D plan. In the government's eyes, this could be a problem, because Medicare beneficiaries would have been cheated out of an additional 2.5% rebate.
- A pharmaceutical manufacturer and a Managed Care Customer 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 Managed Care Customer 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 Managed Care Customer with greater rebates on its commercial plans. Additionally, even if the rebate rates were equivalent under both contracts, the fact that there were commingling and comparison of terms might prompt the government to scrutinize any concessions made to identify whether the commercial deal was made at the expense of Medicare Part D.

In short, "swapping" exists where a Managed Care Customer and a pharmaceutical company agree to "swap" concessions under the Part D agreement to the detriment of Part D beneficiaries. This may lead

to higher costs under Part D, in exchange for more favorable terms for the Managed Care Customer's commercial agreement. Indeed, Managed Care Customers may be willing to accept higher Part D costs in exchange for lower commercial plan costs because the government subsidizes the majority of the Part D plan costs. Thus, it is important that Pfizer colleagues negotiating with Managed Care Customers separate discussions and negotiations of commercial agreements from discussions and negotiations of Part D agreements. Pfizer colleagues must take particular care to ensure that they do not link or reference the terms of the commercial rebate agreement with the Part D agreement, or leverage the commercial arrangement to secure a Part D agreement. Payments to Managed Care Customers who act as Part D sponsors may also implicate the Anti-Kickback Statute and Pfizer should, thus, ensure that all arrangements are properly structured.

Contract Negotiations

Q. May discussions regarding a commercial contract and a Part D contract occur in the same meeting with a Managed Care Customer?

A. Discussions of a commercial contract and a Part D contract may occur in the same meeting with a Managed Care Customer, so long as the two are not discussed contemporaneously (i.e., the discussion regarding commercial agreements must be clearly separate and apart from the discussion of Part D arrangements). For example, a Pfizer colleague may discuss the commercial contract in the first half of the meeting and then indicate to the customer that the later part of the meeting is devoted solely to Part D contract discussions.

Pharmacy and Therapeutic (P&T) Committee Members

Many healthcare organizations and PBMs, including Managed Care Customers administering Part D drug plans, maintain lists of preferred drugs (commonly referred to as formularies) that healthcare professionals within that organization can prescribe, or which are eligible for reimbursement by the organization. Decisions about which pharmaceutical products are included on a formulary are determined by that organization's **Pharmacy and Therapeutics (P&T) Committee**. P&T Committees typically make formulary decisions based upon assessments of safety, efficacy, tolerability, and increasingly, cost-effectiveness. Those organizations with P&T Committees frequently make decisions regarding the drugs that are covered under Medicare Part D, Medicaid, 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 PhRMA Code on Interactions with Healthcare Professionals, any HCPs engaged 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 their relationship with Pfizer. This requirement should generally extend for at least two years beyond the termination of any speaker or consulting arrangement.

When interacting with P&T Committee members it is important that Pfizer colleagues not give P&T Committee members "special treatment." In addition, Pfizer colleagues must take special care not to link any financial transaction (other than disclosed rebate or discount arrangements) to Part D formulary decisions or Part D formulary placement of a Pfizer product. For additional information on interactions with P&T Committee Members, see Chapter 7 of the Orange Guide addressing guidelines applicable to Sales Colleagues' promotional P&T committee interactions and the Green Guide: Governance for Field-Based Medical Activities, covering guidelines applicable to Regional Medical and Research Specialists.

Medication Therapy Management Programs

The MMA mandated the institution of **Medication Therapy Management Programs** (MTMPs), which must be offered to targeted Medicare beneficiaries and are intended to provide a wide range of services designed to improve patient outcomes, reduce the risk of adverse events, and control the cost of drug therapy. Targeted beneficiaries generally include Part D enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to incur annual costs for Part D drugs that exceed a pre-established threshold.

Currently, Part D sponsors have the flexibility to develop and implement an MTMP that best serves the needs of their specific patient populations. Pfizer customers often seek help in developing an MTMP. Since MTMPs are mandated by law, any substantial assistance provided by Pfizer in this area could be construed as remuneration or a subsidy of that customer's business expenses, which would constitute a violation of the Anti-Kickback Statute. Therefore, Pfizer may not provide any substantial assistance in the structuring of a Part D sponsor's MTMP. In addition, Pfizer may not to provide any substantial

resources to, or work with, a Part D sponsor for the purpose of helping such a customer fulfill its MTMP obligations. For additional information on permissible and impermissible activities with respect to MTMPs, consult the CGC Legal team.

Managed Care Customer Resources

Q. May Pfizer provide approved patient care materials in order to help satisfy a Pfizer customer's MTMP obligations?

A. No, Pfizer may not provide Pfizer materials (including Pfizer quality programs and quality care pyramids) with the intent that a customer use them to satisfy its MTMP requirements. Pfizer may not assist in the structuring of MTMPs or encourage the use of Pfizer materials in MTMPs. For additional information regarding MTMPs, consult the CGC Legal team.

Patient Assistance Programs

A **Patient Assistant Program** (PAP) is a program that helps (typically low income or indigent) patients obtain medications at lower or, in some circumstances, zero cost. Pfizer Inc and the Pfizer Patient Assistance Foundation™ jointly formed Pfizer Helpful Answers®, the family of Pfizer's PAPs, to create options for people who may not be able to afford needed prescription medicine. These programs generally provide savings on Pfizer medicines, or provide free Pfizer medicines for people with limited incomes who qualify. The Pfizer Helpful Answers® website, www.pfizerhelpfulanswers.com, provides complete information on all of Pfizer's PAPs. Pfizer may also provide general reimbursement information about its products through Pfizer reimbursement assistance programs.

Over time, and increasingly since the creation of Medicare Part D, the government has become concerned that pharmaceutical manufacturer assistance could run afoul of the Anti-Kickback Statute or other laws. For example, the Office of Inspector General, the enforcement arm of the Department of Human Services (HHS), identified that the Anti-Kickback Statute might be implicated if manufacturers, via PAPs, subsidize cost-sharing obligations for covered Part D drugs. Specifically, the OIG stated that this type of program presents the typical fraud and abuse risks 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 beneficiaries' incentives to use less expensive and equally effective drugs.

At bottom, however, the government has continued to permit PAPs where Medicare Part D beneficiaries are concerned, in certain properly structured scenarios. For example, PAPs that operate "outside of Medicare Part D" minimize risk. In such circumstances, a Part D enrollee chooses to obtain medication without using the Part D insurance and therefore, does not file any claims for payment with the Part D Plan. Pfizer PAPs operate outside of Medicare Part D. For additional information on Pfizer PAPs and Medicare Part D risks, consult the Chapter on Patient Assistance Programs.

Medicaid

Medicaid is a governmental healthcare program jointly funded by federal and state governments. Medicaid offers healthcare benefits, including prescription drug coverage, for the nation's indigent and disabled persons. Although the federal government establishes general guidelines for the program, including minimum coverage requirements and certain quality standards, Medicaid is administered at the state level, with each state setting its own guidelines regarding eligibility and services. Like Medicare, the Medicaid program does not pay program beneficiaries directly, but rather reimburses healthcare professionals and pharmacies for medical services and prescription medicines provided.

Medicaid Drug Rebate Program

In order for its outpatient drugs to be covered by the Medicaid program, a manufacturer must enter into a national rebate agreement with the Secretary of HHS. This agreement generally requires manufacturers to offer Medicaid agencies the lowest or "**Best Price**" available for covered prescription drugs. Pfizer is responsible for calculating and reporting to the federal government on a monthly and quarterly basis various metrics for each of Pfizer's products and, ultimately, for paying corresponding rebates based on Medicaid recipients' purchases of the company's covered drugs. In return for these rebates, state Medicaid agencies must pay for all of the drug company's covered drugs (with certain limited exceptions). If the price of the manufacturer's drug rises faster than the inflation rate, states may require an additional rebate. Pfizer and/or its predecessor entities have signed a Rebate Agreement with HHS for all Pfizer labeler codes and remains vigilant of its obligations under the Medicaid Drug Rebate Program.

For single-source (non-generic) drugs, the basic rebate amount per unit is either:

- 23.1% of the "**Average Manufacturer Price**" or **AMP** for such unit; or
- If greater, the difference between the AMP and the manufacturer's Best Price for such unit.

The Patient Protection and Affordable Care Act ("PPACA") additionally revised the statutory minimum rebates for pediatric, clotting, and generic drug products.

AMP and Best Price are key terms under the Medicaid Rebate Program and are both statutorily defined. Pursuant to PPACA, AMP was redefined to mean the average price paid by wholesalers in the United States to the manufacturer for a drug that is distributed to the retail pharmacy class of trade. A manufacturer's Best Price is the single lowest unit price at which the manufacturer sells the covered outpatient drug to any eligible customer in the United States. Best Price generally includes all sales and associated rebates, discounts and other price concessions provided by the manufacturer to any entity, unless statutorily excluded.

Generally, if Pfizer provides anything of monetary value to its customers as part of price negotiations, it must be reflected in Pfizer's reported price points. When submitting government price reports to the government, 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.

The following transactions are excluded from the Best Price calculation:

- Sales at "nominal prices" (defined as prices less than 10% of AMP) if made to "covered entities" under Section 340B of the Public Health Service Act (see discussion below), intermediate care facilities for the mentally handicapped, and certain state-owned or operated nursing facilities;
- Prices paid by Medicare Part D Plans;
- Prices charged to the Indian Health Service, the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and entities entitled to discounts which

include federally-qualified and migrant health centers and certain high-indigent care hospitals;

- Prices charged under the Federal Supply Schedule of the United States General Services Administration and qualifying single award contract price of any federal agency;
- Prices negotiated from drug manufacturers for covered discount card drugs under a qualifying discount card program; and
- Any prices used under a qualified state pharmaceutical assistance program.

CMS uses AMP and Best Price data to calculate the Rebate Per Unit (RPU) (also called Unit Rebate Amount (URA) values). The RPU is the amount that is owed by the pharmaceutical manufacturer for each unit of its product reimbursed by state Medicaid agencies to dispensing pharmacies. For more information on Pfizer's Medicaid Best Price determinations and AMP and rebate calculations, consult the CGC Legal team.

Notably, under the Medicaid Drug Rebate Program, pharmaceutical manufacturers must provide quarterly AMP, Best Price, customary prompt pay discounts, and nominal price reports to CMS. Manufacturers also must provide monthly AMP data to CMS. Pfizer is committed to reporting its AMP and Best Price values within the mandated 30-day period. Some States also require Pfizer to report certain pricing information.

Medicaid Risk Areas

Inaccurate Price Reporting and Concealing Best Price

The government has become increasingly focused on manufacturers' pricing and price reporting to ensure that its programs are receiving the greatest benefit for taxpayer-funded healthcare dollars. Therefore, the government expects companies to provide complete and accurate data when reporting AMP and Best Price. Under no circumstances may Pfizer conceal information to avoid paying higher Medicaid rebates. Indeed, reporting false or inaccurate information to the government could lead to significant liability under the False Claims Act. In addition, inaccurate or incomplete reporting could be used to prove criminal liability under the federal False Claims Act and/or a violation of the Medicaid

Drug Rebate Agreement, respectively. Significantly, liability under any of these statutes could subject Pfizer to exclusion from federal healthcare programs.

P&T Committee Interactions

From time to time, Pfizer colleagues may interact with P&T Committee members of a state Medicaid agency. Like P&T Committee members for private health insurance plans administering commercial and Part D plans, Medicaid P&T Committee members determine which drugs are reimbursable under the state Medicaid program. As discussed above, it is Pfizer policy not to engage in any activity that could be construed as improperly influencing the formulary decisions of a P&T Committee member in favor of Pfizer products. For additional information on interactions with P&T Committee Members, see Chapter 7 of the Orange Guide addressing guidelines applicable to Sales colleagues' promotional P&T committee interactions and the Green Guide covering guidelines applicable to Regional Medical and Research Specialists.

Section 340B Pricing Program

Section 340B of the Public Health Service Act, established under sections 601 and 602 of the Veterans Healthcare Act of 1992, requires pharmaceutical manufacturers participating in the Medicaid program to enter into a second agreement called a "pharmaceutical pricing agreement" with HHS and provide discounts to certain entities as a condition of reimbursement. Specifically, the Section 340B Pricing Program requires that manufacturers make covered outpatient drugs available to certain purchasers (referred to as Covered Entities) at discounted prices that are approximately equal to the price for such drugs under state Medicaid programs.

Covered Entities include federally qualified health centers, community health centers (including migrant, homeless, family planning, and AIDS health centers), other clinics receiving Public Health Service Act funding, and qualifying acute care hospitals that provide a disproportionate share of indigent care. Further, pursuant to the Deficit Reduction Act and PPACA, certain additional hospital and health centers may be eligible to enroll in the 340B Pricing Program.

Section 340B pricing discounts are calculated using the Medicaid rebate formula and notably are excluded from Best Price calculations. These discounts are deducted from the manufacturer's selling

price, rather than paid as a rebate. To determine these discounts, each quarter Pfizer calculates the **Section 340B Ceiling Price** (the statutorily defined maximum price that can be charged to Covered Entities) for every covered drug marketed by Pfizer using the same pricing data submitted to CMS for the Medicaid Rebate Program. For additional information on Section 340B and Pfizer's pricing policy, consult the CGC Legal team.

Federal Supply Schedule

The Federal Supply Schedule (FSS) program provides federal agencies with a simplified process of acquiring almost everything the federal government uses, including pharmaceutical products, at a discounted price. The FSS is intended to obtain the lowest prices negotiated for prescription drugs between pharmaceutical manufacturers and their "most-favored" commercial customers under comparable terms and conditions.

The Department of Veterans Affairs negotiates FSS contracts with drug manufacturers to establish **FSS Prices**. Under the Veterans Health Care Act of 1992, drug manufacturers must list their drugs on the FSS to receive payment for the purchase of those drugs by federal agencies. In general, those prices must be no greater than certain statutorily set ceiling prices or, in certain instances, the prices manufacturers charge for selected commercial customers. Furthermore, FSS Prices may not increase faster than inflation during a multi-year contract period.

FSS Prices are available to all federal purchasers of prescription drugs, including the "**Big Four**" – the Department of Veterans Affairs (VA), the Public Health Service (PHS, including the Indian Health Service), the Department of Defense (DoD), and the Coast Guard— which represents the four largest purchasers of pharmaceutical drugs within the federal government.

Federal Ceiling Price

The Big Four federal agencies have the right to purchase their pharmaceutical drugs from the FSS like every other federal agency. Under the Veterans Healthcare Act of 1992, however, manufacturers must also make covered outpatient drugs available to the Big Four at a statutorily discounted price, known as the **Federal Ceiling Price**.

The Federal Ceiling Price reflects a minimum discount of 76% of the "**Non-Federal Average Manufacturer Price**" or "**non-FAMP**." Non-FAMP is conceptually similar to the Medicaid AMP, but is calculated based on prices paid by a different class of customers. (AMP is based on prices paid by U.S. wholesalers for drugs to be distributed to the retail pharmacy class of trade, but non-FAMP is the average of actual prices paid by U.S. wholesalers to the manufacturer for drugs to be distributed to non-federal purchasers generally.)

Manufacturers must report their non-FAMP on a quarterly basis, although non-FAMP data is not made publicly available. As with Best Price, in calculating the non-FAMP, a manufacturer must take into consideration any eligible cash discount or similar price reduction during the reporting period. "Nominal" prices and prices paid by the federal government are categorically excluded from non-FAMP calculations. The government also requires an additional discount if the Federal Ceiling Price increases faster than inflation.

Department of Veterans Affairs and the Department of Defense

In addition to purchasing prescription drugs from FSS or from the manufacturer at the Federal Ceiling Price, the VA and the DoD may also negotiate independent contracts with pharmaceutical manufacturers, including "Blanket Purchase Agreements". Through Blanket Purchase Agreements, the VA and DoD negotiate with drug manufacturers for additional discounts. Typically, these involve market share agreements whereby the VA or DoD guarantee a volume purchase in exchange for discounts below the FSS or Federal Ceiling Prices. Blanket Purchase Agreements are negotiated on behalf of the VA by the VA National Acquisition Center in Chicago and on behalf of the DoD by the Defense Supply Center in Philadelphia.

The VA and DoD may also negotiate lower prices through competitively bid national contracts. Generally the VA or the DoD will seek competitive bids from manufacturers for products that are in the therapeutically equivalent class and will enter into an agreement with those manufacturers whose products provide the best value based on efficacy, safety, and price. In exchange for deeper discounts, the manufacturers' products are placed on the VA's national formulary or listed on the DoD's Military Treatment Facility or Mail Order Pharmacy formularies of its managed healthcare program known as TRICARE.

State Pharmaceutical Assistance Programs

State pharmaceutical assistance programs (SPAPs) generally provide pharmaceutical benefits or assistance to a defined population that usually consists of disabled, indigent, or low-income elderly persons. These subsidy programs utilize a combination of state and local funds to pay for a portion of the SPAPs' costs. SPAPs usually obtain discounts or rebates on drugs either through negotiations with drug companies or because such discounts or rebates are mandated under state law.

Pfizer generally only pays rebates to SPAPs if they have been formally qualified by CMS as a SPAP. Pricing discounts offered to an unofficial SPAP may impact Pfizer's Best Price.

AIDS Drug Assistance Programs

AIDS Drug Assistance Programs (ADAPs) are state-operated programs, federally funded through the Ryan White HIV/AIDS Treatment Modernization Act, intended to help HIV positive patients have access to HIV treatments. There are 57 jurisdictions that operate ADAPs, including Puerto Rico, the U.S. Virgin Islands, and other associated territories. Each individual state or territory decides which medications will be covered and how they will be distributed, as well as the clinical and income eligibility for participation in the programs. Reimbursement models include the following:

- **Rebate Eligible States** are states that submit utilization data via invoices.
- **Hybrid States** are states that contract through a central pharmacy that orders and dispenses medication for them.
- **Direct Purchase States** are states that receive an upfront discount from the wholesaler in lieu of a rebate. These customers purchase through a Pfizer-approved authorized wholesaler.
- **Indirect Purchase States** are states that receive a rebate. The rebate and discount are based off of the wholesale acquisition cost (WAC) in effect on the last day of the reporting quarter.
- **Combo States** are states that receive rebates in part, but also act as direct purchase states.

Because of these various models, Pfizer ADAP customers include states and private entities that sell to and/or act on behalf of the states.

FOR MORE INFORMATION

- Orange Guide Chapter 7: P&T Committee Interactions
- The Green Guide: Governance for Field-Based Medical Activities
- www.pfizerhelpfulanswers.com
- Refer any other questions to your team attorney or the CGC team attorney

Chapter 7: SUPPORT OF EXTERNAL ORGANIZATIONS

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Support of External Organizations

Chapter 7: 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 action 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 U.S. 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
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 U.S. 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 very narrow exceptions for logistical expenses discussed in Orange Guide Chapter 9: Speaker Programs for HCPs). 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).

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 WRD 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 WRD SOP 201 for additional guidelines and requirements.

Sponsorships and Charitable Contributions: the U.S. 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)
Opportunity to promote Pfizer and its products or brands (such as via branded materials or a booth at an exhibition). 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.)** Speaking opportunities that directly promote or raise awareness of Pfizer marketed products and/or commercial activities (including policy and disease state related topics). Input into the execution or content of an activity (e.g., providing strategic direction or message development). Directly receiving funded activity output (e.g., funding the development of literature that will be used by Pfizer). Placement of product logos on a podium or in literature aimed at HCPs or patients.	Placement of a Pfizer corporate logo on podium or brochure. Honorable mentions and announcement of thanks, written or verbal. Placement of a Pfizer corporate logo on a purchased table at an event. Tickets to an event.

** 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: Sponsorship vs. Charitable Contribution		
Characteristic	**Sponsorship**	**Charitable Contribution**
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 InterAct.Pfizer.com under the "BU/Pfizer Medical/Policy FRF" tab. Additional resources are also available at OpSource.pfizer.com under the "Funding Requests" 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 healthcare 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 U.S. 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

- Funding to external organizations by colleagues in R&D must follow Worldwide R&D SOP 201.
- 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 or visit www.pfizermededgrants.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 8: NON-PROMOTIONAL AND MEDIA ACTIVITIES

CONTENTS

Non-Promotional and Media Activities

Chapter 8: NON-PROMOTIONAL AND MEDIA ACTIVITIES

Introduction

The Food and Drug Administration (FDA) regulates all promotional statements that Pfizer makes about its products. FDA does recognize, however, that certain activities and provision of information about current research and scientific data can be non-promotional. Thus, manufacturers may distribute certain information, and make some communications, without being subject to the FDA rules governing product promotion. Non-promotional activities can generally be characterized as either service-based relationships or non-promotional communications.

This Chapter summarizes certain key Pfizer policies regarding key non-promotional activities, including media activities. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination.

Key Points to Ensure Compliance

- Non-promotional activities can generally be characterized as either service-based relationships or non-promotional communications
- Non-promotional communications are those which are not designed or intended to promote the use of a Pfizer product in order to impact prescribing. They must be: truthful, accurate and not misleading; supported by the relevant scientific data (including any relevant safety data); narrowly tailored to the topic being discussed; and void of any promotional claims or promotional context.
- Both on-label and off-label information may be presented or discussed with an HCP during his or her performance of a bona fide service for Pfizer so long as any off-label information is narrowly tailored to the specific bona fide purpose of the service arrangement. All applicable policies, procedures and approval processes for engaging HCPs for services must be followed. In all circumstances, information presented at promotional speaker programs must be on-label and consistent with Pfizer speaker program policies.

Key Points to Ensure Compliance (cont'd)

- Scientific exchange constitutes the proactive communication of medical information in a non-promotional manner and may include off-label information. It is generally regarded by Pfizer as an infrequent activity in which **authorized Medical Colleagues** engage and is reserved for exceptional circumstances where the medical information is urgently important.
- Pfizer colleagues are prohibited from making claims of safety or efficacy about an unapproved product (e.g., a pipeline product) or about an unapproved indication for an approved product.
- Pfizer policy only permits certain Pfizer Medical Colleagues to respond to unsolicited requests for medical information about unapproved products or indications. All other colleagues must refer the request to Pfizer's Medical Information Department (1-800-438-1985).
- All press releases must be coordinated with and issued by Pfizer Global Corporate Media Relations. A press release discussing an unapproved product or use or other information that may be considered off-label must be non-promotional in tone and must comply with the principles of scientific exchange. It may not state that an unapproved product (or an unapproved use of a product) is "safe" or "effective."
- Material nonpublic information (i.e., information that might affect the Company's stock price) must be communicated only in a press release, a filing with the Securities and Exchange Commission and/or a webcast presentation to which the public has been invited in advance.
- All media inquiries must be directed to Pfizer Global Corporate Media Relations (1-800-438-1985) and all inquiries from investors and investment analysts must be directed to Pfizer Investor Relations 212-573-2668.

Service-Based Relationships

Pfizer engages HCPs to perform services necessary for the operation of Pfizer business. Generally, such service-based relationships are performed under a service/consultant agreement and provide fair market value compensation to the HCP in return for services performed. At other times, the HCP may be willing to provide services to Pfizer without compensation. In all service-based relationships, Pfizer must have a legitimate, good-faith business need for the services being performed.

When HCPs are engaged to provide actual bona fide services, activities directly related to the service-based relationship are not considered promotional. Both on-label and off-label information may be presented or discussed with an HCP during his or her performance of a bona fide service for Pfizer so long as any off-label information is narrowly tailored to the specific bona fide purpose of the service arrangement. Service-based relationships can never be a pretext for disseminating information that would otherwise be impermissible. Off-label information may also be discussed prior to the service-based relationship for the purpose of recruiting an HCP to enter a service-based relationship; however, extra care must be taken. Any information provided to the HCP prior to an agreement must be essential to enable the HCP to decide whether to enter into the agreement and must not be a pretext for a discussion that would otherwise be impermissible.

Bona Fide Consulting Engagements

Consulting engagements are one type of service-based relationship. Pfizer engages HCPs to serve as consultants in their individual capacity, as well as to serve on advisory boards. In some cases, the services may involve the discussion of unapproved or off-label uses of Pfizer products. Any such discussion must be strictly limited in scope to what is necessary to accomplish the legitimate purpose of an approved engagement. All applicable policies, procedures and approval processes for engaging consultants must be followed. For more information, see White Guide Chapter 5: HCP and Government Official Consulting Engagements.

Speaker Programs

Although speaker programs involve a Pfizer service-based relationship with a speaker, speaker programs are promotional activities because they are intended to influence the prescribing of those HCPs in attendance. To ensure compliance, all speakers must be trained and contractually agree to abide by FDA and Pfizer policies governing promotion. These policies require that all Pfizer speakers use RC-approved materials and provide information consistent with product labeling. Pfizer does, however, permit speakers to respond to unsolicited questions from the audience requesting information outside of product labeling. The speaker may briefly respond to the specific question but must note that the use/information under discussion is off-label, and that he/she is answering the question based upon his/her own experience. It is not permissible to engage a particular HCP as a

speaker in order to influence his or her prescribing, however. For more information, see White Guide Chapter 4: Marketing Programs, and Orange Guide Chapter 9: Speaker Programs for HCPs.

Bona Fide Consulting Engagement

Q. Pfizer is planning to pursue a new indication for an oncology product. The clinical team lead for the product would like to engage a consultant to assist with clinical trial design which would involve discussion of off-label uses for the product. Is this permissible?

A. Yes. In order to obtain services in connection with clinical trial strategy for a new indication, the clinical team would have to discuss off-label uses for the product. Of course the interaction must always be scientific and objective in tone and substance.

Non-Promotional Communications

In general, FDA laws and regulations apply to statements about our products made by all Pfizer colleagues, not just those made by Sales and Marketing Colleagues. All promotional statements must be consistent with a product's approved labeling. A statement is promotional if it is designed or intended to promote the use of a Pfizer product in order to impact a customer's prescribing. (See White Guide Chapter 3: Promotional Interactions with HCPs.) In contrast, non-promotional communications are those which are not designed or intended to promote the use of a Pfizer product in order to impact prescribing.

Non-promotional communications are generally divided into several distinct categories:

- Responses to unsolicited medical requests from HCPs or other customers
- Proactive communication of new clinical or scientific information ("scientific exchange")
- Publications in peer-reviewed journals

Each category has specific rules that govern its appropriate use.

Non-promotional communications must be:

- Truthful, accurate and not misleading

- Supported by the relevant scientific data, including any relevant safety data
- Narrowly tailored to the topic being discussed
- Void of any promotional claims or promotional context

Scientific Exchange Generally

In certain circumstances, the Company may proactively provide scientific information that is outside the scope of an approved product's labeling under the principle of **scientific exchange**. Scientific exchange constitutes the proactive communication of medical information in a non-promotional manner. Whether a communication will be considered non-promotional depends on the **content** of the communication as well as the **context** in which the information is presented. For example:

In terms of content:

- Providing previously disclosed information that is no longer new or is already known within the medical community is more likely to be viewed as promotional while providing new, important scientific information that is not widely known in the medical community is more likely to be viewed as non-promotional.
- Non-promotional communications must not be promotional in tone. Claims about the safety or efficacy of an unapproved product or indication are likely to be considered promotional and are not permitted to be proactively delivered under the guise of scientific exchange.

In terms of context:

- The involvement of Sales or Marketing makes the communication more likely to be viewed as promotional while involvement by Medical Colleagues or investigators (without Sales and Marketing) may make the communication more likely to be viewed as non-promotional.
- If the activity is part of a larger commercial strategy, it is more likely to be viewed as promotional than if it was an activity initiated and led by Medical (without Sales and Marketing involvement).

Scientific exchange is generally regarded by Pfizer as an infrequent activity in which **authorized Medical Colleagues** engage and is reserved for exceptional circumstances where the medical information is urgently important.

Pfizer colleagues are prohibited from making promotional claims of safety or efficacy about an unapproved product (e.g., a pipeline product) or about an unapproved indication for an approved product. Indeed, any information provided during a promotional activity or in a promotional manner must be consistent with product labeling (i.e., on-label).

In addition, disseminating untruthful or misleading information, even if the information is claimed to be part of a scientific exchange, violates FDA regulations. Similarly, any communications, including those under scientific exchange, that are viewed by the government as concerted activity to promote off-label use of a company's product, and/or concerted activity intended to result in improper claims for government reimbursement could lead to civil or criminal prosecution under the federal False Claims Act.

Third Party Scientific Meetings

Third party scientific meetings and congresses provide an important venue at which Pfizer Medical and other authorized colleagues can present, critically review, and discuss ongoing or completed research among a professional peer group. Even so, not all activities at scientific meetings qualify as legitimate scientific exchange or other non-promotional communication. As a result, individual activities must be examined to determine whether the content and context of the interaction qualifies as non-promotional.

The table on the following page provides details and examples of factors that can help determine whether an activity at a third party meeting is likely to be viewed as promotional or non-promotional.

	More likely to be viewed as	
Content	**Promotional**	**Non-promotional**
Type of Presentation	Company-sponsored promotional satellite symposia	Peer-reviewed podium or poster presentation in scientific session
Originality of Content	Previously disclosed information that is no longer new or is already known within the medical community	New, important scientific information that is not widely known in the medical community
Peer Review	Information has not undergone peer review	Information has undergone peer review
Location of Presentation	Commercial booth	Scientific floor
Speaker	An individual with no direct involvement in the research being presented	A Medical colleague or investigator with direct involvement in the research being presented
Role of Sales and Marketing	Sales or Marketing involvement	No involvement by Sales or Marketing

Since no one factor is determinative, the totality of the circumstances must be taken into account when assessing whether a particular presentation or activity constitutes legitimate scientific exchange or other non-promotional communication not subject to promotional standards.

Responding to Unsolicited Requests for Medical Information

To ensure that responses to questions seeking off-label information are considered non-promotional communications, Pfizer policy only permits certain Pfizer Medical Colleagues to respond to such

requests for information. For these colleagues, the provision of off-label information in response to a question is appropriate so long as the question is unsolicited and the response is:

- Truthful, accurate and not misleading
- Supported by the relevant scientific data, including any safety data and complete, i.e., not "cherry-picked"
- Narrowly tailored to answer the question asked
- Void of any promotional claims
- Documented in accordance with relevant Pfizer policy (i.e., USMI SOP and the Green Guide or Purple Guide).

For more information on whether Medical Colleagues not identified below are permitted to respond to a request for off-label medical information, please consult your team counsel.

Specified Roles with Respect to Non-Promotional Communications

Pfizer Medical Information Department

The Pfizer Medical Information Department provides accurate, timely and balanced medical information to internal and external customers, including responses to unsolicited customer requests. Medical Information is structured to enable Pfizer to respond appropriately to inquiries that may require reference to both on-label and off-label data. Any colleague, including Medical Colleagues, who is involved in a promotional interaction with an HCP who has unsolicited question(s) about unapproved products or indications, must refer the HCP to Pfizer's Medical Information Department (1-800-438-1985).

External Promotional Speakers

Non-employee HCPs retained as promotional speakers cannot initiate off-label discussions of our products to other HCPs at Pfizer speaker programs. If a promotional speaker is asked an unsolicited question regarding off-label information, however, he/she may briefly respond to the specific question. Speakers must note that the use/information under discussion is off-label, and that he/she is answering

the question based upon his/her own experience. A promotional speaker retained by Pfizer is "speaking for Pfizer" when he/she presents, and failure to adhere to promotional FDA guidelines exposes Pfizer (and the speaker) to the risk of prosecution and penalties.

RMRS Colleagues and Similar Field-Based Medical Colleagues

Regional Medical & Research Specialists (RMRS) assist outside researchers in the design and conduct of clinical and outcomes research, facilitate research site selection and study placement, provide support to both Pfizer-sponsored and investigator-initiated research activities, and enhance scientific communication among Medical, Worldwide Research & Development, and clinicians and researchers. Please consult the Green Guide: Governance for Field-Based Medical Activities, for RMRS policy on responding to requests for off-label information and other non-promotional activities. The Green Guide is applicable to Canadian and U.S. RMRS, Medical and Scientific Relations (MSR) Colleagues, Regional Rare Disease Specialists (RRDS), Outcomes Research RMRS (OR-RMRS) and Regional Outcomes Research (ROR) Colleagues.

MOS Colleagues and Similar Field-Based Medical Colleagues

Medical Outcomes Specialists (MOS) is a group within U.S. Medical Affairs that primarily works with organized customers such as payers (including formulary and P&T committees), medical groups, colleges of pharmacy and advocacy groups. In general, MOS responsibilities include: (a) demonstrating the pharmacoeconomic value of Pfizer's in-line products to managed care and other MOS customers; (b) collaborating with customers to advance the quality of patient care in areas of interest to Pfizer; (c) working with customers on outcomes research to identify provider or patient knowledge gaps, areas for quality improvement interventions; and (d) providing Pfizer brand teams with customer perspectives to enable the development of appropriate customer-focused tools and medical communications to support patient access to medicines. The MOS group may respond to specific unsolicited requests for off-label pharmacoeconomic information.

All requests received by MOS Colleagues for off-label data concerning anything other than pharmacoeconomic information, including those seeking information on the general safety or efficacy of Pfizer products, must be referred to Pfizer's Medical Information Department. The MOS group and

other similar field-based medical groups must adhere to the Purple Guide: Governance of Medical Outcomes Specialists' Activities.

Other Pfizer Medical Colleagues

As mentioned above, FDA laws and regulations apply to promotional statements made by Pfizer Medical Colleagues about our products in much the same way that they apply to statements by Sales representatives and other Pfizer colleagues. However, there may be limited circumstances in which it is permissible for other Pfizer Medical Colleagues (in addition to the context of consulting engagements outlined above) to respond to an unsolicited request for medical information. For more information on whether it is permissible to respond to a request for medical information, Medical Colleagues should consult their team counsel.

Unsolicited Request for Medical Information

Q. A lead investigator on a Pfizer-sponsored study calls a Pfizer Medical colleague on a brand team seeking data on file relevant to an off-label use of the Pfizer product which is the subject of the study. Can the Medical colleague provide this information?

A. Yes. As long the information provided is: (1) truthful, accurate and not misleading; (2) supported by the relevant scientific data, including any safety data; (3) narrowly tailored to answer the question asked; and (4) void of any promotional claims, it is permissible to provide the requested information.

Press Releases and Other Media Communications

Press releases provide timely updates on an array of topics, such as new business alliances, significant FDA approvals, recalls or safety issues, financial performance, clinical trial results, etc. They are typically disseminated over a paid newswire and to print, broadcast and online news sources, as well as posted on Pfizer.com. Pfizer Global Corporate Media Relations oversees all communications intended for release to the media whether written, verbal or electronic (e.g., press releases, video news releases, submissions for newspapers, media FAQ documents). Pfizer generally issues four types of press releases – SEC, Corporate, New Data, and Promotional (though elements of each may overlap).

SEC Required Disclosures of "Material" Updates

Because Pfizer is a publicly traded company, the financial community must be informed when there are "**material**" updates that could impact the company's stock price. Press releases help Pfizer to meet this obligation. These press releases must provide balanced, accurate, complete and non-misleading information. Failure to do so can trigger lawsuits by investors. For example, investors might seek damages based on a claim that they were not provided adequate information about events that negatively impacted the company's stock price. Pfizer Global Corporate Media Relations includes standard disclaimer information called a "forward looking statement" at the end of these press releases.

Material nonpublic information may not be disclosed in nonpublic conversations, meetings, or written materials other than in the course of internal discussions with Pfizer colleagues or consultants. Such information must be disclosed to the entire investment community in a press release, a filing with the Securities and Exchange Commission (SEC) and/or a webcast presentation to which the public has been invited in advance. For more information, see Corporate Policy #604: Treatment of Material Nonpublic Information.

When Pfizer issues a press release related to products under investigation for new, unapproved uses (even if the product is approved and marketed for other indications), the company must strike an appropriate balance to comply with both FDA restrictions against pre-approval promotion and Pfizer's SEC obligation to disclose material developments to the investor community. As a general rule, press releases addressing new, unapproved uses must be scientific and objective, not promotional in tone and must clearly indicate that the product is not approved for the studied use. There should be no promotion of an unapproved use for a marketed product (i.e., a press release should not claim that a drug is safe and effective for an unapproved indication and any unapproved uses should be described as "investigational.")

If you receive an inquiry from investors or investment analysts you must refer them to Pfizer Investor Relations (212-573-2668). For an inquiry from the media please forward to Pfizer Global Corporate Media Relations (800-438-1985).

Corporate Press Releases

Pfizer announces new business alliances, significant FDA approvals, drug recalls or safety communications, or information regarding financial performance, via "Corporate" press releases. A Corporate press release may not contradict FDA-approved information or promote an unapproved use, i.e., it should not claim that a study "demonstrates" that a Pfizer drug is effective for an unapproved indication. Similarly, it should not claim that the product is "safe." If an unapproved use is discussed, it must be described as "investigational."

- **Review Process** – Corporate press releases are typically non-promotional and must be approved by Pfizer Global Corporate Media Relations in consultation with Legal.

Pre-approval Communications

Q. Is it permissible to issue a press release to the investment community claiming that a new study demonstrates that a product or use that has not yet been FDA approved is safe and effective?

A. No. Press releases that provide details about unapproved products must be objectively factual and should avoid the use of promotional adjectives or conclusory comments about safety or efficacy (as FDA has not yet made its determination about those issues). They should also describe such uses as "investigatory."

"New Data" Press Releases

Pfizer often issues a "new data" press release to disseminate results of a study that have not been previously made public. Press releases announcing new data must describe the size of study, study design, primary and secondary endpoints, the statistical significance of the findings, the adverse events seen in the study or other safety information seen in the study, significant exclusion criteria, and whether the product which is the subject of the press release is or is not approved for the use described in the study. A new data press release also should not omit material information about the study (which might include whether the study results contradicts other major findings). In short, the press release cannot present "cherry-picked" data.

If Pfizer decides to disseminate the same study results on a subsequent occasion via a press release then it would be considered a "promotional" press release, which is discussed in more detail below.

Similarly, if promotional language or tone is used, then the press release needs to be treated as a promotional press release.

Review Process – "New data" press releases must be approved by Medical, Regulatory Affairs, and Legal (Product RC for approved products) and Pfizer Global Corporate Media Relations.

Promotional Press Release

Press releases that discuss marketed products may be subject to FDA standards for promotion. Therefore, a product's approved indication(s) and a fair balance of safety information must be included if the press release includes claims of safety and efficacy.

Safety information typically includes contraindications, warnings, precautions, adverse events, and other material information including approved indications. Unless the press release is targeted to media outlets that primarily reach scientific or professional audiences, a consumer-friendly version of safety information must be included. In addition, the FDA-approved full prescribing information should be supplied with all press releases involving marketed products (paper copies should include a copy of the approved prescribing information and electronic copies should reference the location of the prescribing information on Pfizer.com). A promotional press release may not contradict FDA-approved labeling or promote an unapproved use, e.g., it should not claim that a study "demonstrates" that a drug is effective for an unapproved indication. In addition, FDA views promotional product-related press releases as subject to submission at time of first use. Thus, such press releases must be submitted to Regulatory Affairs for filing prior to dissemination.

Review Process – Promotional press releases must be approved by the Product Review Committee (Medical, Regulatory Affairs, and Legal) and Pfizer Global Corporate Media Relations.

Product-Specific Press Kits and Other Media Materials

Product-specific "press kits" are subject to the same FDA regulatory requirements as written promotional materials. Thus, the items in a press kit must be not misleading, must be on-label and must include appropriate safety information. To fulfill the fair balance requirement, press kits should be evaluated in their entirety, rather than on the basis of individual pieces, so long as their components

are intended to be used together and not disseminated individually. A press kit must also contain a copy of the full prescribing information for the product that is referenced in the press release.

As with press kits, other media materials, such as audio/video news releases are generally regarded as promotional and therefore must meet promotional standards and be RC approved. For more information on the review and approval process of product-specific press kits and other media materials, see White Guide Chapter 2: Advertising and Promotional Materials.

Post-approval Communications

Q. Do we need to submit for internal review a press release that highlights newly published clinical trial data for an approved Pfizer product? What about an unapproved product?

A. Yes. Any release that discusses data about an approved product must be approved by Legal, Medical, and Regulatory Affairs, as well as Pfizer Global Corporate Media Relations. The same requirement applies to unapproved products.

Contact Information & Disclaimer

Press releases must be dated and should contain contact information for the appropriate person in Media and/or Investor Relations (and any other appropriate persons).

If the press release contains any forward-looking information, then it should include a disclosure notice, approved by Investor Relations such as the following:

> *DISCLOSURE NOTICE: The information contained in this release is as of [insert date]. Pfizer assumes no obligation to update any forward-looking statements contained in this release as the result of new information or future events or developments.*
>
> *This release contains forward-looking information about certain product candidates and certain potential additional indications about [insert names of applicable investigational compound(s)], including their potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications and supplemental drug applications that may be filed for such product candidates and such additional*

indications for [names of compound(s)] as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such product candidates and such additional indications for [names of compound(s)] and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K [insert the latest dater for which a 10-K has been filed] and in its reports on Form 10-Q and Form 8-K.

The press release should also direct the audience to other sources where it may find additional information about the product's potential risks. Of course, a press release's disclosure language should be customized to the information included in the press release.

Non-Promotional External Speaking Engagements

Pfizer colleagues may participate in external non-promotional speaking engagements and contribute to articles and publications relevant to their area(s) of expertise. As representatives of Pfizer, colleagues must, however, assure that any company information disclosed in presentation materials, handouts, Q&A sessions, articles, etc., is honest, accurate, complete, timely and representative of the facts and is consistent with Pfizer's publicly stated position on related issues. When invited to speak at a third-party sponsored meeting, seminar, workshop, conference, etc., or to author a document for publication, you must obtain the approval of your manager. Your manager must determine whether it is appropriate for you to participate and should consult Legal, if necessary (If you are unclear whether the content of your proposed activity is likely to be perceived as promotional, you should consult your team attorney or Regulatory Affairs for further guidance).

Colleagues approved to participate in external speaking engagements are not required to obtain prior review and approval of their presentation materials, (including pre-read materials, PowerPoint presentations, handouts, etc.) unless requested by the approving manager, but must be sure not to disclose any confidential information or material non-public information. If you have any uncertainly regarding what information may be considered confidential or material (or if the nature of the engagement involves discussion about Pfizer products) you should consult with your manager or Legal, as necessary. You are responsible for assuring that any company information disclosed in those materials, or in the course of the event itself, is honest, accurate, complete, timely and representative of the facts, and is consistent with Pfizer's publicly stated position on related issues. If you are asserting

any personal opinions in a talk or speaking engagement you must clarify with the audience that the opinions expressed are yours and not necessarily those of Pfizer. If the press or media are likely to be present at a third-party sponsored event, you must contact Pfizer Global Corporate Media Relations well advance of the event to assure effective preparation.

Interviews and Other Requests for Information

From time to time, Pfizer colleagues may be approached by the media or federal, state or local officials to answer questions regarding Pfizer and/or Pfizer products.

- If you receive any type of inquiry or request for information from the media (including verbal or telephone, written or electronic requests): direct the inquiry or request to Pfizer Global Corporate Media Relations (212-573-1226). Unless specifically directed by a member of Pfizer Global Corporate Media Relations, you may not answer any question(s) or supply any information directly to the media, or conduct interviews with the media. For more information, see Corporate Policy & Procedure #409: Relations with the News Media.
- If you receive any type of inquiry from investors or investment analysts: direct the inquiry to Pfizer Investor Relations 212-573-2668
- If you receive any type of inquiry or request for information from any federal, state, or local government entity: **promptly** seek guidance from the Legal Division before responding.

FOR MORE INFORMATION

- Refer any questions to your Regulatory Affairs or Legal team colleague, Pfizer Global Corporate Media Relations (212-573-1226), or Pfizer Investor Relations (212-573-2668)
- Green Guide: Governance for Field-Based Medical Activities
- Purple Guide: Governance of Medical Outcomes Specialists' Activities
- Corporate Policy & Procedure #409: Relations with the News Media
- Corporate Policy #604: Treatment of Material Nonpublic Information
- USMI SOP – Requests for medical information should be directed to Global Medical Information at 1-800-438-1985

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Chapter 9: CLINICAL RESEARCH AND INVESTIGATOR-INITIATED RESEARCH (IIR)

CONTENTS

Clinical Research and Investigator-Initiated Research (IIR)

Chapter 9: CLINICAL RESEARCH AND INVESTIGATOR-INITIATED RESEARCH (IIR)

Introduction

Pfizer engages scientists, healthcare professionals (HCPs), research institutions and academic institutions to conduct research and development projects and studies. These include in vitro experiments (discovery), preclinical animal studies, clinical studies, and consultancies and services related to these areas. This research 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, or better delivery of healthcare to patients.

Pfizer-sponsored clinical studies are designed, conducted, overseen, and analyzed by Pfizer, and thus Pfizer is generally responsible for all of the associated regulatory obligations. Pfizer-sponsored studies are generally intended to support a new product, a significant change in the labeling of a Pfizer product, a new indication, or a proposed advertising claim. The company may engage the services of Contract Research Organizations (CROs) or other service providers to assist in study design, management, monitoring, analysis, or reporting.

Pfizer also provides support for studies designed and sponsored by outside investigators or institutions, often referred to as investigator-initiated research (IIR) studies. IIR projects can include preclinical studies, clinical studies, or records-based research and may or may not involve the use of a Pfizer product. Pfizer may choose to support such studies by a grant of pure substance (for preclinical studies), by providing Pfizer product at no cost to the investigator, and/or by providing a grant of financial support. Pfizer is not the sponsor of IIR studies, and Pfizer employees generally should not be involved in the design, conduct, or supervision of an IIR project. Significant involvement of Pfizer employees in these studies can result in Pfizer's being subject to liability for the study generally and/or for ensuring regulatory compliance of the study.

This Chapter is relevant to all Pfizer colleagues who have responsibility for Pfizer-sponsored clinical studies or IIRs. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination.

Key Points to Ensure Compliance

- Decisions to engage an HCP 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 must never be provided to:
  - Establish or improve Pfizer's relationship with an HCP;
  - Gain or improve access to an HCP;
  - Reward past prescribing practices or influence or induce future prescribing practices; or
  - Reward a past formulary decision or influence an upcoming formulary decision.
- Research sponsored or supported by Pfizer must:
  - Have genuine scientific and/or clinical value;
  - Involve investigators or institutions selected on the basis of criteria relevant to the research;
  - Involve compensation that is "fair market value" for the services provided; and
  - Be conducted in compliance with recognized scientific and ethical standards, as well as applicable laws and regulations.
- Pfizer may provide financial support to independent investigator-initiated research studies through IIR grants. The recipient(s) of IIR grants must be chosen on the basis of the merits of their research proposals and the scientific qualifications of the investigators.
- Pfizer personnel in Sales or Marketing functions may not attempt to influence a decision to engage the services of an HCP as a clinical investigator or to award an IIR grant based on the potential impact to Pfizer product sales.
- Pfizer colleagues must follow all established Pfizer policies and procedures in the placement and administration of Pfizer-sponsored studies and the support of IIR activities.

Healthcare Law Compliance Issues

Payments to HCPs may violate federal or state anti-kickback statutes 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 and the Department of Health and Human Services Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers, forbid the use of "token" consulting arrangements. An example of a "token" consulting arrangement would be one involving payments to investigators to encourage the use 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.

If a clinical study involves the performance of bona fide research in return for fair market value compensation and conforms to the ethical requirements for clinical studies, the study should pass scrutiny under the various healthcare laws. Pfizer policies and procedures, including global Development SOPs and Training (DST 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 Clinical Studies

Regulatory and Ethical Framework

IND Requirements

Clinical drug studies in the United States must be conducted under an Investigational New Drug (IND) application, unless an exemption applies. An IND is required for clinical studies involving an unapproved product and, generally, for those studies that involve an FDA-approved product if the study will be used to support a new indication or advertising claim, a significant change in product labeling, or if the study involves an increased level of risk associated with the use of the drug (21 CFR 312.2). The study team must secure approval from Regulatory Affairs in order to proceed without an IND.

In certain instances, Pfizer may choose to conduct some non-U.S. studies under an IND application to facilitate acceptance of the results of those studies by the FDA. Such non-U.S. studies would then be subject to FDA regulations. In addition, all non-U.S. studies must comply with applicable local laws and regulations.

Privacy Rules

The Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) also impacts the conduct of Pfizer-sponsored clinical studies. While HIPAA is not applicable to Pfizer in its role as study sponsor, it applies to most of Pfizer's contracted U.S. investigators with respect to their use and disclosure of protected health data collected in studies. HIPAA (and most non-U.S. data privacy rules) requires investigators to protect the confidentiality of any identifiable health information about a study participant that they obtain in connection with the study and to secure appropriate consents from study participants before disclosing such information to Pfizer. Pfizer personnel must always consider the confidential nature of study participant information that they review and ensure that appropriate safeguards are taken to protect such study data in accordance with Corporate Policy 404: Protecting the Privacy of Personal Information. For a more detailed discussion of protected health information, please see White Guide Chapter 11: Privacy: Protecting Personal Information.

Good Clinical Practices

All Pfizer-sponsored studies must be conducted in accordance with the principles of recognized international ethical and data integrity standards, including the International Conference on Harmonization Good Clinical Practice (ICH GCP) guidelines and other applicable regulatory standards. DST SOP CT19: Policy on Global Standards for Clinical Studies, describes Pfizer clinical study standards that are applicable worldwide, including in those countries that do not have established laws or infrastructure for human subject protection.

Interactions with HCPs and Government Employees

All interactions with HCPs in connection with Pfizer-sponsored studies must comply with Pfizer's Global Policy on Interactions with Healthcare Professionals (GPIHP). Pfizer is also committed to compliance with relevant industry standards, including PhRMA's Principles for Conduct of Clinical Trials and

Communication of Clinical Trial Results. In addition, all interactions with government officials or persons likely to interact with government officials in Pfizer-sponsored studies must comply with the Pfizer International Anti-Bribery and Anti-Corruption Procedure. See White Guide Chapter 5: HCP and Government Official Consulting Engagements, for additional information on interactions with government officials.

Additional Requirements

Unless an exemption applies, all Pfizer-sponsored clinical studies must be reviewed and approved by a qualified Institutional Review Board (IRB) or Independent Ethics Committee (IEC) to ensure the protection of the rights and welfare of study participants. Clinical investigators must also secure voluntary and fully informed consent from each study participant or, in appropriate circumstances, his or her legal representative.

In the case of controlled studies, Pfizer policy also requires that the medical care provided to the control group is medically and ethically appropriate. Placebo-controlled studies are appropriate only when use of a placebo does not present undue risk to the health or well-being of the study participants. Pfizer-sponsored clinical study teams should also address post-study care issues and whether to provide the study drug to study participants after the study concludes, and, if offered, which participants may qualify for this benefit. Applicable regulatory and ethical requirements and industry standards for Pfizer-sponsored clinical studies are reflected in the DST SOPs on Clinical Trials.

Scientific Validity and Value to Pfizer

A Pfizer-sponsored clinical study must be a bona fide research project; that is, it must be scientifically valid and have a clear and appropriate purpose, with goals that are relevant to product development or other Pfizer research or business needs. Before the study teams develop a study protocol, they must establish the purpose of the study and how the study deliverables (e.g., study data or report, biological samples) are likely to be used.

In contrast, "studies" intended to familiarize clinicians with a new drug rather than to collect scientifically important information are not acceptable. Such projects are likely to be viewed as "sham" or "seeding" studies and compensation to participating HCPs could violate anti-kickback laws.

Selection of Investigators

As the study sponsor, Pfizer must select only those investigators who possess the appropriate professional qualifications, training, experience, time, and resources to adequately conduct the study. Investigators must also be evaluated to ensure that they are appropriately licensed, are not disqualified to conduct clinical research by any relevant regulatory body, and have not been previously assessed by Pfizer as unacceptable. Under no circumstances may Pfizer select study investigators or institutions on any improper basis, such as to reward or influence prescribing practices or formulary decisions.

To reduce the risk of bias and ensure data integrity, investigators must also be free from significant conflicts of interest. For those "covered studies" used to support a U.S. regulatory application, FDA regulations require investigators to disclose any significant financial interests in Pfizer, any proprietary interest in the study drug, or any compensation affected by the outcome of the study. Significant payments (exceeding $25,000) to the investigator or institution that are in addition to the costs of conducting the clinical study must also be disclosed.

The role and responsibilities of Pfizer clinical investigators in a Pfizer-sponsored study are documented in a Clinical Study Agreement between Pfizer and the investigator or his or her institution. The Clinical Study Agreement also memorializes the investigator's commitment to conduct the study in accordance with an approved protocol, comply with all regulatory obligations, report to Pfizer any adverse experiences that occur over the course of the study and secure study participant informed consent.

Pfizer policy and procedures relating to selection of investigators and financial disclosure are described in DST SOP CT08: Clinical Site Management and Monitoring, and DST SOP CT23: Financial Disclosure by Investigators.

Conflict of Interest

Q. May Pfizer engage an investigator to conduct a Pfizer-sponsored clinical study if the investigator owns stock in Pfizer or a subsidiary of the Company?

A. Yes. Ownership of Pfizer stock does not disqualify an investigator from participating in a Pfizer-sponsored clinical study. However, it is also important to remember that, under FDA regulations, the investigator must disclose any significant (more than $50,000) equity interest in Pfizer during the time the investigator participates in the study and up to one year after the study's completion.

Data Monitoring Committee Members

Q. May a member of a Data Monitoring Committee (DMC) for a Pfizer-sponsored study be engaged as an investigator for another Pfizer study? May a DMC member be engaged for other services, such as consulting or speaking for Pfizer?

A. Members of Data Monitoring Committees for Pfizer-sponsored studies relating to a particular product are not permitted to serve (concurrently or within the prior 12 months) as an investigator on a study relating to the same product. They are permitted, however, to serve as a DMC member for one product and simultaneously be an investigator for a different product. With strictly limited exceptions, individuals may not contract with Pfizer in any other capacity (e.g. on an advisory board, as a speaker or as a consultant) while serving as a DMC member for a Pfizer study. For further details, see DST SOP CT 22: Use of Data Monitoring Committees and Conduct of Interim Analysis, and White Guide Chapter 5: HCP and Government Official Consulting Engagements.

Study Design, Conduct, and Monitoring

Pfizer-sponsored studies are conducted according to a general study plan and clinical protocol developed and documented by Pfizer. Pfizer oversees the conduct of Pfizer-sponsored studies through monitoring and auditing activities. Pfizer DST SOPs on Clinical Trials identify Pfizer requirements for the preparation of clinical protocols, as well as the requirements for securing IRB or IEC approval, informed consent, study participant recruitment, participation and compensation criteria, data collection and privacy, and study documentation and monitoring practices, including adverse event monitoring and reporting. Pfizer may also engage the services of Contract Research Organizations (CROs) or other service providers to assist in study design, management, monitoring, analysis, or reporting of Pfizer-sponsored studies.

Managing Study Conduct Deviations

It is the responsibility of all Pfizer colleagues and third parties with whom Pfizer contracts to promptly report any suspected significant deviations associated with the conduct or management of Pfizer-sponsored studies to the appropriate Pfizer Quality Assurance group. Examples of significant deviations are those that involve non-compliance with accepted ethical research norms or are likely to impact the integrity of the study data or the safety or rights of participants, such as repeated departures from the study protocol or the falsification of research records. It is Pfizer policy to

promptly investigate any suspected significant deviation from applicable standards in study conduct. Pfizer will take appropriate action to remedy the deviation, when possible, and to prevent future recurrence. Pfizer's requirements and procedure for reporting and handling suspected significant deviations are described in DST SOP CT11: Management of Suspected Significant Deviations.

Safety Information & Adverse Event Monitoring

Q. Are the Pfizer study teams obligated to report safety information from Pfizer-sponsored studies? Can Pfizer choose what type of information it reports to regulatory authorities?

A. Study sponsors cannot choose what safety information they report to regulatory authorities. As a study sponsor, Pfizer is required to record and evaluate all safety information received from any source and to provide expedited reports to regulatory authorities regarding adverse events that are both serious and unexpected. Pfizer study teams must immediately notify all investigators, IRBs, and IECs, as well as the relevant regulatory authorities of significant unanticipated problems such as new safety information, in accordance with DST SOP AEM01: Adverse Event Monitoring (AEM) System. If significant safety information is discovered after study participants have agreed to be involved in the study, the study participants must be provided this new information, regardless of whether it may affect their willingness to continue to be involved in the study.

Compensating Investigators

Pfizer compensates its investigators and study sites for performing services necessary to conduct a study. Compensation must reflect the fair market value of the services performed. The rate of compensation may take into consideration factors such as investigator expertise, required procedures, time commitment, study complexity, and locale. Pfizer does not, under any circumstances, provide compensation to reward or influence prescribing or formulary decisions.

Requirements relating to investigator compensation are set out in DST SOP CT18: Policy on Compensation to Investigators in Clinical Studies, and include the following:

- Compensation must be linked to specific services or associated activities (e.g. reimbursement of reasonable travel, lodging and meal expenses associated with attendance at investigator meetings);

- The basis of compensation must be documented in a study budget that serves as an attachment to the Clinical Study Agreement;
- Compensation must be reasonable when compared to compensation for similar clinical studies sponsored by the pharmaceutical/biotechnology industry in the country where the study is conducted; and
- Study participants should be informed, as part of the informed consent process, that Pfizer is providing compensation to the investigator or institution for his or her involvement in the study.

Under no circumstances may financial compensation to investigators in Pfizer-sponsored studies:

- Be tied to the outcome of the study;
- Include Pfizer stock or stock options;
- Include payments to physicians outside the study for referring potential study participants;
- Include special incentives such as enrollment bonuses, awards, or gift certificates designed to reward the achievement of participant enrollment goals within a specified time period; or
- Include any other type of additional incentives or rewards, except those prospectively identified in the Clinical Study Agreement or approved by the IRB or IEC. An acceptable basis for an incentive payment could be, for example, to recognize timely reporting of clinical data.

Investigator Compensation

Q. If, in a sponsored study, enrollment is lagging, can Pfizer offer investigators increased compensation to help expedite enrollment? For example, can we pay investigators an extra $700 per enrolled study participant?

A. While Pfizer may compensate investigators with fair market value payments for their participation in a clinical study, it would not be appropriate to offer investigators increased per-participant incentives to accelerate enrollment. Investigator compensation must be linked to bona fide services. If enrollment is difficult, Pfizer can make arrangements to cover the cost of additional advertising, staff time, or recruitment work by the investigator. It is important to remember that additional payments will need to be made to an investigator's institution or clinical trial office, rather than to an individual investigator or his or her staff. If a study team has questions about whether a particular type of additional compensation is acceptable, the team should consult with WRD Legal.

Investigator Meetings

Pfizer routinely invites investigators and key research staff to study-related meetings. Such meetings are usually held at the launch of a study and, as needed, intermittently as the study progresses. These investigator meetings provide information about the drug and study protocol, as well as opportunities for training and other activities designed to increase the consistency and quality of study conduct. Because investigator meetings are an expected component of clinical study participation, reimbursement for expenses associated with such meetings may be made in accordance with the terms of the Clinical Study Agreement. A separate agreement is not required. Reimbursement to investigators and staff for travel to investigator meetings and associated expenses must comply with Corporate Procedure #301: Travel, Entertainment and Other Business Related Expenses. The venue of investigator meetings should be conducive to the business purpose of the meeting, convenient for the participants, and not be "resort-like" or "lavish." International investigator meetings must comply with Pfizer's Global Procedure for International Meetings and require use of the International Meeting Approval System ("iMAS"). The Pfizer Compliant Meetings & Controls group is responsible for organizing investigator meetings. Its procedures are outlined in the Pfizer Inc HCP Meetings User Manual.

Financial Support

In a Pfizer-sponsored study, Pfizer covers the cost of the investigational aspects of the study. This includes any treatments, procedures, or tests that are required by the protocol and that the study participant would not have received had he or she not participated in the study. In studies involving the use of a Pfizer product as the study drug, Pfizer generally provides or covers the cost of the Pfizer product.

Some studies also include certain protocol-required Standard of Care (SOC) services. SOC services are medically necessary treatments, procedures, or tests that would be administered to the patient even if he/she had not enrolled in the study, consistent with good medical practice. Under certain circumstances, the costs of SOC services are not required to be covered by the study sponsor. However, Pfizer generally will not charge study participants for the costs of a Pfizer drug used in a Pfizer-sponsored study, even if the use of that drug is standard of care. For studies conducted in the United States, the determination of whether SOC costs may be charged to the study participant/insurer is governed by DST SOP CT10: Policy on U.S. Protocol Required Standard of Care. For studies conducted outside the United States, this determination requires consultation with local Legal and Regulatory Affairs.

Pfizer also covers the costs of treatment for any study-related research injury. A research injury is a physical injury caused by treatments or procedures required by the protocol that the study participant would not have received if he or she had not participated in the study. Pfizer does not offer compensation for lost wages, expenses other than medical care, or pain and suffering. Pfizer's research injury compensation practices for non-U.S. studies may differ based on the impact of local law or conformance to generally accepted local or regional guidelines. Study participants must be free to withdraw from a study at any time without penalty or loss of benefits to which they are otherwise entitled.

Participant Compensation

Q. May Pfizer compensate research participants for their time and any reasonable expenses that were incurred during their participation in a sponsored clinical study? Can any payment be made contingent upon the completion of the study?

A. Pfizer is committed to compensating research participants fairly. Study participants should not have to bear unduly burdensome costs as a result of their participation in a Pfizer-sponsored study, but should also not be offered compensation that is seen as excessive and, therefore, could undermine the principle of voluntary informed consent. Pfizer may choose to offer payment to research participants so long as the payment has been reviewed and approved by an IRB or IEC prior to the commencement of the clinical study. Payments must also be prorated (e.g., per visit) and must be based on the nature of the procedures, or the actual or anticipated expenses of participation, such as parking fees, and travel and lodging expenses. While the entire payment may not be contingent upon completion of the study, Pfizer may choose to reserve a small portion of the compensation as an incentive to complete the study, provided that the incentive is not excessive.

Public Disclosure and Access to Study Data

Pfizer recognizes that there are public health benefits associated with making clinical study information widely available to HCPs and study participants through clinical study registries and results databases. Pfizer prospectively registers Pfizer-sponsored interventional studies (and non-interventional studies with prospectively-defined data collection) on ClinicalTrials.gov, a publicly-available study registry provided as a service by the United States National Institutes of Health. Pfizer posts results of those studies following the FDA approval of the product or, for studies on FDA-approved products, one year after study completion.

Pfizer is committed to compliance with all federal and state requirements regarding access to clinical study information and results.

Pfizer also voluntarily complies with PhRMA's Principles for Conduct of Clinical Trials and Communication of Clinical Trial Results and encourages the publication of the results of its sponsored studies by investigators, whether or not the results are favorable to the Pfizer study drug. Under those principles and Pfizer policy, study results must be reported in an objective, accurate, balanced and complete manner and must discuss study strengths and limitations. Reports must also disclose Pfizer's

financial support. Pfizer reserves the right to prospectively review any proposed publication or other disclosure of the results of a Pfizer-sponsored study in order to prevent inadvertent disclosure of Pfizer proprietary information, and may request a short delay in publication if necessary to protect intellectual property rights. In addition, all investigators who participated in the conduct of a single or multi-site clinical study are entitled to review relevant statistical tables, figures and reports for the entire study at a designated Pfizer facility or other mutually agreeable location.

Pfizer supports the authorship criteria established by the International Committee of Medical Journal Editors (ICMJE), which ensures that only those individuals who deserve authorship credit based on their contributions to the publication are identified as authors. Individuals who contribute to the publication in roles other than authors, including technical writers, should be appropriately acknowledged, and sources of financial support for the study should be disclosed.

Pfizer's policy on the public disclosure of information, access to data and publication related to Pfizer-sponsored studies is outlined in DST SOP CT20: Policy on Public Disclosure and Authorship. Authorship of publications, including the standards for acknowledgment as an "author" or "contributor" is also discussed more fully in White Guide Chapter 17: Publications.

Study Registration

Q. In general, what types of studies does Pfizer register? Does Pfizer communicate the results of all Pfizer-sponsored registered studies?

A. Pfizer is committed to publicly registering Pfizer-sponsored Phase 1-4 interventional studies that involve the use of a Pfizer product, as well as non-interventional studies that involve prospective data collection. Results are posted on clinicaltrials.gov following FDA approval or, for studies on approved products, within one year of study completion. For additional information regarding Pfizer's policy on clinical study registration and disclosure, please see DST SOP CT20: Policy on Public Disclosure and Authorship.

Compassionate Use

Pfizer is sometimes requested to provide an investigational product that has not yet received regulatory approval to treat a seriously ill patient who has exhausted approved treatment options and is ineligible for participation in any ongoing clinical study. Such requests are handled in accordance with DST SOP CT16: Policy on Expanded Access for Treatment Use and Compassionate Use, which

identifies the criteria that must be met for Pfizer to consider a "compassionate use" request. Compassionate use requests are decided on a fair and equitable basis. Generally, a compassionate use request will not be honored unless the investigational product (which Pfizer intends to pursue for marketing approval) is being investigated under an appropriate regulatory authorization and there is meaningful human clinical data to support the determination that the potential benefits to the patient outweigh the risks. Non-clinical factors, such as the identity of the patient or the requestor, must not play a determinative role in the consideration of a compassionate use request. The relevant study team is responsible for evaluating compassionate use requests and the clinical lead will make the final determination on whether or not to honor the request.

Investigator-Initiated Research (IIR) Studies

Through its IIR program, Pfizer supports research that advances medical and scientific knowledge about Pfizer products and disease areas of interest and generates promising medical interventions. Pfizer's IIR program and the process used to review, approve, support, and follow-up on IIR proposals is outlined in DST SOP CT25: Investigator-Initiated Research.

Receipt of Proposals

Pfizer accepts proposals for IIR grants submitted by interested investigators and institutions. Investigators may propose to conduct **clinical studies** of approved and unapproved uses of marketed products, or involving unapproved Pfizer drugs; **in vitro** or **animal studies; observational studies**; or other types of **independent research on disease states**. To ensure Pfizer receives all necessary information, Pfizer requires the investigator to submit their requests through the IIR submission portal at www.pfizer.com/IIR.

Pfizer Headquarters (non-Sales) teams may also choose to implement a competitive grant award program for research relating to a particular product, disease, or area of scientific inquiry. Such an award program may be in addition or in place of ongoing grant submissions for that area of interest. These programs typically have a defined set of research criteria and are limited to a certain timeframe. These programs can be publicized broadly to a specific audience via professional journals or websites and typically have an external independent advisory committee review and approve the program's IIR grant recipients.

Scientific Validity and Value to Pfizer

Pfizer provides support for investigator-initiated research projects that are of interest to Pfizer and that are intended to advance medical and scientific knowledge. Multi-disciplinary Pfizer teams review IIR proposals for medical and scientific merit and study feasibility. The teams also consider the investigator's qualifications, including his or her experience, training, and capability to perform all sponsor responsibilities such as filing for any necessary regulatory approvals. The IIR investigator also must agree to provide Pfizer with a copy of any final study results and any resulting publications for Pfizer's review. The team that approves the IIR study must document the scientific rationale for Pfizer support.

With limited exceptions, IIR studies are not intended to support a regulatory submission and Pfizer generally does not receive any raw or participant-level data. Any decision by a clinical study team to receive or reserve the right to receive raw data must be clearly documented in the IIR agreement, and is subject to enhanced review by the appropriate multi-disciplinary team.

IIR Support

Q. Can Pfizer encourage an HCP to submit a proposal for an IIR grant involving an off-label use of a Pfizer product? Could our clinical personnel help him or her with the protocol?

A. While appropriate Pfizer colleagues can encourage the submission of bona fide scientific research proposals, it would not be appropriate to encourage the submission of a proposal for non-scientific reasons. Research involving an off-label use of a Pfizer product would be eligible for IIR funding only if the proposed research is likely to provide valuable scientific or clinical information, improve clinical care, lead to new or improved treatments, or benefit patients. Encouraging an HCP to submit an IIR proposal is permissible, as long as the funding decision is based on the scientific merits of the proposal and is not an attempt to influence the HCP's prescribing behavior. In other words, we may only fund research having compelling scientific merit and may only select investigators based on their credentials and research capabilities. Assistance in drafting a protocol can be provided if it does not rise to the level of actual protocol preparation. Pfizer may also provide limited input in the following areas: Patient safety, dosage, co-medications, inclusion/exclusion criteria, and statistics. Investigators interested in learning more about Pfizer's IIR Program or who wish to submit a request should be directed to www.pfizer.com/IIR. Note that while Sales Colleagues may respond to an HCP's questions about the process for requesting IIR funding from Pfizer, Sales should not proactively encourage or seek out IIR proposals. Sales colleagues should consult Orange Guide Chapter 6: Clinical Research and Investigator Initiated Research, for further details.

Nature and Basis of Pfizer Support

An IIR grant may include free Pfizer product (including marketed or investigational products, finished goods, and pure substance), funding, or both. IIR grants are only provided to support specified, prospectively approved, research projects. IIR grants may not be provided to support general research, educational or training programs, studies being conducted on behalf of Pfizer, or where services are being provided for Pfizer's benefit, such as development of software, technology, or methodologies to which Pfizer would be granted ownership or other rights. With limited exceptions, IIR grants may not support studies that involve new product registration, a change in Pfizer-product labeling, or other regulatory approval efforts. Furthermore, when considering IIRs for a given asset program, it should be understood that Pfizer does not own the data and therefore cannot use study results for promotion.

Brand teams, however, may approve a published IIR study reprint for use in promotion per the guidelines outlined in White Guide Chapter 2: Advertising and Promotional Materials.

A clinical study team interested in supporting an IIR grant which may be used in conjunction with a regulatory submission may do so in accordance with the guidelines set forth in DST SOP CT25, provided they have obtained prior approval from Regulatory Affairs and Legal.

IIR grants may not be provided to reward or influence the prescribing practices of the investigator or institution. IIR grants must not be based in any way on any preexisting or future business relationships with the investigator or institution or on any decisions the investigator or institution has made or may make in the future related to Pfizer or Pfizer products.

Funding for an IIR study must represent fair market value for the activities being funded, including appropriate institutional overhead. As part of Pfizer's review of an IIR study proposal, the team must assess the reasonableness of the study budget. When feasible, payments should be milestone-based and the final payment should be conditioned on Pfizer receipt of agreed-upon deliverables, documented in the IIR agreement.

Pfizer support can only be initiated once an IIR agreement has been fully executed, and Pfizer has received a final study protocol and all of the other required documents outlined in the agreement. Such documentation may include, for clinical studies, IRB/IEC approval and documentation of compliance with any applicable local pre-study regulatory requirements.

Independence and Investigator Responsibilities

All IIR protocols must be developed by the outside investigator or institution and, as the sponsor, the principal investigator or institution must assume all legal and regulatory responsibilities. The study sponsor is also responsible for selecting participating sites and investigators, as well as managing the publication of study data.

Pfizer may not design the study or write the protocol, nor may it be actively involved in the conduct or monitoring of the research as the study supporter. Pfizer, however, may track study progress, as well as review and comment on a draft protocol and provide suggested content (e.g., information relating to the Pfizer product or Pfizer safety reporting requirements). In certain circumstances, Pfizer's support

and participation in an IIR study may be associated with Pfizer's desire to receive raw data for possible regulatory or future research use even though Pfizer does not own the data. These IIR studies require enhanced scrutiny, consultation with Legal and Regulatory Affairs, and customized contracting, as appropriate.

Regulatory and Ethical Framework

IND Requirements

As with Pfizer-sponsored studies, investigator-initiated clinical drug studies in the United States must be conducted under an Investigational New Drug (IND) application, unless an exemption applies. An IND is required for clinical studies involving an unapproved product, and generally, for those studies that involve an FDA-approved product if the study will be used to support a new indication or advertising claim, a significant change in product labeling, or if the study involves an increased level of risk associated with the use of the drug (21 CFR 312.2). For clinical trials in the U.S. utilizing a Pfizer product, Pfizer requires documentation of IND submission or exemption.

IRB/IEC Approvals

Unless an exemption applies, all investigator-initiated clinical studies must be reviewed and approved by a qualified Institutional Review Board (IRB) or Independent Ethics Committee (IEC) to ensure the protection of the rights and welfare of study participants.

Pfizer support of IIR studies is documented by an IIR agreement, which includes the following:

- The investigator or institution agrees to serve as study sponsor and assume all associated regulatory responsibilities;
- The investigator and institution agree to conduct the study in accordance with the approved protocol, ICH GCP guidelines (for clinical studies), and all applicable laws and regulations;
- For clinical IIR studies involving the use of a Pfizer product, the investigator or institution agree to advise Pfizer of all serious adverse events experienced by study participants receiving Pfizer product and, for studies in which Pfizer provides the Pfizer product, agree to provide that drug at no cost to study participants; and

- For IIR studies involving funding, the investigator and institution also agree to use IIR grant funds only for the conduct of the study and to confirm in writing after the study's completion that the funds have been so used.

Consistent with the independence of the IIR study, Pfizer grants itself only limited rights to terminate IIR grant support early, such as a lack of participant enrollment or study progress or if the IIR study design is no longer scientifically relevant.

Publication of IIR Study Results

Pfizer supports the exercise of academic freedom and encourages the investigator to publish the results of an IIR study, whether or not the results are favorable to a Pfizer product. As with sponsored studies, Pfizer requests an opportunity to review proposed publications or other public disclosures of the results of the project prior to publication. Pfizer also expects the investigator or institution to comply with recognized ethical standards concerning publications and authorship, including the disclosure of Pfizer support of the study in any publication of study results. For further information, see White Guide Chapter 17: Publications.

An IIR grant may include funding for publication costs, including manuscript preparation. This will be specifically documented in the IIR agreement and associated project budget. Pfizer must decide before the grant is awarded whether to include publication support in the IIR grant. Pfizer cannot make this decision after completion of the study, as a third party could conclude that Pfizer's decision was based on whether the results of the project are favorable to a Pfizer product.

FOR MORE INFORMATION

- Global Policy on Interactions with Healthcare Professionals
- International Anti-Bribery and Anti-Corruption Procedure
- PhRMA's Principles for Conduct of Clinical Trials and Communication of Clinical Trial Results
- Global Procedure for International Meetings
- Consult the following SOPs
    - DST SOP CT08: Clinical Site Management and Monitoring

- DST SOP CT10: Policy on U.S. Protocol Required Standard of Care
- DST SOP CT11: Management of Suspected Significant Deviations
- DST SOP CT16: Policy on Expanded Access for Treatment Use and Compassionate Use
- DST SOP CT18: Policy on Compensation to Investigators in Clinical Studies
- DST SOP CT19: Policy on Global Standards for Clinical Studies
- DST SOP CT20: Policy on Public Disclosure and Authorship
- DST SOP CT 22: Use of Data Monitoring Committees and Conduct of Interim Analysis
- DST SOP CT23: Financial Disclosure by Investigators
- DST SOP CT25: Investigator-Initiated Research
- DST SOP AEM01: Adverse Event Monitoring (AEM) System

- Corporate Procedure #301: Travel, Entertainment and Other Business Related Expenses
- Corporate Policy #404: Protecting the Privacy of Personal Information
- Refer any other questions to your manager or Clinical Trial Attorney

Chapter 10: PATIENT ASSISTANCE PROGRAMS

CONTENTS

Patient Assistance Programs

Chapter 10: 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 action 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® 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® 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 further questions to your team attorney

Chapter 11: PRIVACY: PROTECTING PERSONAL INFORMATION

CONTENTS

Privacy: Protecting Personal Information

Chapter 11: PRIVACY: PROTECTING PERSONAL INFORMATION

Introduction

Privacy is often described as the universal desire of an individual to keep his/her personal information confidential and by extension, to determine for himself/herself when, how, and to what extent his/her personal information is communicated to others.

Personal information or **PI** includes any information that can be used to identify a person such as name, address, phone number. **Sensitive Personal Information** is a subset of Personal Information and includes information relating to a person's physical or mental health (e.g., a person's medical history, physical or mental condition, diagnosis or treatment).

There are many U.S. federal and state laws applicable to Pfizer's use of Personal Information and Sensitive Personal Information. Moveover, other countries impose even more stringent limitations on the use, access, or transfer of Personal Information. The European Union is widely regarded as having imposed among some of the most stringent privacy protections for individuals in the world. Other countries with comprehensive rigorous privacy regimes include Argentina, Australia, Canada, Mexico and Japan.

Although this Chapter is focused largely on certain U.S. privacy topics, it is important to consider whether any sales and marketing activities conducted in the U.S. can have privacy implications for complying with the laws of other countries. Consult your team attorney or the Global Privacy Office (GPO) should a proposed activity present potential privacy implications for individuals outside of the U.S. or involve the transmission of PI collected outside the U.S. to the U.S.

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 that 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 safeguard all

Personal Information it receives and maintains, regardless of the form, format, location, or use. For additional information, see Corporate Policy #404: Protecting the Privacy of Personal Information.

This Chapter highlights certain key Pfizer policies regarding the protection of Personal Information. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination.

Key Points to Ensure Compliance

- Do not sign a document that is called a "**Business Associate Agreement**" or otherwise relates to "Business Associate" status without receiving explicit written approval to do so by your team attorney or the Global Privacy Office.
- Pfizer's Corporate Policy 404: Protecting the Privacy of Personal Information, requires all Pfizer colleagues and contractors to protect Personal Information collected by or on behalf of Pfizer. Before your team collects Personal Information (directly or via any third party service providers), your team attorney must be consulted and approve the collection and use of the data.
- If Pfizer or its business partner or service provider will be receiving health information, consult with your team attorney. Pfizer colleagues and contractors must ensure that such information may be received in compliance with applicable law and, if applicable, that a proper patient authorization has been obtained by the entity that is disclosing the information.
- All Pfizer-sponsored third-party communications to patients, healthcare professionals (HCPs) and other customers must be approved by the appropriate Pfizer Review Committee (RC), which will consider issues of privacy and consent as part of its review process.
- **When using personal data to communicate with Pfizer customers (HCPs or consumers) it is important to work through Multi-Channel Management vendors and systems to ensure compliance with Do Not Contact lists and appropriate management of data.**
- When setting up a mentorship or preceptorship, Pfizer colleagues must ensure that physicians serving as mentors or preceptors know they must obtain their patients' written authorization before Pfizer colleagues may be allowed to observe any consultation, examination, and/or treatment of any patient.

Key Points to Ensure Compliance (cont'd)

- Avoid situations likely to lead to the inadvertent disclosure of Personal Information, such as being present at or near private conversations between HCPs and patients.
- Pfizer colleagues should not engage health fair attendees in specific discussions regarding a patient's health. These discussions should occur between the patient and appropriate HCP.
- Always disclose that you are a Pfizer employee or representative when interacting with patients, such as at a consumer health fair or during a mentorship. Wear your Pfizer name tag at all times.
- Safeguard 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.
- Do not share an HCP's prescriber data with anyone outside of Pfizer other than properly on-boarded vendors with appropriate contracts in place who may be assisting with your initiative. Check with your team attorney before sharing HCP prescriber data with anyone outside of Pfizer.

The Legal Landscape

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The **Health Insurance Portability and Accountability Act of 1996 (HIPAA)** imposes strict limitations on the use and disclosure of "**Protected Health Information**" or "**PHI**" by "**Covered Entities**".

Pfizer is Not a Covered Entity

Under HIPAA's privacy and security regulations, the term "**Covered Entity**" includes HCPs that engage in electronic transactions for which a standard has been adopted under HIPAA, as well as health plans, and healthcare clearing houses. The HIPAA privacy and security regulations require Covered Entities to take certain reasonable steps to protect the privacy and security of PHI. To accomplish this, HCPs and other Covered Entities must maintain appropriate administrative, technical, and physical safeguards to

protect PHI. Pfizer's employee group health plan is deemed a Covered Entity under HIPAA. However, Pfizer is not a Covered Entity under HIPAA.

Pfizer Is Not a Business Associate

In addition to protecting PHI in the hands of a Covered Entity, HIPAA also protects PHI created or maintained by a Covered Entity's "**Business Associate**." A Business Associate is a person or entity that conducts certain activities on behalf of the Covered Entity that involve the use or disclosure of PHI. Under the HIPAA privacy and security regulations, Covered Entities are obligated to enter into a written contract called a **Business Associate Agreement** with a Business Associate before any PHI is disclosed to the Business Associate. Among other things, a Business Associate Agreement establishes limitations on the Business Associate's use and disclosure of PHI in connection with the functions performed or services provided. In the vast majority of situations, Pfizer does not perform work on behalf of an HCP or other Covered Entity and does not function as a Business Associate. It is theoretically possible that a situation might arise in which Pfizer would act as a Business Associate. **Therefore, it is not appropriate for any Pfizer colleague or contractor to enter into a Business Associate Agreement without the express written consent of the team attorney or the GPO**.

HIPAA Still Relevant for Pfizer

Notwithstanding the fact that Pfizer is not a Covered Entity and that Pfizer is almost always not a Business Associate, in limited circumstances Pfizer will have access to Sensitive Personal Information that constitutes **Protected Health Information** or **PHI under HIPAA**. In such circumstances, Pfizer should secure contractual assurances that the Covered Entity has complied with its obligations under HIPAA prior to the Covered Entity permitting access to such PHI. You should consult your team attorney to ensure that an appropriate agreement is in place with the Covered Entity.

Health Information Technology for Economic and Clinical Health Act (HITECH)

In February 2009, Congress passed legislation referred to as the Health Information Technology for Economic and Clinical Health Act (HITECH) that significantly broadens existing federal health information privacy and security requirements. Subtitle D of HITECH represents the most significant change in federal health information privacy. Most of the statutory provisions took effect on February 17, 2010.

There are several groundbreaking provisions in HITECH with important potential implications for pharmaceutical manufacturer sales and marketing activities, such as manufacturer-sponsored third party communications, disease management and health outcomes activities, and manufacturer-sponsored online health tracking tools. In July 2010, the U.S. Department of Health and Human Services issued proposed regulations to implement a number of these provisions. The proposed regulations have not yet been finalized. The GPO is currently considering the impact of the changes in HITECH and the proposed regulations. Please consult with the GPO for advice on whether HITECH may have implications for any proposed business arrangement or program involving health information (even if Pfizer is not receiving such information), such as point-of-sale marketing communications at the pharmacy or marketing communications distributed by a health plan or plan benefits administrator.

State Medical Information Protection

There are also state laws protecting health information. Some of these state laws may be more stringent than HIPAA in certain respects. For example, unlike HIPAA, California's medical privacy law allows an individual to sue for damages for the negligent release of his/her confidential information in violation of the law. By contrast, HIPAA is enforced through government regulators such as the U.S. Department of Health & Human Services Office for Civil Rights.

HIPAA does not preempt (override) state medical information privacy laws that do not conflict with the federal standards or that are more stringent than those standards. Therefore, Pfizer will want to take steps to ensure compliance with both HIPAA and these state laws in connection with Pfizer programs or initiatives even if Pfizer is not directly subject to the laws itself.

Information Security Laws

Section 5 of the FTC Act prohibits "unfair and deceptive" trade practices. This federal law has been interpreted to require companies to provide reasonable information security for Personal Information. Significant fines have been levied against companies that have suffered information security breaches and were found not to have adequate information protection security controls in place.

In addition, some states mandate special privacy and security protections for specific classes of data. For example, Massachusetts has implemented information security requirements applicable to certain

types of Personal Information (e.g., social security number, driver's license, and financial account information) about Massachusetts residents. These requirements include encryption of portable devices, e-mail and back-up tapes that contain such classes of Personal Information. Since information related to Massachusetts residents is intermingled with data relating to residents of other states, this law has effectively raised the bar for information security requirements more broadly.

Security Breach Laws

Nearly every U.S. state has a security breach notification law. In addition, there is pending national security breach legislation in Congress. These state breach laws require that the individuals whose data has been compromised be notified of the breach and/or that government officials be notified. These laws are not consistent. Consequently, managing even a relatively small breach (e.g., a lost laptop containing Personal Information) can be complex, time-consuming and costly.

Laws Protecting the Personal Information of Children

The federal Children's Online Privacy Protection Act prohibits the collection of Personal Information from children younger than thirteen via the Internet without the consent of a parent or guardian and is enforced by the U.S. Federal Trade Commission (FTC). There is also pending "*Do Not Track*" federal legislation that would prohibit the use of Personal Information for targeting minors.

Requirements for Transparency, Notice and Consent

There is a strong trend toward transparency, notice and consent with respect to all Personal Information collection and use. Section 5 of the FTC Act has been used to ensure robust notice of information collection and use practices. Recently, the FTC made it clear in its December 2010 Report on Protecting Consumer Privacy in an Era of Rapid Change that it was critical for businesses to provide, clear, simple notice of their privacy practices at the appropriate time in the data collection process, i.e., before data is collected.

Concerns about transparency, notice and consent are particularly acute in the online space. For example, the FTC issued a report on Self-Regulatory Principles for Online Behavioral Advertising in February 2009. Behavioral advertising involves the tracking of a consumer's activities on the Internet and then using that information to target advertising. There are several "Do Not Track" bills pending

before Congress that would restrict the circumstances under which advertising could be targeted using Personal Information. These concerns are echoed internationally. For example, the EU amended its privacy law recently to require affirmative consent prior to dropping an internet cookie for a wide range of tracking purposes.

As the privacy law is constantly evolving, Pfizer colleagues and contractors should consult with their team attorney before engaging in any activity that may impact an individual's privacy, whether that individual is an HCP, patient or other consumer.

Pfizer's Policies Relating to Privacy and Personal Information

Pfizer respects the privacy of individuals including patients, caregivers, HCPs and others. Pfizer also respects your privacy. As noted in the Introduction, Pfizer policy is to safeguard all Personal Information it receives and maintains, regardless of the form, format, location, or use.

Every colleague and contractor has the obligation to play his or her role in protecting Personal Information in light of the Personal Information he or she possesses or accesses, as well as any initiatives involving Personal Information that he or she is handling. This includes understanding any Personal Information that such initiatives or campaigns will collect, use or share and the life cycle of that data (e.g., to whom it will flow, how it will be stored and retained, etc.) and for ensuring that all such Personal Information is handled and safeguarded in compliance with all applicable Pfizer policies and procedures.

Notice and Consent

Pfizer may obtain access to Personal Information as part of critical business activities such as:

- Communicating directly to patients through approved Pfizer-sponsored third-party communications;
- Engaging in a mentorship or preceptorship involving patient contact;
- Collecting Personal Information as part of an approved survey, screening tool, or other similar activity;

- Collecting Personal Information from consumers in connection with coupon/co-pay programs, internet activities, and other consumer offerings;
- Collecting patient information in connection with patient assistance programs;
- Collecting personal information in the course of recruiting patients as speakers; and
- Analyzing HCP prescriber information in connection with sales and marketing activities.

To be compliant with law and Pfizer policy, it is critical that the appropriate disclosures and consents (and in some cases contracts) be in place prior to accessing, collecting or using Personal Information. Before your team collects any Personal Information or designs any program which could result in Personal Information being directly or inadvertently disclosed to Pfizer, you must first consult your team attorney to ensure that any required notice and consent have been provided and/or obtained.

Aggregated or De-Identified Data

It is sometimes permissible for Pfizer to obtain previously personally identifiable information from an HCP or health plan administrator without an individual's consent if the information has been **aggregated or de-identified**. "**Aggregated**" data is information about multiple individuals that is compiled and does not allow for the identification of any one participant. "**De-identified**" data is data that cannot be identified as belonging to any specific individual and usually involves removing certain key identifiers (including the individual's name, many elements of the individual's address, telephone number, and social security number, among others), which either alone or in combination with other identifiers, could link the information with a specific individual. HIPAA regulations include strict standards for what is "de-identified." Accordingly, before assuming information is "de-identified," consult your team attorney and/or the GPO.

Avoiding Exposure to Protected Health Information

You must avoid situations in which you may be exposed to PHI without an individual's consent. With certain exceptions, HCPs are generally only permitted to use or disclose an individual's PHI if the individual has authorized the use or disclosure in writing in advance. In the event an HCP or other person inadvertently or intentionally exposes you to the PHI of others, you should not document or reproduce the information in any media or form. You must also strictly maintain the confidentiality of the information in accordance with Pfizer's policy of safeguarding the privacy of all patient-related

data. You should also discuss the situation with your team attorney to determine whether any additional steps should be taken.

Vendor Obligations

All vendors with whom Pfizer does business and who will have access to Personal Information of or on behalf of Pfizer must follow our policy of safeguarding Personal Information. To this end, Pfizer has a **Privacy and Security Addendum** that may be included as part of contracts with such vendors as appropriate following consultation with Procurement and/or the Global Privacy Office. Please note that in addition to the contractual requirements, any vendors that will have access to or process Personal Information on behalf of Pfizer must complete and pass appropriate Pfizer vendor vetting processes.

Activities That May Result in the Use and Disclosure of Protected Health Information

When using personal data to communicate with Pfizer customers (HCP or consumer) it is important to work through Multi-Channel Management vendors and systems to ensure compliance with Do Not Contact lists and appropriate management of data.

Marketing Initiatives and Other Communications

Pfizer-Sponsored Third Party Communications

There are a variety of marketing initiatives and other communications that may raise privacy concerns. For example, from time to time, Pfizer may want to sponsor a medication compliance/adherence program to be provided by or through a customer (e.g., a Managed Care Operation ("**MCO**") or a pharmacy). These programs usually involve sending scheduled mailings to patients to remind them to fill or refill a prescription.

Under certain limited circumstances, PHI may be used by HCPs such as pharmacists to tailor communications for treatment of the individual. From time to time, and with strict limitations, Pfizer may pay entities, such as MCOs, to mail Pfizer-approved disease management or educational materials to certain patients. Pfizer also may pay pharmacies and health plans for medication compliance

mailings to certain patients in order to inform or remind them when to fill or refill a prescription for a medication. When considering such arrangements, you must consult with your team attorney, who may consult with the GPO as appropriate, to determine whether an arrangement you are considering is compliant with applicable privacy laws and regulations.

Importantly, Pfizer-sponsored third party communications to patients must be the subject of a Pfizer-approved service agreement between Pfizer and the third-party. Depending on the origin of the Service Agreement (Headquarters or the field), the appropriate team attorney must review it and if the relationship involves a MCO customer, the agreement must also undergo HQ-CGC Legal review and approval.

A key reason to enter into a service agreement is to ensure the protection of patient privacy. The Pfizer form agreement requires the third-party pharmacy or health plan to guarantee that it has the right to send the Pfizer-approved information to the recipients. They also must promise to adhere to Pfizer's Personal Information protection policies. In general, it is not appropriate for a health plan or pharmacy to disclose PHI to Pfizer or its vendors. In virtually all circumstances, only the pharmacy or health plan (and their vendor(s)) may access or use the PHI in connection with these communications. Consult with your team attorney before allowing any PHI to be accessed or received by Pfizer or its vendors.

All materials sent to patients must be approved by the appropriate Review Committee which will consider issues of patient privacy and patient consent as part of its review process. The RC can consult with the Global Privacy Office on such issues as appropriate.

Digital Marketing Initiatives

Existing and pending laws prohibit or limit the use of Personal Information in order to target online marketing. In addition, companies must appropriately secure Personal Information collected and transmitted via the Internet.

Pfizer teams proposing to conduct web-based marketing and promotional activities (e.g., advertising, websites, Facebook pages, etc.) that collect Personal Information should consult their team attorney or the GPO to determine whether there are privacy concerns. In addition, any externally-facing Internet application (such as a website, mobile phone application or Facebook page) must undergo and pass **Vulnerability and Threat Management Testing**.

Pfizer's Patient Programs

As a general policy, Pfizer does not communicate directly with patients based on their health information unless, among other requirements, the patient has affirmatively consented (or "opted in") to receiving such communications.

Pfizer has a standardized privacy and consent policy for all U.S.-based consumer activities that involve the collection of consumers' Personal Information by any channel, including hard copy or online forms, business reply cards or telephone/fax. To obtain the current privacy and consent policy and related requirements, contact the Multi-Channel Management team. These activities include, but are not limited to, disease management program enrollment forms, coupons and rebate offers, and sweepstakes offers. The guidelines apply only when the consumer provides Personal Information, such as name and address or e-mail address. Whenever a Pfizer program requires a consumer to provide such information, the program must also include a simple, timely, cost-free mechanism (a toll-free telephone number or a prepaid mail-in form) that allows participating individuals to promptly discontinue or "opt-out" of the program. In addition, all programs must contain appropriate privacy language. This privacy and consent policy must also be communicated to and followed by any vendors preparing materials on behalf of Pfizer. Therefore, it is important that Pfizer teams considering programs that would collect Personal Information consult the Multi-Channel Management team to determine whether appropriate authorizations and guidelines are in place. In addition, **it is important to work through Multi-Channel Management vendors and systems to ensure compliance with "Do Not Contact" lists and appropriate management of data**.

Working with HCPs

When interacting with HCPs you may find yourself in situations that would provide you with access to Personal Information or Sensitive Personal Information. As noted above, these situations should be avoided to the extent possible. If such exposure cannot be avoided or is a routine, unavoidable element of the engagement with the HCP, be sure to follow these guidelines.

HCPs may incorrectly request that you sign a Business Associate Agreement (BAA). As noted above, Pfizer does not generally function as a BAA and therefore signing such Agreements is prohibited absent the express written approval of your team attorney or the GPO. The protections HCPs seek can more appropriately be provided through a confidentiality agreement. A confidentiality agreement commits

you and Pfizer to treat the Personal Information you may have access to with care and safeguard its confidentiality. To address this need and provide an alternative to a Business Associate Agreement, 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 Personal Information confidential:

1. 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.
2. 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 might inadvertently come into contact with patient health information.

No changes can be made to these templates before signing them unless your team attorney has approved the change in advance.

A copy of the Privacy Pledge and Patient Health Information Confidentiality Agreement can be downloaded from PfieldNet 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?

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 using the templates 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 team attorney for assistance.

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 the version the HCP wants me to sign?

A. Maybe. Sometimes these agreements are acceptable to sign, but you should never do so unless your team attorney has first reviewed and approved the agreement.

Mentorships and Preceptorships

A **mentorship** allows a Pfizer colleague to observe or "shadow" an HCP engaged in his or her daily office or institutional practice. A **preceptorship**, on the other hand, is a training presentation by an HCP to a team or group of Pfizer colleagues about a particular therapeutic area or the clinical use of one or more Pfizer products in professional practice. Pfizer colleagues must follow Pfizer's HCP Engagements SOP to retain an HCP to provide preceptorship or mentorship services. For more information on these activities, see White Guide Chapter 5: HCP and Government Official Consulting Engagements.

Mentorships and preceptorships can be valuable educational tools, but may impact patient privacy if Pfizer colleagues are permitted to observe treatment and/or consultation sessions with a patient, or if Pfizer colleagues discuss an individual's treatment with a patient's HCP.

When setting up a mentorship or preceptorship, Pfizer colleagues must ensure that physicians serving as mentors or preceptors know they must obtain their patient's written authorization before Pfizer colleagues may be allowed to observe any consultation, examination, and/or treatment. You may offer Pfizer's sample Patient Authorization Form to an HCP. This form includes language and provisions required by HIPAA and may not be altered. The requesting HCP should maintain the signed authorization form as part of the patient's record and provide a copy of the form to the patient.

Patient Consent

Q. Does a patient have to sign an authorization form before a Pfizer Sales Colleague can observe an examination or treatment as part of a mentorship or preceptorship, or is oral permission sufficient?

A. The patient must sign an authorization form. It is the HCP's responsibility to secure appropriate patient authorization in a mentorship or preceptorship. Under HIPAA, a patient must authorize the disclosure of his or her PHI in writing. Oral permission is not acceptable under Pfizer guidelines. It is also important to remember that once proper authorization is obtained from the patient, the Pfizer colleague participating in the mentorship or preceptorship must identify himself or herself as an employee or contractor of Pfizer, as the case may be. A Pfizer name badge must be worn at all times when interacting with a patient.

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 oral permission sufficient?

A. Oral permission is not acceptable under Pfizer guidelines. 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 a Pfizer name tag at all times during mentorships.

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. Colleagues should never conduct a chart review. In addition, as discussed earlier, Pfizer is generally not a Business Associate of an HCP and, therefore, field-based colleagues must not sign Business Associate Agreements without the prior express consent of their team attorney or the Global Privacy Office.

Consumer Health Fairs or 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 specific discussions regarding a

patient's health. 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 state that the patient should discuss the matter with his or her physician.

For more information on health fairs and screenings, see White Guide Chapter 12: Promotional Interactions with Consumers.

Medical Colleague (e.g., MOS, RMRS) Interaction with Consumers at Health Fairs and Screenings

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. Colleagues are not permitted to practice medicine or provide clinical advice to patients.

Patient Assistance Programs and Protected Health Information

Q. May Pfizer receive Protected Health Information from health plans for the purposes of Pfizer's Patient Assistance Programs?

A. Pfizer's policy is that it may receive PHI from health plans in order to verify an individual's eligibility for Pfizer's Patient Assistance Programs only if the information is transferred to Pfizer with the patient's written authorization and the information received is used solely for the program or other appropriate Pfizer uses explicitly identified on the authorization form. For more information on Pfizer's Patient Assistance Programs, see White Guide Chapter 10: Patient Assistance Programs.

Patient Information and Clinical Trials

Pfizer-sponsored and investigator-initiated clinical study teams are responsible for securing appropriate consent for the use of patient information obtained from clinical trials.

In accordance with DST SOP CT08: Clinical Site Management and Monitoring, clinical study team members must always protect the confidential nature of the Personal Information that they review. If Personal Information is copied or referred to in monitoring reports, appropriate written authorizations must generally be obtained from patients. Although Pfizer is not directly covered by HIPAA, it is subject to other laws which protect the confidentiality of subjects' Personal Information. Pfizer is committed to protecting the privacy and security of the Personal Information generated in clinical

trials, including with respect to the electronic transmission of clinical trial data. Pfizer has established technical, physical, and administrative security measures, which include integrity controls and encryption (where appropriate), to guard against unauthorized access to Personal Information that it electronically transmits or receives.

Use of Data from Clinical Studies

Q. May Pfizer use records from its sponsored clinical studies for marketing purposes?

A. No. Pfizer's policy is that PI in clinical study records may never be used for marketing purposes. Prior to patient enrollment in a clinical study, investigators are required to explain what health information will be collected, how that information will be used, and to whom and for what purposes it will be disclosed. In general, study participant medical data is generated or received by the clinical study investigator and maintained by the investigator during the course of the study. Pfizer does receive a report of study-related data, however, the clinical investigator "de-identifies" the data by replacing the identities of the participants with unique codes. Pfizer does not receive the keys to these codes, nor does the Company receive the names or other contact information of study participants except in very limited circumstances, such as reporting adverse events.

Other Privacy Issues

Healthcare Professional Prescriber Data

From time to time, Pfizer may choose to use de-identified prescriber data to facilitate effective marketing communications with HCPs. HCP de-identified prescriber data serves a variety of purposes, including the tracking of Pfizer-product adverse events and the ability to focus marketing initiatives on HCPs who would most likely benefit from information about a particular Pfizer product.

Certain states have enacted legislation that limits the use of prescriber data in certain contexts, including marketing and promotional activities, unless the HCP provides consent. However, these laws are controversial and have been challenged with success. Pfizer adheres to all applicable state laws regarding the use of prescriber data. Pfizer also respects the confidentiality of this data and shall abide by the wishes of any HCP that asks that his or her prescriber data not be made available to Pfizer Sales Colleagues. Pfizer has also designated the Leader of Commercial Information Management (CIM) in

U.S. Commercial Operations as the internal contact to respond to inquiries regarding Pfizer's policy on the use of prescriber data. Given that this area of law is quickly evolving, Pfizer colleagues must consult with their team attorney or the GPO before engaging in an activity that involves the use or disclosure of prescriber data for marketing or promotional purposes.

Handling Healthcare Professionals and Other Customer's Personal Information

As a general policy, Pfizer restricts access to sensitive information, including Personal 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 to tell stakeholders when such information is lost or stolen. Disclosure of certain types of Personal Information, even if accidental, can expose Pfizer colleagues and, contractors and 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.

Pfizer Policy on Your Responsibility for Safeguarding Personal Information

You are responsible for handling Personal Information in accordance with all applicable Pfizer policies and procedures. You should familiarize yourself with:

- Corporate Policy #403: Acceptable Use of Information Systems;
- Corporate Policy #404: Protecting the Privacy of Personal Information; and
- Corporate Policy #405 : Enterprise Records and Information.

Pfizer's Procedures for Handling Personal Information and Personally Identifiable Information for Colleagues and Contractors provide important guidance about appropriate information handling and security procedures, which include, but are not limited to:

- 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 Handling Sensitive Information Guidelines or speak with your team attorney or the GPO.

FOR MORE INFORMATION

- Corporate Policy #403: Acceptable Use of Information Systems
- Corporate Policy #404: Protecting the Privacy of Personal Information
- Corporate Policy #405: Enterprise Records and Information Management
- Pfizer's Procedures for Handling Personal Information and Personally Identifiable Information for Colleagues and Contractors
- DST SOP CT08: Clinical Site Management and Monitoring
- Refer any questions to the Multi-Channel Management team, your team attorney or the Global Privacy Office

Chapter 12: PROMOTIONAL INTERACTIONS WITH CONSUMERS

CONTENTS

Promotional Interactions with Consumers

Chapter 12: PROMOTIONAL INTERACTIONS WITH CONSUMERS

Introduction

Pfizer interacts with consumers (non-HCPs) at various types of events including speaker programs, health fairs, public screenings, disease management programs and other Pfizer or non-Pfizer events. Laws and industry standards specifically govern promotional interactions with consumers and require that Pfizer treat promotional interactions and activities with consumers differently than those with HCPs. Like interactions with HCPs, however, interactions with consumers can involve promotional risks. The U.S. Department of Health and Human Services' Office of Inspector General has warned that offering incentives to consumers, such as remuneration or free services, may implicate the federal Anti-Kickback Statute. Consumer protection laws that prohibit unfair or deceptive trade practices have been interpreted by some state Attorneys General to encompass off-label promotion.

The FDA has established stringent requirements regarding direct-to-consumer communications. Also, PhRMA has adopted its Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines to provide guidance to Pfizer and other member companies 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. For more information on the development of DTC promotional materials, see White Guide Chapter 2: Advertising and Promotional Materials.

This Chapter summarizes certain Pfizer policies regarding promotional interactions with non-HCP consumers. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination.

Key Points to Ensure Compliance

- Pfizer colleagues may provide occasional meals of minimal value to consumers ($25 or less per person). Meals may never, however, be provided (1) to solicit business; or (2) in a manner that might suggest that the recipient is being bribed or improperly influenced.
- As with speaker programs for HCPs, Pfizer is responsible for the conduct of the speaker and the content of the presentation at speaker programs for consumers. The program and speaker must follow all applicable EZSpeak requirements. The content of a consumer program should be appropriate for a "lay" audience consistent with Pfizer Principles for Clear Health Communication.
- Pfizer sales colleagues may promote Pfizer products at health screenings as long as the exhibit and display booth is physically separate and apart from the screening area.
- 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 may not offer any medical opinions, advice or consultation, even if you have a license to practice medicine or are any type of healthcare professional.
- The Managed Care Review Committee (MCRC) or CGC Legal must approve all disease management program arrangements with managed care organizations. Such arrangements must be documented in a service agreement that sets forth the basis for payment, as well as the program materials.
- Employees are consumers. Pfizer interactions with company employees (such as at a health fair) must conform to the same principles applicable to consumer interactions.

Meals and Items of Value to Consumers

Pfizer may provide occasional gifts or meals of minimal value ($25 or less per person) to consumers. Some examples of such items include providing a modest snack or refreshment (e.g., fruit, granola bars, bottled water) to consumers that visit a Pfizer exhibit or display, or providing a modest meal to attendees at a Pfizer consumer speaker program. However, gifts and meals may never be provided (1)

to solicit business; or (2) in a manner that might suggest that the recipient is being bribed or improperly influenced.

Exhibits and Displays

Pfizer is routinely offered the opportunity to purchase display space (booths) at medical meetings, or sponsor health-related meetings that allow booths or displays. Such events may include health fairs where consumers can be educated about Pfizer and its products.

As long as the Pfizer exhibit booth is separate and not joined with the health screening, Pfizer can provide approved consumer materials at a health fair where Pfizer is also conducting a health screening. However, it should never appear or be the case that Pfizer is conducting the screening in order to drive people to ask their doctor about Pfizer products. Health fairs and public screenings are discussed later in this Chapter. For more information regarding exhibit and display space, see White Guide Chapter 4: Marketing Programs.

Providing Food to Consumers at a Display

Q. I have a 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 heath 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.

Consumer Speaker Programs

A speaker program for consumer audiences is a promotional activity controlled by Pfizer in which an HCP presents a Pfizer RC-approved slide deck intended for consumers. As with speaker programs for

HCPs, Pfizer is responsible for the conduct of the speaker and the content of the presentation to consumers. Pfizer colleagues must adhere to Pfizer policies regarding consumer presentations and EZSpeak procedures to set up the speaker program. All speakers are required to complete training prior to engaging in any speaking engagements on (1) the brand's core product training or topic training slide kit, as applicable; and (2) Pfizer's compliance requirements. The content of a consumer program should be appropriate for a "lay" audience consistent with Pfizer Principles for Clear Health Communication. When developing a consumer speaker program slide deck, Pfizer must be mindful that many consumers have different educational backgrounds and their ability to understand medical information varies.

Slide decks for consumer programs should be designed and executed with the following principles in mind:

- Use easy to follow layouts and simple pictures
- Write information at an appropriate reading level
- Replace complicated medical or technical words with plain language
- Use pictures and diagrams that clarify written concepts
- Focus materials on behavior rather than on medical facts
- Make information culturally sensitive and personally appropriate

Consumer programs should be broadly advertised such that each program will likely result in an audience of at least five consumers. The chosen venue for the program must be conducive to providing educational information. A modest meal of $25 or less in value per person (including food, beverages, tax and tip) may be provided, but Pfizer may not offer entertainment or recreation. Of course, an HCP hired for the program must not provide specific medical advice to a consumer attendee, nor may the speaker use the Pfizer program as an opportunity to promote his or her medical services or practice, or recruit new patients. For more information on speaker programs generally, see White Guide Chapter 4: Marketing Programs.

Health Fairs and Public Screenings

Pfizer colleagues may interact with consumers at health fairs and, at times, organize public screenings. Screenings promote the early detection of diseases and offer patients a meaningful opportunity to treat a disease or condition.

Health screenings fall under two major categories: (1) Screenings offered to employees of a single employer; and (2) screenings offered to the public at large. For both types of screenings, Pfizer colleagues that are present during any patient interactions must clearly identify themselves as Pfizer employees. Wearing a Pfizer name tag at all times is a good way to provide identification. Also, under no circumstances may Pfizer employees offer any medical opinions, advice or consultation, even if the employee has a license to practice medicine or is a type of healthcare professional.

Screenings Offered to Employees of a Single Employer

Pfizer health screenings offered to employees of a single employer promote Pfizer goodwill. The screenings must be conducted by an approved third-party vendor that routinely conducts such screenings and has entered into an appropriate contract with Pfizer (i.e., the vendor must sign Pfizer's form agreement).

These screenings may not be offered for employees of healthcare providers or payers of healthcare items and services, including hospitals, medical practice groups or managed care organizations (MCOs) that seek reimbursement from the federal government. The screening must be limited to current employees and their beneficiaries only, and must expressly exclude retirees who are beneficiaries under the employer's retiree health plan. Also, the screening cannot be organized or designed in any way to generate referrals for any particular customer.

Pfizer Sales Colleagues may 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 the screening event.

Screenings Offered to the Public at Large

Screenings offered to the public at large may be organized by a third party or Pfizer directly. If an IRS 501(c) (3) healthcare-related charitable organization requests Pfizer support for a screening, the request

must be submitted directly by the organization to Pfizer's Medical Education Group (MEG) via the charitable contribution website at www.pfizerhealthcharitables.com. See White Guide Chapter 7: Support of External Organizations, for additional information about healthcare-related charitable contributions.

If a public health screening is organized by Pfizer, the screening proposal must be approved by the management of the team organizing the screening. Like screenings offered to an employer for its employees, the screening cannot be organized or designed in any way to generate referrals for any particular customer. 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 form agreement.

Sales 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. Again, however, no financial ROI analysis can be tied to the screening event. Screenings offered to the public must be advertised and open to the community at large. This means the screening should have a broad, community audience and should not be targeted to members of any particular group. It does not mean that an entire city must be invited, or that the event be advertised in a city newspaper. The public screening must, however, be advertised in a broad manner and not merely at a particular hospital or in particular medical offices. All advertising or publicity materials must be approved by the relevant product Review Committee (RC) or the Corporate and Government Customer RC.

Additional Guidelines for All Screenings

All consumer health fairs and screenings implicate privacy issues when they involve obtaining personal information from individuals. If an individual's affiliation with Pfizer and Pfizer's sponsorship of the screening are disclosed and apparent, a consumer's participation in the event is deemed to be his/her consent to share this personal information with a Pfizer representative. Pfizer's ability to use de-identified data obtained at consumer health fairs or public screenings is strictly limited by the terms specified on Pfizer's Patient Authorization and Release form, which the screening vendor must require that all screening participants sign. You may obtain a copy of the form at http://Betsy.pfizer.com under the "Forms" tab. Aggregated de-identified data can only be provided to an employer and/or managed care customer if the screening participant has signed a Patient Authorization and Release form which

specifically authorizes that the data can be provided to the employer and/or managed care plan managing the Rx drug benefit. For more information on the topic of patient consent, see White Guide Chapter 11: Privacy: Protecting Personal Information.

Health fairs and screenings also raise concerns regarding the doctor/patient relationship. An HCP who works for the screening vendor and provides disease screening services may explain the test results, but cannot prescribe a specific drug or treatment even if licensed to do so. In all cases, consumers should be encouraged to speak to their individual HCPs about the results of the screening.

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 may not offer any medical opinions, advice or consultation even if you have a license to practice medicine or are any type of healthcare professional.

For more information, contact the Consumer Marketing Group or your team attorney.

Managed Care Customer Health Screening

Q. A Managed Care Organization (MCO) would like Pfizer to conduct a disease screening for employees of an employer to which the MCO provides pharmacy benefit services. The MCO also wants Pfizer to provide it with the de-identified, aggregate data from the screening. Can Pfizer organize the screening and provide the data?

A. Maybe. The only reason Pfizer may conduct a disease screening is to improve employee health. Pfizer cannot subsidize the operating expenses of the MCO or the employer by conducting a screening that the MCO would do on its own. If there is an independent valid reason for Pfizer to fund the screening, Pfizer can organize it. If, for example, the employer suggested by the MCO is one of the larger employers in an area, Pfizer would have an independent, valid reason to be screening such a large employee population. Also, if conducted, Pfizer may provide aggregated, de-identified data from the screening to the MCO only if Pfizer's Patient Authorization and Release form has been signed by the screening participant and specifically authorizes Pfizer to provide the data to both the employer and the managed care plan administering the drug benefit. Employees of the MCO are not eligible to participate in the screening and the MCO should not appear as the co-sponsor of the event unless the MCO independently provides funding or services.

Health Screening Vendors

Q. Is there an approved vendor list or list of vendors that can be used to conduct health screenings?

A. No. Some national vendors that have been used in recent years include Vitalogy and Cardinal but Pfizer does not require that these vendors, or even a national vendor, be used. Pfizer does prohibit the use of vendors that are healthcare providers/payers. This policy is intended to protect against the potential risks involved when making payments to such providers/payers, as well as the risks that the use of such providers/payers could be perceived as being aimed at generating patient referrals for such providers/payers. If you are unsure about whether a vendor is a healthcare provider/payer, contact your team attorney.

HCP Screener

Q. Can a doctor or nurse from a healthcare provider/payer, such as a hospital or private practice, conduct the screening free of charge if Pfizer pays for screening materials?

A. No, the screening must always be conducted by a vendor that is not a healthcare provider/payer, even where no payment is being made to the screener.

Product Support Programs

Disease Management Programs

Pfizer or an MCO may at times mail Pfizer RC-approved disease management, patient education materials or other types of branded materials to healthcare providers and/or patients. When arrangements are made to support MCO mailings of materials, the following guidelines should be followed:

- There must be a written service agreement between Pfizer and the MCO that clearly states the services to be provided and the basis for payment;
- The Managed Care Review Committee (MCRC) must approve the proposed arrangement and agreement before any commitment can be made to the MCO;
- The amount paid must be directly attributable to an invoice for mailing costs and calculated on a per-unit (e.g., per letter) basis;

- A lump sum payment to the MCO in excess of actual project costs is not permissible because any excess payment could be interpreted as an attempt to enrich the MCO and as an illegal inducement;
- The proposed mailing must conspicuously disclose Pfizer's financial support; and
- It is preferable, but not required that a third-party mailing operation perform the services and receives the payment.

Sometimes Pfizer is asked to pay the costs of producing and/or mailing materials developed by a health plan or MCO. Whether or not these activities can be funded will depend on the specific facts. Pfizer colleagues should consult the MCRC or CGC Legal for guidance.

Finally, because of privacy concerns, disease management program customer mailings must *not* involve disclosure to Pfizer of patient names and addresses or other personal information. All logistics that could lead to disclosure of sensitive personal information must be handled through the MCO or a third-party mailing operation that has been retained by the MCO.

Medication Compliance Programs

From time to time, Pfizer may want to pay for a medication compliance program to be provided by or through a customer (e.g., a MCO or a pharmacy). These programs usually involve sending scheduled mailings to patients to remind them to fill or refill a prescription to treat a chronic condition. Such programs are appropriate promotional activities, and Pfizer can provide payment on a fair market value basis for the cost of each mailing or contact. The proposed mailings must conspicuously disclose Pfizer's support.

The team RC must approve the program, which must be documented in a service agreement that sets forth the basis for payment, as well as the program materials. If the customer is an MCO, the Managed Care Review Committee (MCRC) or CGC Legal must review and approve the proposed arrangement. Since the use of confidential patient medical information to communicate with patients has privacy implications even if patient identifiable information is not disclosed, please consult the sub-section titled "Pfizer-Sponsored Third-Party Communications" in White Guide Chapter 11: Privacy: Protecting Personal Information.

Sweepstakes and Prizes

Sweepstakes and skill contests are governed by a variety of federal and state laws, including state lottery and sweepstakes laws, state prize notification statutes, state registration statutes, the Federal Sweepstakes Law and the Deceptive Mail Prevention and Enforcement Act (DMPEA). Sweepstakes sponsors may also be defendants in consumer class action suits.

Sweepstakes that are directed to children may also be subject to the Children's Online Privacy Protection Act (COPPA) and the Children's Online Privacy Protection Rule. Generally, sponsors of sweepstakes or contests directed toward children need to get parental consent if the site collects personal information from children, including e-mail addresses. Similar rules may apply to sweepstakes conducted "off-line" (e.g., through the mail or via television advertising). COPPA and other privacy regulations are discussed in White Guide Chapter 11: Privacy: Protecting Personal Information.

The CAN-SPAM Act of 2003, which restricts the transmission of unsolicited commercial e-mail, also regulates how companies may offer prizes and sweepstakes. Further, online sweepstakes and contests may have additional requirements that must be followed. Consult your team attorney if you are considering a sweepstakes or contest.

When designing a sweepstakes program, remember:

- The contest rules are Pfizer's contract with entrants, so it is vital to make sure the rules are very clear and contain all the elements described in the "minimum rules checklist." (The "minimum rules checklist" contains reminders for information that must be included in contest rules, such as "no purchase necessary," "decision of judges are final," "void where prohibited," etc.);
- In a sweepstakes, "consideration" or "substantial effort" (such as a purchase, payment of a fee, or significant expenditure of time) cannot be required in order for the entrant to participate. If consideration is required, then the contest is a lottery (which involves a prize, consideration and chance), and lotteries are illegal unless sanctioned by the government;
- If a sweepstakes requires a method of entry that might constitute consideration (e.g., it requires a significant expenditure of time or effort) the sponsor must also provide an alternate method of entry that does not require consideration; and

- Customer-only sweepstakes are acceptable provided that the sponsor ensures that the customer status was obtained prior to the start of the sweepstakes (i.e., sponsors should not induce anyone to become a customer in order to enter the sweepstakes).

Other questions to ask when designing a sweepstakes or contest include:

- Is the sweepstakes permitted in all areas?
- Does the sweepstakes need to be registered with the state?
- What advertising regulations need to be followed?
- What are the eligibility requirements?
- Is it a sweepstakes or a skill contest? (In skill contests, there is no element of chance or chance does not play a dominant role in determining the outcome.)
- Are all the criteria for winning clear? What is the method of selection?
- Must all prizes be awarded?
- Must a list of winners be posted?
- How must winners be notified?
- Is an appeal process needed?

Pfizer colleagues should be aware that the Federal Sweepstakes Law contains a provision for a private right of action against promoters for individuals who receive mailings after requesting that their names be removed from lists used by such promoter(s). Such an action may seek an injunction and/or recovery of monetary loss or $500 for each violation by the applicable promoter (whichever is greater).

All sweepstakes programs, including rules, prizes and advertising, must be reviewed and approved by the relevant team RC before they may be implemented.

Employees as Consumers

Employers are increasingly making decisions regarding the access their employees have to medicine. As a result, Pfizer colleagues may have an interest in calling on employers to present information about

Pfizer products relevant to the employer in making these decisions. It is important to understand that working with employers has both business and legal risks, which require careful attention.

Employers will often request that Pfizer interact directly with their employees in the interest of providing health education. It is important that Pfizer treat these employees as consumers. Accordingly, Pfizer must ensure that it applies the same principles set forth in this Chapter to its interactions with employees.

Also note that discussions with employees, as consumers, must comply with FDA regulations. For more information on interactions with employer representatives (such as benefit managers and medical/non-medical personnel who play a role in administering health benefits for an employer), see White Guide Chapter 13: Promotional Interactions with Employer Groups.

FOR MORE INFORMATION

- Guidance for the Implementation of the Updated PhRMA DTC Principles
- Pfizer Principles for Clear Health Communication
- White Guide Chapter 7: Support of External Organizations
- White Guide Chapter 11: Privacy: Protecting Personal Information
- White Guide Chapter 13: Promotional Interactions with Employer Groups
- Refer any other questions to Regulatory Affairs or your team attorney

Chapter 13: PROMOTIONAL INTERACTIONS WITH EMPLOYER GROUPS

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Promotional Interactions with Employer Groups

Chapter 13: PROMOTIONAL INTERACTIONS WITH EMPLOYER GROUPS

Introduction

Employers are increasingly involved with decisions regarding their employees' prescription drug benefits. As a result, Pfizer colleagues may at times address the benefits and risks of Pfizer products with employers. It is important to understand that working with employers has both business and legal risks if not done in the appropriate manner. It is also important to distinguish between interactions with employer representatives who make formulary or coverage decisions regarding Pfizer products and interactions with employees who also may be patients taking a Pfizer product.

This Chapter summarizes certain key Pfizer policies regarding interactions with employers and employer representatives. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination.

Key Points to Ensure Compliance

- Coordinate all employer-related activities with the relevant Director, Employers (DE).
- Treat employer representatives as healthcare professionals (HCPs) regardless of professional status. Conversely, treat employees as consumers.
- Always provide a fair and balanced presentation to employer representatives that includes the proven benefits of the product along with a summary of the relevant safety information.
- Treat all employer representatives as if they are subject to federal healthcare laws, including the Anti-Kickback Statute, even those employers that may not participate in government programs.
- When interacting with employer representatives, tailor any product discussion carefully to the representative's background, especially if the employer representative does not have a medical background.

Coordinate with Director, Employers

In order to best leverage existing relationships and avoid providing inconsistent messages, all employer activities should be coordinated with the Director, Employers (DE). DEs (formerly called NEAMs) are Pfizer colleagues in the U.S. Corporate and Government Customers Group (CGC) who are dedicated to working with employers. National DEs work directly with national employers, brokers, employee benefit consultants, unions and national associations and coalitions, and also coordinate with regional account management with respect to regional employers and associations. They work to understand the employer market, develop clear plans, and coordinate implementation of those plans with other colleagues. In many cases, DEs have established relationships with employers, unions or other associations, and have a clear understanding of permissible and impermissible discussions and activities with these individuals and entities.

Treat Employer Representatives (Decision Makers) as HCPs

Pfizer colleagues may interact with medical and non-medical employer representatives, such as CEOs, CFOs, CMDs and benefit managers. These employer representatives play a role in the treatment of patients by influencing the recommendation, purchase, or reimbursement of products. Pfizer policy requires you to treat these representatives as HCPs (not as consumers).

As with other HCPs, Pfizer colleagues must always give a fair and balanced presentation and, for product information, include the proven benefits of the product along with a summary of the relevant safety information. All unsolicited inquiries requesting off-label information about unapproved products or uses must be referred to U.S. Medical Information. Pfizer colleagues must treat all employer representatives as if they are subject to federal healthcare laws, including the Anti-Kickback Statute, even those employers that may not participate in government programs. As a result, Pfizer colleagues may never engage in any actual or perceived quid pro quo, including offering or appearing to offer any remuneration or item of value in exchange for prescription or formulary recommendations or referrals.

Employers and Employees

Q. May Pfizer employees treat employer representatives (decision makers) and employees in the same manner?

A. No. Pfizer colleagues must treat employer representatives as HCPs. Employees should be treated as consumers. When interacting with employer representatives, however, Pfizer colleagues must tailor any product discussion carefully to the representative's background, especially if the employer representative does not have a medical background.

Tailor Discussion to Individual Employer Representative

When interacting with employer representatives, Pfizer colleagues must tailor any product discussion carefully to the representative's background, especially if the employer representative does not have a medical background. Use appropriate, approved employer market-specific tools when working with employers, since resources that are designed for other audiences may not resonate with these customers.

Benefit Managers

Benefit managers may want to discuss the coverage offerings and access availability for Pfizer products. As with HCPs at medical groups or hospitals, Pfizer colleagues may engage in discussions about coverage and access, provided that their statements are truthful, accurate and not misleading, and that Pfizer colleagues only use approved materials, such as approved access grids. Pfizer colleagues may not direct employers to a specific PBM/HMO, or encourage an employer to switch to a different PBM/HMO. Pfizer colleagues may not discuss whether or not Pfizer has a rebate agreement with a particular PBM/HMO or any of the contractual terms with any employer, even if the employer is a customer of the PBM/HMO in question.

State/Municipal Employees

Some of the larger employers in an area may be public entities, such as state universities, state agencies or municipalities. Interacting with these employers may subject you to additional guidelines relevant to interacting with public employees, such as restrictions on gifts or meals or reporting obligations arising from lobbying laws. For more information, see White Guide Chapter 15: State Law:

HCP and State Employee Restrictions, and White Guide Chapter 16: Federal Employee Interactions and Lobbying. Pfizer colleagues should consult with the Government Relations Director or Legal before interacting with a state or municipal employer.

Unions

Certain interactions with unions are subject to federal reporting obligations and possibly other limitations. Pfizer colleagues should check with a DE and Legal before interacting with any union representative.

Brokers and Consultants

When interacting with employer groups, Pfizer colleagues may come in contact with employee benefit consultants or brokers. There are national DE leads specifically assigned to work with brokers and consultants. To ensure that Pfizer presents a consistent message, Pfizer colleagues must consult with their DE before interacting with any broker or consultant. Pfizer colleagues may not direct or influence employers to work with a specific broker or consultant.

Materials Used With Employers

Q. What type of information may Pfizer provide to employer representatives?

A. Pfizer may only use RC-approved materials when interacting with employer representatives. However, keep the employer representative's background in mind when deciding which materials to use, especially if the employer representative does not have a medical background. Consider using the tools that have been specially developed for use with employers. As always, all product information must be on-label, fair and balanced, and must include the proven benefits of the product along with a summary of the relevant safety information.

FOR MORE INFORMATION

- Contact a member of the Director, Employers team or a CGC attorney
- White Guide Chapter 3: Promotional Interactions with HCPs
- White Guide Chapter 12: Promotional Interactions with Consumers
- White Guide Chapter 15: State Law: HCP and State Employee Restrictions
- White Guide Chapter 16: Federal Employee Interactions and Lobbying
- The Orange Guide

Chapter 14: STARTERS

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Starters

Chapter 14: 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 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 puts 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 who 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 Starter Operations and the responsible District Manager. Significant losses and thefts must be reported by the Starter Operations 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 his or her 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. Sales Colleagues should check with their manager, Starter Operations, or Regional Attorney or 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 Starter

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 a 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 with 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 a 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 Program 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 White Guide Chapter 6: Government Healthcare 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

- Questions may be referred to Starter Operations, the relevant Sales manager, Regional Attorney or team attorney.
- 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.

Chapter 15: STATE LAWS: HCP AND STATE EMPLOYEE RESTRICTIONS

CONTENTS

State Laws: HCP and State Employee Restrictions

Chapter 15: 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 in which 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 laws puts the Company at risk and can subject Pfizer colleagues to disciplinary action 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 OpSource.pfizer.com
- 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
California	Companies shall adopt a comprehensive compliance program which sets specific dollar limits on gifts, promotional materials and activities.	Accurately and completely record all expenditures on HCPs. Monitor expenditures per HCP and coordinate with your colleagues to ensure compliance with Pfizer's annual limit of $3,500 per CA HCP.
Connecticut	The Connecticut Compliance Program Law requires companies to adopt a marketing code of conduct – the PhRMA Code is acceptable.	No specific requirements other than follow all Pfizer policies and procedures and the PhRMA Code.
District of Columbia	All representatives must secure a license to legally detail in person in D.C. Companies must report certain marketing costs. Members of the D.C. Medication Advisory Committee must not receive gifts, including meals or remuneration, for speaking or consulting.	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. Accurately and completely record all HCP expenditures. Do not provide any gift to any member of the Medication Advisory Committee, no matter how nominal the value.

State	Important Provisions of the State Law	Key Points to Ensure Compliance
Massachusetts	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). Pfizer must give HCPs the opportunity to withhold prescriber data. Pfizer must report certain HCP expenditures to MA.	Do not invite MA HCPs to out-of-office speaker programs that provide meals (even if the program is conducted outside of MA). Do not provide MA HCPs with out-of-office meals or snacks (except snacks in a convention setting). Accurately and completely record all expenditures on HCPs. 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 OpSource.pfizer.com or under the Compliance tab on PfieldNet. You can also check iCUE, which flags most (but not all) MA HCPs. You must make a good faith effort to determine whether an HCP is licensed in MA.

State	Important Provisions of the State Law	Key Points to Ensure Compliance
Minnesota	Gifts to practitioners are prohibited. Pfizer policy prohibits HCP meals to MN practitioners, including nominal meals and snacks. Pfizer policy prohibits providing text books, journal subscriptions, online subscription services (e.g., Epocrates), and anatomical models, to MN practitioners. Pfizer policy also prohibits engaging MN practitioners as paid consultants, except for the following type of projects: • R&D, clinical, or development-related projects • Outcomes Research or medical publication-related projects • Speaking and Speaker training Pfizer must report permissible non-gift expenditures that exceed $100/year.	Do not invite MN practitioners to any speaker programs that provide meals (even if the program is conducted outside of MN). Unless an exception applies, do not provide MN practitioners with meals or snacks. Do not provide MN practitioners text books, journal subscriptions, online subscription services (e.g., Epocrates, including trial memberships), or anatomical models. Do not engage MN HCPs as commercial consultants. 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. You must make a good faith effort to determine whether an HCP is licensed in MN. Accurately and completely record all practitioner expenditures.

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
Vermont	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). 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. Pfizer must report certain HCP expenditures, as well as samples, coupons and vouchers, to VT. Price Disclosure Forms must be provided to HCPs when detailing and posted on Pfizer's website.	Do not invite VT HCPs to any speaker programs that provide meals or snacks (even if the program is conducted outside of VT). Do not provide VT HCPs with meals or snacks (except refreshments or snacks in a convention setting). Do not engage VT HCPs as part of any paid marketing research surveys. Accurately and completely record all HCP expenditures, as well as samples, coupons, and vouchers provided to VT licensed HCPs. 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 OpSource.pfizer.com or under the Compliance tab on PfieldNet. Also, iCUE flags most (but not all) VT HCPs. You must make a good faith effort to determine whether an HCP is licensed in VT. Provide VT Price Disclosure Forms to HCPs as appropriate (available on PfieldNet).

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 is 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 healthcare 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 proceeding 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 employees cannot be engaged as promotional speakers for Pfizer.

The Louisiana Board of Ethics has stated, however, that a public servant 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 textbooks, 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 HCP 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 the 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 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 16: FEDERAL EMPLOYEE INTERACTIONS AND LOBBYING

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Federal Employee Interactions and Lobbying

Chapter 16: 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 professionals (HCPs) 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 Pfizer 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;
  - 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 from 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, 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 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 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 at $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.

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

- Federal Employee Interaction Questions may be referred to your manager or team attorney.
- 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.

Chapter 17: PUBLICATIONS

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Publications

Chapter 17: PUBLICATIONS

Introduction

As part of its commitment to publishing the results of company-sponsored clinical research studies, Pfizer supports the publication of manuscripts associated with these studies. Pfizer also supports other types of publications, such as abstracts, congress presentations and review articles.

This Chapter summarizes policies and procedures for managing Pfizer-supported publications, including author selection, informing external authors of Pfizer's publication policies, payments to authors (where applicable), contracts with authors, manuscript development and disclosure of Pfizer support.

Publications subject to the requirements of this Chapter include:

- Submissions to peer-reviewed medical and scientific journals, such as primary and secondary manuscripts, review articles, letters to the editor;
- Submissions to scientific congresses, such as abstracts, posters and presentations;
- Book chapters; and
- Those associated with Pfizer-sponsored clinical trials, as well as pre-clinical studies involving a Pfizer-marketed product.

Pfizer colleagues, external authors and the parties with which Pfizer contracts (e.g., publications agencies), who are involved with Pfizer-supported publications must understand Pfizer's publications policies. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination.

Key Points to Ensure Compliance

- **Publications are not marketing tools**. While they may eventually be used in a promotional context, the planning and development of a publication must be true to the data and independent of commercial strategy or messaging.
- Each member of a Publications Subcommittee must understand his or her role and responsibilities and the applicable Pfizer policies.
- Marketing representatives must not influence the publication planning process or content of publications.
- The selection of authors must be consistent with the International Committee of Medical Journal Editors (ICMJE) authorship criteria and all applicable disclosure obligations. Only those contributors who meet the following conditions may be considered authors: (1) Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; (2) Drafting the article or revising it critically for important intellectual content; and (3) Final approval of the version to be published.
- Pfizer colleagues may be listed as authors if they satisfy the ICMJE criteria for authorship. General supervision of a research group that is conducting or supervising a project is not sufficient for authorship.
- In those rare circumstances in which healthcare professionals or healthcare institutions are paid to author or produce publications, Pfizer must ensure those payments are consistent with a fair market value determination and other applicable requirements of Pfizer policy, including Pfizer's Global Policy in Interactions with Healthcare Professionals (GPIHP) and Anti-Bribery and Anti-Corruption Policies and Procedures. Pfizer does not compensate authors who are investigators of a Pfizer-sponsored clinical study for work associated with the preparation of the primary abstract, congress presentation, or manuscript for the study.

First and foremost, Pfizer publications are not marketing tools. Publications are disclosures consistent with Pfizer's commitment to data transparency. While a publication may eventually be used in a promotional context, the planning and development of a publication must be true to the data and independent of commercial strategy or messaging. Second, Pfizer colleagues must ensure that any engagement of healthcare professionals (HCPs) or healthcare institutions (HCIs) to author or produce publications does not give rise to inappropriate financial relationships with or influence over HCPs.

Importantly, the process by which authors are selected and compensated, if not structured appropriately, may violate the federal or various states' anti-kickback statutes. For example, if an HCP is being paid to author publications but in reality is just "rubber-stamping" an article written by a third party, the government may look to whether that HCP has been chosen and/or paid as an inducement for his continued or increased prescribing of a particular product.

Even if an HCP has made some contribution to the development of a publication, the government may look to whether any compensation received was based on fair market value (FMV), or could instead be viewed as a potential kickback.

Similarly, omitting an individual's name from a scientific article where the individual has contributed materially to that article may be viewed as a form of research misconduct.

Publication Planning

Pfizer publication activities involving a payment to an author are subject to a **needs assessment process** prior to engagement of any HCP or HCI to work on a publication. The needs assessment must include specific details about the publication activities to be performed (e.g., a description of the proposed work to be done, the type of work product to be generated and the purpose for the work). Currently, the needs assessment must be documented using the "Development & Publications Business Rationale / Needs Assessment Form" available on the InterAct website. Legal approval is required if the proposed publication relates to a Pfizer marketed product.

Further, publications supported by a Pfizer product team should be managed by the product's Publications Subcommittee (PSC) responsible for developing and implementing the publications plan for a product within Pfizer. The PSC is a multidisciplinary committee that is convened regularly. The PSC's purpose is to ensure that clinical study results are published, to identify gaps in medical

knowledge about the product, and to determine whether existing science can address those gaps through a Pfizer-supported publication.

The PSC is chaired by the Clinical/Medical Lead responsible for the oversight of the publication program for a product, and includes Medical or Clinical Directors (who can also be ad hoc members), a Biostatistician and a Publications Specialist.

Marketing representatives are not permitted to:

- Influence the decision-making process as it relates to publications planning;
- Make decisions regarding prioritization of publications;
- Select congresses, authors or journals;
- Author a medical or scientific publication;
- Comment on draft publications;
- Contract with a vendor for a publication; or
- Liaise with vendors or authors to discuss publications.

Authorship and Disclosures

Pfizer has adopted the authorship criteria established by the International Committee of Medical Journal Editors (ICMJE) and the Pharmaceutical Research and Manufacturers of America (PhRMA) Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results. According to these guidelines, authors should meet all three of the following conditions:

- Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
- Drafting the article or revising it critically for important intellectual content; and
- Final approval of the version to be published.

Only individuals who meet all of the ICMJE criteria should be named as authors on medical/scientific publications. All those who deserve authorship based on these criteria should be named in the byline.

If a Pfizer employee meets the criteria for authorship, he/she should be listed as an author. All those who do not deserve authorship but have contributed in some way to the publication should be acknowledged elsewhere, as appropriate. Importantly, pursuant to the ICMJE criteria, general supervision of the research group that is conducting or supervising a project is not sufficient for authorship. Similarly, participation solely in the acquisition of funding or collection of data does not justify authorship. All individuals providing editorial support must work under the direction of the authors.

In addition to the ICMJE criteria, authors of a Pfizer-supported publication must fully comply with all applicable disclosure obligations that may be externally imposed on them based on their affiliation with any publication, HCI, medical committee, or other medical/scientific organization, including biomedical journals, with which the author is affiliated. The authors should also obtain and adhere to the requirements for acknowledging financial and material support of the journal to which a publication is being submitted. Authors must acknowledge in the publication the individuals who provided editorial support, the funding source, and the author's relationship with Pfizer. Authors must also determine the content and type of publication, the order of names on the byline, and the journal for submission. All potential external authors should be given sufficient time to review and approve a manuscript.

Pfizer's Policy on Public Disclosure and Authorship includes specific recommended wording for disclosure/acknowledgement statements in a variety of situations. For example, where a publication reports the results of a Pfizer-sponsored study, the statement should read, "This study was sponsored by Pfizer Inc." See the CT20 USA-11 Implementation Guideline for additional examples of suggested disclosure wording.

Prior to, or during, publication development, the Publications Specialist (or designee) is responsible for ensuring that a letter is sent to each potential external author that describes, and requests their acknowledgment of, Pfizer's policies on authorship and disclosure of Pfizer support. Also, prior to submission, the Publications Specialist must perform a final check to ensure that the publication is compliant with Pfizer's policy and that the data are accurate and support the statistical interpretation.

Contracting and Payments to Authors

In general, Pfizer does not compensate authors for work associated with the development of publications. In certain circumstances, however, Pfizer may pay authors for services in connection with the development of a publication so long as the individual is providing legitimate services or work product to Pfizer, e.g., preparation of a review article, supplement or manuscript, abstract or congress presentation where the author was not a study investigator (if a primary publication).

All compensated external authors of Pfizer publications must enter written agreements describing the scope of work to be performed, the fees to be paid in connection with the publication, and the compliance obligations of the authors, including representations that they will adhere to the authorship criteria and disclosure obligations described above.

For payments related to the development of a publication, Pfizer must contract with and make payments to HCPs and HCIs directly. A vendor may not contract with and may not make payments to an HCP or an HCI on Pfizer's behalf.

Any payments to authors must be in accordance with a centrally managed, pre-set rate structure that is determined based on an FMV analysis conducted by Pfizer, and all payments to HCPs or HCIs must be recorded and disclosed.

Requests for payments from authors that are greater than $4,000 per abstract, $10,000 per poster, and $25,000 per manuscript must be approved by Legal.

Note that Pfizer does not compensate authors for their time presenting a poster or an oral presentation at a congress. However, Pfizer may provide authors with funding for registration and travel associated with such congress presentations. Such funding may only be granted if the presentation satisfies a bona fide business purpose set forth in a Business Rationale Form approved by Legal. Colleagues must contact a Publications Specialist for support.

Supplements

Journal supplements are collections of papers that deal with related issues or topics, published as part of a regular issue of a journal or as a separate issue, which are usually funded by sources other than the journal's publisher. Pfizer-sponsored/funded supplements are permitted under Pfizer policy. However, because supplements are a paid communication mechanism, they are viewed as intrinsically promotional in nature. As a result, supplements cannot contain off-label information or information about products that are not yet approved. To ensure compliance with this restriction, an overview or synopsis of the supplement must be reviewed and approved by Legal prior to contracting. The needs assessment process must also be completed if an HCP or HCI will be engaged to develop the supplement. All contracts must ensure that Pfizer has the final say as to the supplement contents. In addition, unlike other types of publications, supplements must be reviewed by the relevant product Review Committee prior to final submission to the journal, where Marketing has an opportunity to review the supplement. Because Medical is the common point of contact between the PSC and RC, it is Medical's responsibility to ensure the PSC-reviewed supplement comes to RC.

Publication of IIR Study Results

As with publications related to the results of Pfizer-sponsored studies, Pfizer supports the exercise of academic freedom and encourages investigators to publish the results of an Investigator-Initiated Research studies (IIRs), whether or not the results are favorable to a Pfizer product. Also, as with Pfizer-sponsored studies, as part of the IIR process, Pfizer requests an opportunity to review proposed publications or other public disclosures of the results of the project prior to publication. Pfizer also expects the investigator or institution to comply with recognized ethical standards concerning publications and authorship, including the disclosure of Pfizer support of the study in any publication of study results.

Support for and management of IIRs and IIR publications (as well as publications related to Pfizer-sponsored studies) is described in White Guide Chapter 9: Clinical Research and Investigator-Initiated Research.

FOR MORE INFORMATION

- Policy on Public Disclosure and Authorship (DST SOP CT 20)
- DST SOP CT 20 USA-11, Publications Policies and Procedures
- Other DST SOP CT 20 Implementation Guidelines
- ICJME Guidelines on Authorship and Contributorship
- PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results
- Refer any other questions or concerns to a member of Pfizer's Publications Management Team/External Medical Communications or your team attorney

Chapter 18: MEALS, EDUCATIONAL ITEMS, AND HCP PAYMENT DISCLOSURE

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Meals, Educational Items, and HCP Payment Disclosure

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 action 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 representatives 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

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 <u>any</u> 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 PhrmaCode@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 White Guide and Orange Guide Chapters on Clinical Research and Investigator-Initiated Research 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 x 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/about/principles-guidelines/code-interactions-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 OpSource.Pfizer.com, or e-mail PTI@Pfizer.com