



# The Orange Guide

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Living our value of Equity requires that we act with integrity. One way we demonstrate our commitment to integrity is by complying with laws and the rules governing our business. Compliance with these laws builds trust with patients, Healthcare Professionals, institutions, purchasers, and the government. It is also critical to achieving our purpose of *breakthroughs that change patients' lives*.



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## **CHAPTER #1 – OVERVIEW AND KEY PRINCIPLES**



Chapter

#1

OVERVIEW AND KEY PRINCIPLES

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## Chapter #1 Overview and Key Principles

### Introduction

Living out value of Equity requires that we act with integrity. One way we demonstrate our commitment to integrity is by complying with laws and the rules governing our business. Compliance with these laws builds trust with patients, **Healthcare Professionals (HCPs)**, institutions, purchasers, and the government. It is also critical to achieving our purpose of *breakthroughs that change patients' lives*.

All Pfizer colleagues must understand how the laws, regulations, guidance, and industry codes that govern our business apply to their roles, including, but not limited to:

#### Key Healthcare Laws

- Anti-Kickback Laws (state and federal)
- Medicaid Best Price Law & Medicare Part D Regulations
- FDA Laws & Regulations
- Federal and State Pharmaceutical Disclosure and Compliance Laws

#### Other Key Laws

- False Claims Act
- Privacy Laws
- State Consumer Protection Laws
- Foreign Corrupt Practices Act

#### Industry Codes, Guidance, and Government Agreements

- PhRMA Code on Interactions with Healthcare Professionals
- PhRMA Guiding Principles on Direct to Consumer Advertising
- OIG Compliance Program Guidance for Pharmaceutical Manufacturers
- Pfizer's Corporate Integrity Agreement and State Attorneys General Agreements



**Anti-Kickback Laws:**

Make it illegal to offer to pay or provide anything of value knowingly and willfully in order to induce an individual or entity to recommend or prescribe a product or service that is reimbursed by the government. It is also illegal to ask for or receive a payment in exchange for prescribing or recommending a product or service that is reimbursed by the government.

**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 help ensure that your activities comply with these laws, regulations, guidance, industry codes, any applicable CIAs and State Attorneys General Agreements. Alternative approaches may be permissible in particular circumstances if approved by Legal.

Non-compliance with these policies can subject Pfizer colleagues to disciplinary action up to and including termination of employment. 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.

### Field Commercial Colleague Roles

While integrity is required of, and the laws discussed in this Chapter apply to, all Pfizer colleagues, the Orange Guide is designed specifically for U.S. field commercial colleagues (“**Field Commercial Colleagues**”) to help guide them in the appropriate conduct of their responsibilities. Field Commercial Colleagues are Pfizer colleagues whose primary responsibility is to interact with Pfizer customers. Field Commercial Colleagues include, but are not limited to, Pfizer Sales Colleagues (e.g. Sales Representatives,



Area Business Managers (ABMs), Regional Business Directors (RBDs), Account Managers (e.g. Key Account Managers (KAMs), Vaccines Account Managers (VAMs), Vaccines Account Directors (VADs), PCA Account Directors, and Patient Support Roles (e.g. field reimbursement managers).

### **Sales Colleagues**

Generally speaking, when used in this Guide, the term “**Sales Colleague**” refers to those Field Commercial Colleagues, and their managers, who are charged with the promotion of Pfizer products to drive sales in assigned accounts and with assigned targets. Sales Colleagues engage, influence, educate and, support customers throughout the selling process. For Sales Colleagues, customers are generally individual HCPs. In this context, HCP is a broad term that includes any individual who directly interacts with patients or has a role in patient diagnosis or treatment. Most crucially, Sales Colleagues are typically compensated based in part on sales credit and quota. As of this writing, Sales Colleagues include, but are not limited to, Pfizer Sales Representatives, OASs, HASS, DBMs, and RMs. Sales Colleagues’ focus on individual HCPs and the manner in which Sales Colleagues are compensated differ from Account Managers, as discussed below.

### **Account Managers**

The term “**Account Manager**” refers to Field Commercial Colleagues whose primary focus is calling on and developing productive relationships with key decision makers at Integrated Delivery Networks (IDNs), large medical groups, specialty and retail pharmacies, health plans (e.g., Health Maintenance Organizations (HMOs), Pharmacy Benefit Managers (PBMs), and other managed care entities), state departments of health, county/city health departments, purchasing groups, Group Purchasing Organizations (GPOs), military accounts (VA/DoD), Medicare, Medicaid, and advocacy groups/coalitions (“**Accounts**”). Key decision makers may include persons serving in an executive or administrative capacity at an account but would not typically include individual prescribing HCPs. The responsibilities of an Account Manager include establishing and maintaining product access, leveraging compliant clinical and financial information, leading the coordination of appropriate advocacy, and working cross-functionally to capitalize on synergistic opportunities within assigned Accounts. Account Managers are assigned to Accounts and not individual HCPs. Of critical importance is the manner in which Account Managers are compensated; Account Managers do not have credit or quota. Rather, their compensation is based in part on the achievement of business goals and objectives, some of which may be tied to achievement of sales goals achieved more broadly by the Account Manager’s Business Unit, region, or district. At the time of this writing, Account Managers includes, but is not limited to, Account Directors, Key Account Managers (KAMs), HIT Specialists and Vaccine Account Management roles).





The differences between Sales Colleagues and Account Managers also extend to the resources they may use with their respective customers and the types of customer engagements in which they may participate. Resources approved for use by Sales Colleagues with customers are predominantly promotional and specific to a Pfizer biopharmaceutical product or a therapeutic area associated with a product. In contrast, Account Manager resources generally are above brand and intended to educate customers, benefit patients, and improve patient outcomes by promoting wellness, disease prevention, patient awareness, and high quality health care (See Orange Guide Chapter 14: Organized Customer and Payer Tools and Resources for additional information). Furthermore, while Sales Colleagues typically engage in face-to-face product details with individual HCPs, Account Managers may engage Accounts on matters relating to health systems and medical groups (See Orange Guide Chapter 5: Interactions with Health Systems and Medical Groups), Contracting (See Orange Guide Chapter 12: Discount and Rebate Contracting), and Quality Engagements (See Orange Guide Chapter 14: Organized Customer and Payer Tools and Resources). See the Chart below for a high level description of differences between Sales Colleagues and Account Managers.

### Patient Support Roles

Pfizer is committed to supporting patient access to the medicines prescribed by HCPs in a manner consistent with all applicable laws and regulations. As part of this commitment, some Pfizer brands may offer brand-specific reimbursement and patient support activities that are carried out by field-based colleagues (hereinafter "Patient Support Roles"). Generally, Patient Support Roles are field-based commercial roles that seek to expand access to, reimbursement of and education about Pfizer products in a non-promotional manner. As of the publication of this chapter, Patient Support roles include Field Reimbursement Managers ("FRMs"), Clinical Educators ("CEs") and Patient Affairs Liaisons ("PALs"). Patient Support Role activities are intended to facilitate patient access to Pfizer medicines and associated patient support programs when a Pfizer medicine is prescribed by a patient's HCP, or to provide training and/or education regarding relevant Pfizer products or therapeutic areas. Although Patient Support Roles are commercial roles, they are separate from the sales organization and are not intended to promote Pfizer products.



Typical Characteristics of Roles		
	Sales Colleague	Account Manager
Compensation	Includes Sales Credit and Quota ( i.e. a product Rx sales target for assigned customers).	Exclusively Business Goals and Objectives (without an assigned Sales Credit and Quota).
Customers	Individual HCP.	IDNs, Health Plans, Employers, Group Purchasing Organizations.
Tools (examples)	Promotional Visual Aid.	Organized Customer Tool (see Orange Guide Chapter 14: Organized Customer and Payer Tools and Resources).
Engagements (examples)	Face-to-face product detail to educate HCPs about the benefits and risks Pfizer products may have for individual patients.	Generally, C-Suite level interactions to discuss population health, Collaborations (see Orange Guide Chapter 5: Interactions with Health Systems and Medical Groups), Contracting (see Orange Guide Chapter 12: Discount and Rebate Contracting), and Quality Engagements (see Orange Guide Chapter 14: Organized Customer and Payer Tools and Resources).

In addition, the differences between the Sales Colleague and Account Manager roles require that they interact with internal Pfizer colleagues, and particularly with Field Medical Colleagues, differently. For purposes of this guide, “**Field Medical Colleagues**” include Field-Based Medical Directors (FMDs), Medical Outcome Specialists (MOSs), and Health Data Analytics Specialists (HDAS). Interactions between Field Commercial Colleagues and Field Medical Colleagues must be limited so as to preserve the independence of Field Medical Colleagues. Field Commercial Colleagues may not, nor should they appear to, direct the activities of Field Medical Colleagues. For this reason, internal interactions between Field Commercial Colleagues and Field Medical Colleagues and external interactions between such colleagues and Pfizer customers must be carefully considered to ensure the content and context of the medical activity is appropriate. Further distinctions in how Sales Colleagues and Account Managers may interact with Field Medical Colleagues are discussed throughout the Orange Guide.



The differences between Sales Colleagues and Account Managers are driven not only by business needs but also the need to mitigate inherent risks specific to each role in customer interactions. Therefore, while the laws and policies discussed in the Orange Guide apply to all Field Commercial Colleagues, application of those laws and policies may differ depending on whether the Field Commercial Colleague is a Sales Colleague or an Account Manager. Where relevant, the Orange Guide tailors its guidance for the two distinct Field Commercial Colleague roles. Except where a unique policy or application of a policy to one of the roles is called out, one should assume that the Orange Guide policy applies in the same manner to both Sales Colleagues and Account Managers.

**The Orange Guide is an overview of the laws, regulations, and policies that govern the activities of Field Commercial Colleagues. It is not intended to cover every activity or issue that may present itself. Just because an activity is not specifically prohibited by the Orange Guide does not mean it is permissible or compliant. As compliance is everyone's responsibility you are expected to apply the principles in the Orange Guide broadly and seek guidance from your manager or team attorney if you have a question.**

### Overview of Key Healthcare Laws and Regulations

#### ***Anti-Kickback Laws***

An HCP's treatment decisions should not be tainted by motives of personal gain or enrichment. Federal and state anti-kickback laws seek to eliminate improper influences on healthcare decisions, to reduce the overutilization of services and to prevent patient harm. These laws make it illegal to offer to pay or provide anything of value knowingly and willfully to induce an individual or entity to recommend or prescribe a product or service that is reimbursed by the government. It is also illegal to ask for or receive a payment in exchange for prescribing or recommending a product or service that is reimbursed by the government. In certain states, relevant anti-kickback laws also punish the transfer of remuneration to induce business that is payable by a commercial insurer (not just government-funded healthcare plans). The anti-kickback laws prohibit such activities as:

- Providing a gift, payment, or anything of value to an HCP (including a pharmacist) intended to influence the prescribing, dispensing, or recommending of pharmaceutical products;
- Providing a gift, payment, or anything of value 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;



- 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 in exchange for prescribing or giving favorable treatment to a Pfizer drug; and
- Providing valuable services for free or below **fair market value** to an HCP or other customer with intent to induce prescriptions for Pfizer products.

Similarly, U.S. law provides for the imposition of civil monetary penalties against any person who offers or transfers "remuneration" to a Medicare or state healthcare program (including Medicaid) beneficiary that is likely to influence the beneficiary's selection of a particular provider or supplier of healthcare product or service that is reimbursed by a federal healthcare program.

#### **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 any person or entity in a position to purchase, prescribe, endorse, or recommend our products fair market value for the good or service Pfizer receives in return. For example, Pfizer must pay HCPs fair market value compensation for speaking and consulting services. Similarly, for example, Pfizer must pay a Specialty Pharmacy fair market value compensation for any prescribing data Pfizer wishes to purchase from it.

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 healthcare programs. Indeed, as noted above, certain states punish exchanges of value with HCPs and other customers even where the services are paid for by commercial insurers (and not just by government healthcare 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. Because the federal Anti-Kickback Statute is an intent-based statute, failure to satisfy a safe harbor does not mean the conduct is illegal. Because of this, the Pfizer Legal Division is required to provide guidance on the analysis for each arrangement or activity that potentially implicates the Anti-Kickback statute.



#### HHS

United States 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 and Management Contracts safe harbor:** Protects legitimate service arrangements recorded in a written agreement where the compensation is determined in advance and is based on fair market value for the service. This safe harbor is applicable in Pfizer's engagement of HCPs for consulting and speaking services as well as other entities from whom Pfizer may purchase services and that are in a position to purchase, prescribe, endorse, or recommend Pfizer products.

### Federal Health Care Programs

Many federal healthcare programs, such as Medicaid and Medicare, purchaser prescription drug products or reimburse for their purchase. Under Medicaid, the government covers the cost of prescription medicines for low income and disabled patients. Since 2006, Medicare coverage has included outpatient prescription medicines purchased by eligible senior citizens through a pharmacy.

Pharmaceutical manufacturers additionally 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 (VA)** and the **Department of Defense (DoD)**, as required by statute. Companies also provide discounts under the **Public Health Services 340B Outpatient Drug Discount Program**, as well as through 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, a failure to provide the government with preferential pricing in certain situations may expose a manufacturer to liability under various federal and state laws. The government's increased role in purchasing or reimbursing for 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. It is critical that Pfizer remain vigilant of – and responsive to – all federal and state laws that may be implicated while doing business with the government.

### ***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 account for discounts or other price concessions accurately could result in inaccurate price reporting to the federal government. This could occur if, for example, Pfizer mischaracterizes discounts provided to a managed care or retail customer, such as through a rebate disguised as an educational grant or by paying more than fair market value for a service that Pfizer purchases from a Specialty Pharmacy in order to reduce the net cost of the Pfizer products that organization purchases. If Pfizer reduces the net cost in this way without accurately reporting such discounts to the federal government, Medicaid could end up paying more for the Pfizer products than the managed care or retail customer, a violation of 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: Discount and Rebate Contracting and White Guide Chapter 6: Government Healthcare Programs.

### ***Medicare Part D Regulations***

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

MA-PDs and PDPs are private health plans that 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” that they receive from pharmaceutical companies. Accordingly, Pfizer must 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 promotional labeling 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

United States federal agency responsible for regulation of most foods, dietary supplements, drugs, vaccines, biological medical products, blood products, medical devices, radiation-emitting devices, veterinary products, and cosmetics.

## Advertising

The FDA also strictly regulates the “**advertising**” of all prescription drug products marketed in the United States.

### Advertising

Includes advertisements published in journals, magazines, newspapers, and other periodicals, as well as broadcast media such as radio, television, and telephone.

All Pfizer promotional materials (whether in print or electronic form)—including all visual aids, brochures, journal advertising, promotional programs, and other sales aids—must be consistent with the product's FDA-approved labeling, contain balanced statements about the product's benefits as well as risks, be truthful and not misleading, and supported by substantial evidence. In addition, all promotional materials, unless **Reminder Advertisements** or **Reminder Labeling**, must also include the product's **Prescribing Information (PI)** or, for print advertisements making product claims, a **Brief Summary** that includes a drug's side effects, contraindications, and effectiveness.



Field Commercial Colleagues must adhere to the policies set forth in Orange Guide Chapter 2: Detailing to HCPs, and all other colleagues must adhere to the policies set forth in White Guide Chapter 2: Advertising and Promotional Labeling, White Guide Chapter 3: Promotional Interactions with Healthcare Professionals, White Guide Chapter 12: Promotional Interactions with Consumers, and White Guide Chapter 13: Promotional Interactions with Employer Groups, and any other relevant policies and guidance.

### Promotional Labeling

The FDA strictly regulates the “**labeling**” of all prescription drug products that Pfizer markets in the United States, including “promotional labeling.”

#### Labeling

Includes all “labels and other printed, written or graphic matter: (1) upon any article or any of its containers or wrappers, or (2) accompanying such article” including sales materials in the Veeva CRM system and other promotional materials.

### 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 any individual (including physicians) 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 provided to an HCP for the wrong reason. Starters should never be distributed to benefit an HCP personally or to induce an HCP to prescribe our products. 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. Depending on state law, not all HCPs may accept starters. For more information on how to develop a compliant starter strategy, see the Starters Chapter 10 in this Guide.

### Federal and State Pharmaceutical Disclosure and Compliance Laws

Pharmaceutical manufacturers operating in the United States are required to submit reports to the government regarding payments and other transfers of value made to U.S.-licensed physicians and





teaching hospitals under the transparency provisions of the federal Patient Protection and Affordable Care Act (often referred to as “**Open Payments**” or “**Sunshine Act**”). In addition, a growing number of states and even municipalities regulate pharmaceutical companies’ interactions with HCPs. These state and municipal laws and regulations include disclosure of payments made to HCPs, restrictions or prohibitions on gifts and meals, 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 law or regulation.

For more information on whether your activities are affected by federal or state pharmaceutical disclosure requirements or state compliance laws, see the Meals, Educational Items, and HCP Payment Disclosure Chapter and the State Laws: HCP and State Employee Restrictions Chapter in this Guide.

## 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. 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.

For example, if a company pays a kickback to a HCP to prescribe its product, the government can allege that when the claim was submitted to the government for the product, the claim was false because it was the result of an illegal kickback. The government has also used the FCA to combat instances of off-label promotion. Under the government’s 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, the government has argued that the pharmaceutical company has “induced” another party to submit a false claim, resulting in an alleged violation by the pharmaceutical company. Sales Colleagues must ensure that all HCP interactions comply with Orange Guide Chapter 2: Detailing to HCPs, and all other colleagues must ensure that marketing materials and other commercial activities comply with White Guide Chapter 2: Advertising and Promotional Labeling and White Guide Chapter 3: Promotional Interactions with Healthcare Professionals, and any other relevant policies and guidance.

### ***Privacy Laws***

Pfizer and its partners and service providers perform various services (e.g., advertising and promotion agencies) that may collect and process various types of personal information (e.g., healthcare data). Also,



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, including data breach notification laws.

For more information about your obligations to maintain patient privacy, see Orange Guide Chapter 8: Privacy: Protecting Personal Information and White Guide Chapter 11: Privacy: Protecting Personal Information.

### ***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 further contend that state consumer protection laws encompass off-label promotion. You should direct any questions regarding state consumer protection laws and their impact on your activities to your team attorney.

### ***Foreign Corrupt Practices Act***

The **Foreign Corrupt Practices Act (FCPA)** is a US federal law that prohibits corrupt or improper payments to non-US government officials. The definition of "**government official**" includes any officer or employee of, or acting on behalf of, a non-U.S. government (any department, agency, or instrumentality) or public international organization. HCPs at foreign government-owned hospitals, for example, may qualify as foreign officials under the FCPA.

The FCPA contains both anti-bribery and accounting provisions. Violations of the FCPA may result in criminal prosecution and/or civil sanctions against Pfizer and any of its individual employees, including for the misconduct of third parties acting on Pfizer's behalf.

The anti-bribery section of the FCPA prohibits U.S.-based companies from, directly or indirectly, offering, paying, promising to pay, or authorizing payment of anything of value to a non-U.S. government official to improperly or corruptly influence that official to take any governmental act or decision to assist a company in obtaining or retaining business, or gaining an improper advantage (examples of such decisions could include influencing clinical trials, writing prescriptions, awarding business contracts or regulatory approvals, or not enforcing requirements such as mandatory inspections). The FCPA contains no minimum threshold and "**anything of value**" can be considered a bribe (e.g., gifts, a contract, meals, employment for a family member). Additionally, a bribe need not actually be paid in order to violate the law.

The accounting provision requires companies with securities listed on US stock exchanges to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls.



Pfizer colleagues who are permitted to enter into any interaction in which a payment or other benefit may be given to a non-U.S. HCP (e.g., engaging the individual as a consultant), must follow [My Anti-Corruption Policy and Procedures \(MAPP\)](#). MAPP sets forth Pfizer's global policy and procedures that are designed to help colleagues use good judgment and comply with the anti-bribery and anti-corruption laws of the US and the other countries in which we operate. For more information, see White Guide Chapter 5: HCP and Government Official Consulting Engagements and [MAPP](#).

## Industry Codes, Guidance, and Our Government Agreements

### ***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 including Pfizer. It applies to relationships with physicians and other HCPs. Pfizer is committed to following its principles.

The PhRMA Code is intended, among other things, to protect patients from undue influences on healthcare decision-making and reaffirm that interactions between company representatives and HCPs should be ethical and focused on informing HCPs about the benefits and risks of medicines in order to help enhance patient care.

The PhRMA Code, as well as "Frequently Asked Questions," can be viewed on [Global Policy Xchange on GCO On Demand](#).

### ***PhRMA Guiding Principles – Direct To Consumer Advertisements About Prescription Medicines***

[PhRMA Guiding Principles – Direct to Consumer Advertisements About Prescription Medicines](#) set forth the industry's commitment to use of DTC advertising as a means to increase the awareness of various diseases and conditions, inform patients about potential treatment options, motivate patients to talk to their physician, and help patients communicate more effectively with their physician. In 2018, PhRMA updated these Principles by adding that all product-related DTC television advertising should direct patients to information about the cost of the medicine being advertised—the list price and average, estimated or typical patient out-of-pocket costs, or other context about the potential cost of the medicine. Pfizer provides this information through a website. Pfizer [Guidance for the Implementation of the Updated PhRMA DTC Principles](#) must be followed when developing DTC advertising. When developing DTC advertising, Marketing colleagues must also adhere to the policies set forth in White Guide Chapter 2: Advertising and Promotional Labeling.



### ***OIG Compliance Program Guidance for Pharmaceutical Manufacturers***

The [OIG Compliance Program Guidance for Pharmaceutical Manufacturers](#) 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 effective compliance programs. The Guidance states that 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 Government 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, typically five years from the date the CIA is executed.

A **State Attorney General Agreement** is a written agreement with one or more state Attorneys General that imposes certain integrity obligations for a specified period of time or as an ongoing obligation. We may also enter into agreements with city or municipal governments or regulatory agencies that require certain integrity obligations.

### ***Pfizer's Corporate Integrity Agreements***

Pfizer has entered into CIAs as part of four settlements with the U.S. government 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 lawsuit (a whistleblower suit filed by a private individual on behalf of the government) 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 a 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.

- **Independent Charity Patient Assistance Program Contributions CIA (2018):** In 2018, Pfizer paid \$23.5 million to resolve civil claims by the U.S. government and entered into a five-year CIA. The government alleged that Pfizer's donations to charitable foundations that provided copay assistance to patients being treated for renal cell carcinoma and certain types of irregular heartbeats did not comply with federal law. Pfizer medicines Sutent, Inlyta and Tikosyn are among those prescribed to treat these conditions. The CIA sets certain compliance-related requirements, most of which were already reflected in Pfizer's Compliance Program. Our CIA obligations include: annual compliance training for U.S. colleagues; certain certifications; disclosure of certain violations of company policy or law; annual third party reviews of certain systems, policies, processes, and transactions; policies and procedures regarding donations to Independent Charity Patient Assistance Programs, Pfizer's free drug program, and financial assistance in the form of cost-sharing (co-pay coupons or co-pay cards); and monitoring of certain activities associated with donations to Independent Charity Patient Assistance Programs.

#### ***Pfizer's State Attorneys General Agreements***

Pfizer has entered into written agreements directly with several state Attorneys General, cities, and municipalities, which impose certain integrity obligations upon Pfizer. Because these agreements are entered into with individual states, cities or municipalities, the obligations can and do vary among agreements and may be more restrictive than applicable law. Generally, these agreements include obligations related to promotional activities, incentive compensation, medical information, reprints, and physician payment posting. While some obligations exist only for a pre-specified time period, some of the obligations do not expire. As applicable, obligations impacting Pfizer colleague activities are implemented through policies and procedures governing the relevant activities.

For additional information regarding these agreements, please visit the [State AG Agreements](#) page on the Corporate Compliance Division website.

#### **Violations and Penalties**

The OIG, the U.S. Department of Justice, the FDA, state Attorneys General and certain local governments aggressively enforce the anti-kickback and other laws and regulations discussed in this Overview. In addition to violating our obligations under our government agreements, 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 regulations, in particular, can result in the need to run corrective advertising or to "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.

In addition, Pfizer may face regulatory investigations, significant fines and litigation for failure to comply with applicable privacy laws and regulations, including state data breach notification laws.

### Pfizer's Compliance Program

Pfizer takes compliance with these laws, regulations, and agreements very seriously and expects every colleague to do the same. Pfizer's Compliance Program is regularly enhanced to help ensure that we meet or exceed the complex and evolving legal, regulatory and industry requirements, as well as the expectations of patients and providers. Your commitment to integrity and owning compliance is essential to achieving our purpose of *breakthroughs that change patients' lives* and is critical to Pfizer's success. Acting with integrity requires that colleagues promptly disclose potential violations and cooperate with investigations of possible violations. Each colleague has a **Duty to Act** by reporting suspected compliance violations to Pfizer Human Resources, Legal, or **Compliance via the Compliance Helpline (1-866-866-7349 or online at <https://pfizer.alertline.com>)**, via e-mail at [corporate.compliance@pfizer.com](mailto:corporate.compliance@pfizer.com), or by phone (1-212-733-3026).

If you are involved in a compliance investigation in any capacity (for example, as a witness or complaining party), you are expected to keep the details of the investigation confidential. Maintaining confidentiality helps to preserve the integrity of the process and protects the individuals participating in the investigation. Unless prohibited by local law, any exceptions to confidentiality must first be discussed with the Compliance Division.

#### **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 – INTERACTIONS WITH HCPs**





Chapter

#2

INTERACTIONS WITH HCPs

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## Chapter #2 Interactions with HCPS

### Introduction

Your interactions with Pfizer customers, including individual Healthcare Professionals (“HCPs”), health plans, and Integrated Delivery Networks (“IDNs”), are essential to Pfizer's success. Being compliant with the law and Pfizer policies is another component of success and this Chapter sets forth policies and guidelines for interacting with Pfizer customers.

For this Chapter, an HCP is defined broadly as any individual who has a direct role in patient diagnosis and/or treatment. HCPs include nurses, nurse practitioners, physicians, and pharmacists. It also may include individuals who do not work directly with patients but have influence over the recommendation, purchase, or prescribing of Pfizer products, such as Health Plan Administrators, Organized Customer Administrators, Pharmacy & Therapeutics (“P&T”) Committee members, and Formulary Committee members who may not see patients. The definition of an HCP may differ in certain contexts, including a broader definition of an HCP under certain state laws.

Portions of this Chapter, such as those pertaining to product detailing, may seem more relevant to Field Sales Colleagues. Other portions may seem more relevant to Account Managers. Nonetheless, all Field Commercial Colleagues as defined in Orange Guide Chapter 1: Overview and Key Principles, regardless of role or responsibility, should familiarize themselves with this Chapter, as it illustrates how to apply the core compliance principles in situations relevant to their roles. Account Managers can find additional policies and guidance tailored more specifically to their roles in Orange Guide Chapter 5: Interactions with Health Systems and Medical Groups.

For additional information on interactions with medical colleagues, you may review the [Green Guide](#), which serves as the main compliance resource for US-based BU Medical colleagues.

**Non-compliance with these policies can subject Pfizer colleagues to disciplinary actions up to and including termination of employment. 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 any policy is unclear to you, discuss the issue with your manager or your team attorney.



### ***Key Points to Ensure Compliance***

- All items shown or provided to HCPs must be Review Committee (RC)-approved for the specific use. Do not use materials that you have created or altered in any way, or materials meant for internal or other use.
- Field Commercial Colleagues may not discuss new products or indications until they have received RC-approved materials and messaging for promotion and completed any required training.
- All statements regarding a Pfizer product must be on-label (consistent with the product's package insert), truthful, and not misleading. Only use promotional statements that are consistent with RC-approved materials and guidance (including any Implementation Guides).
- When discussing a product, always give a fair and balanced presentation of the benefits and risks.
- Field Commercial Colleagues who utilize Veeva CRM are required to record all promotional interactions with their customers in the app and synchronize it daily.
- All inquiries about off-label information, unapproved uses or unapproved products must be unsolicited and referred to Pfizer U.S. Medical Information Department (USMI) using Veeva CRM or another approved process.
- Unless the brand team, Legal, or Compliance provide guidance otherwise, Sales Colleagues on Veeva CRM are expected to use materials on their approved device (i.e., tablet or iPad) whenever possible when engaging in customer interactions. Furthermore, under no circumstances are non-RC approved applications, e.g., MMIT (formulary coverage app), to be used with customers.
- Disease state and other unbranded discussions should not imply an off-label use for a Pfizer product and should be executed in accordance with RC guidance on the use of the materials.
- Field Commercial Colleagues may not detail, provide co-pay cards, vouchers, educational materials, meals, or starters, invite to a speaker program, or otherwise promote a product to, any HCP who is considered an excluded specialty for the specified product. (For individual state restrictions, including California, Louisiana, Massachusetts, and Colorado please see Chapter 17). In addition, Sales Colleagues should not engage in these activities with any HCP whom they believe is likely to prescribe the product off-label.



### ***Key Points to Ensure Compliance***

- Field Commercial Colleagues must never engage in any actual or perceived quid pro quo.
- Field Commercial Colleagues must follow the provisions set forth in Orange Guide Chapter 18: Meals, Educational Items, Greenstone Giveaways, and HCP Payment Disclosure when providing food, beverage, or other items to HCPs, as well as the provisions in Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions.
- Treat employer representatives and administrators at organized customers as if they are HCPs when engaging in promotion and detailing activities.

## **Core Compliance Principles**

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

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

## **Use Only RC-Approved Materials and Selling Statements**

### ***Using RC-Approved Materials in Details***

Pfizer may be held legally responsible for anything that you say or show to customers. The guidance below must be followed when presenting information to customers and/or engaging in detailing:

- Show only materials that have been approved by the relevant Review Committee (RC) for promoting to HCPs. Colleagues are prohibited from altering these materials in any way.
- In general, if a promotional item or material is not available for ordering through Pfizer's online ordering system ([PROMOSprime](#)) or not available on Veeva CRM, it is not approved for detailing with customers. Certain other RC-approved content may be approved for use with customers(e.g., certain content may be approved for use outside of Veeva CRM).



- Unless the brand team, Legal, or Compliance provide guidance otherwise, Veeva CRM should be used as the primary resource for accessing promotional materials that may be used when detailing HCPs. When using materials in Veeva CRM, you are using materials that are up to date, compliant, and RC-approved. Furthermore, under no circumstances are non-RC approved applications, e.g., MMIT (formulary coverage app), to be used in customer interactions.
- In limited circumstances, Account Managers may be permitted to use materials that have not been subject to RC review. Account Managers must always check with their team attorney before using such materials.



Key Points: Permitted vs. Prohibited Activities	
Permitted	Prohibited
Using promotional materials that have been approved by the relevant RC.	Showing a chart put together based on two RC-approved pieces.  Using any RC-unapproved item as a visual aid to illustrate a point or concept (e.g., pill bottles, money, food, candy, water bottles, and software applications).  E-mailing/Texting website links that are not RC-approved for that purpose.
Marking a training copy of your clinical reprint (that you don't show to HCPs) to help you learn key points.	Showing an HCP any promotional material that has been marked or altered in any way (e.g., highlighting, sticky notes, handwritten notes, check marks, arrows, etc.).
Leaving a handwritten thank you note that includes the name of the product but does not make any direct or indirect product claim.	Leaving a thank you note that contains more than the name of a product, including any direct or indirect product claim (e.g., mentioning indications or disease state information).
Using or disseminating Pfizer training materials and other "Do Not Detail" pieces <b>internally</b> for educational purposes only, ensuring that the materials and the e-mail transmitting those materials are clearly marked as "Do Not Detail."	Showing Pfizer training materials, information from web-based or mobile applications not RC-approved for detailing, or other "Do Not Detail" pieces to customers.





### Key Points: Permitted vs. Prohibited Activities

Permitted	Prohibited
Sending a very brief e-mail/text to a customer (using your Pfizer device) asking if you can schedule an appointment to discuss a specific product <b>or</b> an indication (e.g., "Dr., I'd like to set up an appointment to discuss Lyrica with you." <b>or</b> "Dr., I'd like to set up an appointment to discuss fibromyalgia with you.").	Sending an e-mail/text to a customer asking if you can schedule an appointment to discuss a specific product <b>and</b> including information relating to indication or therapeutic area (e.g., "Dr., I'd like to set up an appointment to discuss Lyrica and fibromyalgia with you.").
Using an RC-approved resource to inform customers about co-pay cards and patient access/reimbursement support resources.	Filling out any forms on an office or patient's behalf, including but not limited to Prior Authorization forms or enrollment forms for Pfizer RxPathways or hubs.

#### Modifying a Pfizer Approved Patient Survey



	A medical practice that I am working with wants to modify one of Pfizer's RC-approved patient surveys to better meet their needs. The change does not alter the substance of the survey. Can I make the change and return it to the practice?
	No. If you make any alteration to RC-approved material, it results in an impermissible homemade promotional piece.

#### Communicating Formulary Status



	Can I discuss with physicians the formulary status of Pfizer products as compared with competitor products? If so, can I create a chart showing the different formulary statuses by health plan?
	In some circumstances, it might be appropriate to discuss the formulary status of Pfizer and competitor products with HCPs provided that all statements are accurate, non-misleading, and are RC-approved. For example, if the information is part of your RC-approved materials, you can point out when a Pfizer product has a favorable formulary status, but you may not state or imply that the formulary status makes the Pfizer product more effective or safer than a competitor product. You are not permitted to create a formulary status chart because this would be considered an impermissible homemade promotional piece.





### Communicating Formulary Status

	What materials are available to me to help discuss formulary status?
	Resources regarding formulary status vary by brand and may include cost and coverage content within an iDetail, rep triggered letters and e-mails, and sell sheets available on <a href="#">PROMOSprime</a> or print on demand from a print portal. All materials to be used for customer discussions must be RC-approved.

### Mailing RC-Approved Pieces to HCPs

	Am I permitted to mail or e-mail an RC-approved promotional piece to an HCP?
	Only if there is explicit guidance and RC permission to do so.

### Discussing Prior Authorizations and Other Access/Reimbursement Topics

	Can I engage in discussions with HCPs about Prior Authorizations and other topics relating to product access or reimbursement?
	<p>You should follow any applicable RC-approved guidance when engaging in a discussion about specific prior authorization criteria or forms. In order for you to give or show a specific prior authorization form, it must be approved by the relevant review committee.</p> <p>If there are RC-approved materials or messages discussing cost, coverage, or access/reimbursement resources, you may discuss these with customers consistent with applicable implementation guidance. You may not engage in any patient-specific reimbursement support activities unless you are in a field reimbursement role (e.g., Field Reimbursement Manager). For all other field commercial colleagues, if any patient-specific questions or issues arise you should provide the customer with the contact information for the relevant function or hub or refer the case as directed by your Compliance or Legal support.</p> <p>You should never assist HCPs or staff in filling out a prior authorization form, nor should you assist in completing forms related to enrollment in RxPathways or hubs. To ensure appropriate and independent clinical decision making on the part of HCPs, it is important that Pfizer sales representatives and other field personnel avoid</p>





### Discussing Prior Authorizations and Other Access/Reimbursement Topics

providing, or the appearance of providing, more than limited reimbursement support assistance to patients, and Pfizer has centralized its reimbursement support within various product-specific hubs to mitigate these risks. In addition, you may not coach anyone on fulfilling or evading a prior authorization forms requirements in order to obtain approval for either a specific patient or a type of patient. HCPs must independently determine each patient's diagnosis and clinical information supporting a prior authorization request. For more information related to Pfizer's hubs and their role in supporting patients with prior authorizations, please see Chapter 11 of this Orange Guide.

### ***Selling Statements***

It is critical that you only make selling statements (including openers, closers, and probing questions) 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 ensure appropriate execution.

Sometimes Field Commercial Colleagues share suggested selling statements internally, often by e-mail or before or after internal meetings. Although sharing recommended selling statements can sometimes help improve selling skills, it is critical that these statements be consistent with RC-approved selling messages and any documents (including e-mails) sharing such statements be marked as "DO NOT DETAIL." Suggesting inappropriate selling statements or statements that are not consistent with claims contained in RC-approved materials can carry significant risks for Pfizer. Thus, if you determine that it might be beneficial to discuss a proposed selling statement, either by preparing a document or sending an e-mail about it, you must carefully review the statement to make sure it is consistent with RC-approved materials, including any relevant Implementation Guide(s). You must obtain your manager's approval prior to disseminating any documents containing any modifications to RC-approved selling statements to other Pfizer colleagues (including, for example, e-mails, PowerPoint presentations, and summaries of district meetings or workshops). Further, any changes to RC- approved selling statements cannot be used with customers until they are reviewed and approved by relevant brand RC.

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



### ***Selling Statements: Key Points to Ensure Compliance***

- Do not make selling statements (including openers, closers and probing questions) that are inconsistent with RC-approved materials and messaging, including any relevant Implementation Guides.
- Do not send any documents to other Pfizer colleagues that contain any deviations from RC-approved materials or selling statements (including relevant Implementation Guides) without your manager's approval. Such modifications can only be used with customers after they are reviewed and approved by the relevant brand RC.
- Do not make or imply comparative claims of any kind, especially superiority claims, unless the claim is specifically made in RC-approved promotional materials.

### **E-mailing / Texting HCPs**



Am I permitted to e-mail/text an HCP to schedule an appointment about one of my products? Is it OK if I write a product name in my e-mail/text?



Yes. You may use either the product name or indication when scheduling an appointment with a customer (including the subject, body or signature line). Combining both the product name and indication in the same communication may result in a product claim that is subject to FDA labeling requirements. The communication must contain logistical and non-substantive information (e.g., time, date, place of appointment). You may not use e-mail or texts to discuss substantive business matters unless RC-approved, e.g., by sending a rep-triggered e-mail (RTE) or, for Account Managers, sending a message through [PROMOSprime](#). You may not use texting apps (e.g. What's App) for any communication.





Permissible: "Doctor, I'd like to make an appointment with you to discuss Lyrica."

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



It is a best practice to start a new e-mail thread when e-mailing a customer. Using an old e-mail thread requires additional review to ensure consistency in using either the product name or the indication.



#### E-mailing / Texting HCPs

	What should I do if I receive an inappropriate text or e-mail from a customer?
	It depends. Receipt of inappropriate communications may require action on your part to ensure the communication is not improperly attributed to you or Pfizer. Consult your team attorney if you are unsure if a response is necessary or if you need assistance in developing an appropriate response.
	Am I permitted to use a non-Pfizer e-mail account, a non-Pfizer device with texting capabilities, or other social networking tools (e.g., LinkedIn®, Facebook®), to interact with HCPs or other customers regarding Pfizer business?
	No. You may only use your Pfizer e-mail account to e-mail with customers, HCPs or colleagues regarding Pfizer business. Only the number associated with your Pfizer-issued device, or a personal device that has been registered with Pfizer via the MaaS360 App, may be provided to HCPs or colleagues for business purposes. Business cards may only list phone numbers registered with Pfizer. You may not use any unapproved cloud-sharing or storage applications to share or store business information or data. See <a href="#">Corporate Policy 403 – Acceptable Use of Information Systems for additional information</a> .

#### Texting Internally

	Is it appropriate to have internal discussions about selling statements or other substantive business topics over text message?
	No. Communications with Pfizer colleagues via text message must be limited to logistical information only. E-mail should be used when discussing any substantive topics. As noted below, any "call notes" must be entered in Veeva CRM before they can be shared internally.

#### Stay On-Label and Discuss Only Approved Products and Indications

Pfizer may only promote FDA-approved products and FDA-approved uses and dosing of its products. All promotional statements made about a drug must be consistent with the product's labeling and must be based on the information contained in RC-approved materials. Off-label promotion is taken very seriously by Pfizer and the government.



Uses or indications that have not been approved, that remain under investigation, or that are under FDA review are considered off-label and may not be discussed. Pre-approval promotion can jeopardize the approval of a new product or indication and may result in severe penalties. Therefore, Pfizer policy mandates that you discuss only approved products, indications, and dosing in accordance with RC-approved promotional materials, including any applicable product Implementation Guides. No matter how appealing or robust the scientific evidence, you cannot discuss any product or indication with customers prior to FDA approval (and receipt of RC-approved messages and materials). Do **not** reference “new medication” or “new indication” in connection with any currently unapproved products or uses when trying to schedule an HCP meeting or otherwise communicating with an HCP.

If an HCP asks an unsolicited question about an unapproved product, an unapproved indication, or any other clinical content that you are not permitted to discuss, you may only refer the question to USMI using the process outlined below, for Unsolicited Medical Requests (UMRs).

Critical to staying on-label is making sure that the right discussions and activities are taking place with the right HCPs. Therefore, you must make a good faith effort to avoid presenting product information to, or otherwise engaging in promotion with, HCPs who are excluded for the product you are promoting. This means you must not detail, provide starters, vouchers, co-pay cards, educational materials or meals, or invite to speaker programs any HCPs who practice in a specialty that is excluded for a specific product (e.g., a pulmonologist for Viagra).

#### ***Do Not Engage in Promotional Interactions with Excluded Specialty HCPs***

The specialty exclusion lists by product are available on [GCO On Demand](#). Although Veeva CRM will not allow you to record a detail with an HCP that is excluded for the specified product, you should be cautious not to promote a product to any such HCP inadvertently (for example, in an unexpected situation where an HCP joins a group conversation about a certain product). If you inadvertently detail or leave starters with an excluded HCP, please contact your team attorney or the Samples COE. Veeva CRM functionality supports compliant detailing and starter distribution activities by indicating when an HCP belongs to an included specialty for a product and ensuring that a call cannot be closed when an excluded specialty for a product is involved. Careful Veeva CRM pre-call planning will help ensure your interactions regarding a product will be conducted with specialists who are appropriate to be detailed on that product.

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



product or included in your Territory Credit List (TCL), or you are unsure, you should discuss with your manager.

Account Managers who are engaged with customers around disease state topics also must be mindful of relevant Pfizer products and remaining consistent with our labels. This is of particular concern when discussing a therapeutic area where the risk of off-label use is high, or where a Pfizer product is the only available product in the disease state. For more information on this type of situation, see Orange Guide Chapter 5: Interactions with Health Systems and Medical Groups.

#### Detailing and Promotional Materials: On-Label vs. Off-Label Claims

On-Label Claims (Appropriate)	Off-Label Claims (Inappropriate)
Statements about a product's efficacy for the approved indication.	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 overly broad or minimize risk.  e.g.: Toviaz is well tolerated and patients do not really experience side effects.
Statements that accurately reflect an approved indication.	Statements that inappropriately broaden an indication.  e.g.: Lyrica is effective therapy across the full spectrum of painful neuropathic conditions.



### Comparative Claims

**You can only make comparative claims** (claims that compare any attribute of a product to an attribute of another product) **when there are RC-approved promotional materials (including Veeva CRM slides and any applicable product Implementation Guides) that expressly make such claims.** The FDA considers promotional materials or claims to be false and misleading if they state or imply 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 implications. 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 separate trials. In addition, it is not appropriate to detail two or more Pfizer products in a manner that falsely or misleadingly conflates the properties of the respective products. It is also not appropriate for field commercial colleagues to make or allude to inappropriate comparative claims in internal communications, because it may create the perception that these statements are being used with HCPs.

#### Comparative Claim

Comparing any attribute of a product to an attribute of another product. The FDA requires "substantial evidence" to make comparative claims on the safety or efficacy of products. Substantial evidence generally requires two adequate, well-controlled studies comparing the two drugs head-to-head using comparable dosage regimens or a single, large, well-controlled study.

### Superlative Claims



Is it ever appropriate to use superlatives like "great", "best", "excellent," or "safest" in discussing a Pfizer product?



No. It is almost never appropriate to use such unqualified superlatives in making claims about our products because they are rarely supported by substantial evidence.

### Comparing Product Package Inserts



Can I compare information contained in the package insert of a Pfizer product with the information in the package insert of a competitor's product?



No, you may never make package insert comparisons unless such comparisons are expressly made in RC-approved materials.



## Provide an Accurate and Balanced Presentation

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

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

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

### Fair Balance

Statements made about the efficacy of a product must always be balanced with relevant statements about the risks of the product, i.e., relevant contraindications, warnings, precautions, side effects, and other material information.

### Fair Balance and Accurate and Not Misleading Claims



Can a promotional presentation include a claim that a product is “safe” if the product has a strong and established safety profile?



No. The word “safe” should never be used without qualification because all products have benefits and risks and patients may experience an adverse event. RC-approved materials may include safety-based claims (e.g., an “established safety profile”), and you should only make safety claims that appear in RC-approved materials and should not elaborate or rephrase such statements.



## Never Engage in Actual or Perceived Quid Pro Quo

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

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

### Patient Assistance Programs and Inappropriate Quid Pro Quo



I am a sales representative and in the middle of my product presentation the HCP interrupted and said that he will only prescribe the product if Pfizer makes life easier by handling the reimbursement related paperwork. He then asks about Pfizer's HUB support. Can I provide the HCP with details of Pfizer's product HUB offerings so that the HCP prescribes the Pfizer product?



No. This request is for a quid pro quo. Pfizer does not provide its patient support programs as a reason for HCPs to prescribe its products. In this scenario, even using RC approved talking points to discuss Pfizer's HUB offerings could be perceived as an inappropriate inducement (reward) for prescribing Pfizer products. Pfizer's patient support services are not a promotional tool and these services should never be discussed in a way that implies that the services are a reason to prescribe or provides independent value to the office. In this situation the sales representative should respond: “Thanks doctor, Pfizer believes strongly in supporting appropriate access to our medicines, but our patient support offerings only come into play after you have made an independent clinical determination that the product is the right one for the patient. In such a case, here is a website where you or your staff can see how the patient can be assisted with access and reimbursement issues.” You should then notify your manager and/or your Team Attorney of the HCP's comment.

Commented [ELJ1]: Chang “is” to “In” per Jeff M. on 1/14/20.

## Interacting with C-Suite Administrators

C-Suite Administrators at practice groups and other organized customers increasingly have a role in influencing access to medicine. Thus, Pfizer has an interest in calling on them. Working with these customers has both business and legal risks if not done in an appropriate manner.





C-Suite Administrators at practice groups and organized customers often will also be HCPs, sometimes even reserving part of their time for treating patients. The manner in which you engage C-Suite Administrators must align with your role as a Pfizer colleague and the resources and messaging you are allowed to provide. For Sales Colleagues, generally this means engaging these individuals in their capacity as HCPs rather than Administrators. Sales Colleagues must limit their engagements with C-Suite Administrators to product and disease state details as well as other topics approved for Sales Colleagues (e.g., extending invitations to speaker programs where appropriate).

Account Managers, in contrast, may engage C-Suite Administrators at an institutional level, focusing on topics such as population health management and quality initiatives. In some instances, Account Managers may have limited product responsibilities that usually relate to formulary placement at organized customers. Otherwise, Account Managers must not engage in product promotion to individual HCPs.

Account Managers and Sales Colleagues may only use resources approved for their respective roles and available on [PROMOSprime](#) (and in Veeva CRM for Sales Colleagues). It is not appropriate for Account Managers to use Sales Colleague-only resources or for Sales Colleagues to use Account Manager-only resources.

Notwithstanding the above limitations, Sales Colleagues may play an active role in identifying C-Suite Administrators or other contacts at medical groups or organized customers who might be appropriate contacts for Account Managers. If the circumstances warrant the Sales Colleagues making an introduction in person, the Sales Colleague is generally permitted to sit in on an introductory meeting between the customer and the Account Manager. Otherwise, the Sales Colleague and Account Manager may only participate in joint meetings with the customer on an infrequent basis when there is a legitimate business need to do so and the programs or materials to be discussed are RC-approved for joint sales and account management customer interactions. The Sales Colleague, however, may not participate in other meetings between the Account Manager and the customer or otherwise deploy any Account Manager-only resources or materials with the customer.

For more information on engaging C-Suite Administrators, see Orange Guide Chapter 5: Interactions with Health Systems and Medical Groups.

### Interacting with Employer Representatives

Pfizer also calls on employers that make decisions regarding the access their employees have to medicine. To best leverage existing relationships and avoid providing inconsistent messages, consult a PCA representative and the Director of National Employer Accounts ("DE") in your region to ensure proper coordination of activities with employers. DEs are Pfizer PCA Colleagues who are dedicated to working with employers. The DEs understand the regional employer market, develop plans, and coordinate



implementation of those plans with the regional colleagues. In many cases, the DE may already have established relationships with employers in your area or have clear guidance on areas to avoid.

As with C-Suite Administrators, when working with employers, colleagues might interact with medical personnel such as on-site HCPs, as well as non-medical personnel such as CEOs, CFOs, CMDs, benefit managers, and brokers/consultants. These employer representatives often have influence over the products to which employees have access and over the coverage levels provided by their health benefit plans. As required in any discussion of a product, you must always give a fair and balanced presentation that includes both the benefits and risks. You should treat all employer representatives and benefits professionals as if they are subject to federal and state healthcare laws, including Anti-Kickback Statutes, even if they may not participate in government programs.

When interacting with employer representatives and benefits professionals, you should tailor any product discussion carefully to their background, especially if they do not have a medical background. Use appropriate, RC-approved, employer market specific tools since resources that are designed for other audiences may not resonate with or be appropriate for these customers. In addition, when working with employers, you must treat their employees as consumers. See Orange Guide Chapter 16: Consumer, Patient, and Employee Interactions for further guidance.





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

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

- Only PCA Colleagues (and certain other authorized colleagues who have received appropriate training) are permitted to engage in discussions regarding health screenings. In addition, depending on the resource, only PCA Colleagues and Account Managers may engage in discussions regarding certain quality programs.
- Certain interactions with unions are subject to federal reporting obligations and possibly other limitations. Check with your team attorney before interacting with any union.



### Hospital Protocols

	May I detail an HCP who is involved in the development of a hospital clinical protocol or who is in a position to influence which products are included in a hospital clinical protocol?
	Yes. You may detail any such HCP if your detailing is otherwise done in accordance with all applicable Orange Guide principles, including the four Core Compliance Principles discussed in this Chapter.
	May I detail an HCP in order to ask the HCP to consider inclusion of a Pfizer product in a hospital's clinical protocol?
	Yes. Pfizer colleagues may encourage an HCP to consider including a Pfizer product in a hospital protocol or standing order provided that such use would be consistent with labeling and promotion is strictly limited to approved, on label messaging of the Pfizer product, and all Orange Guide principles are followed.
	May I participate in the development of a hospital clinical protocol?
	No. Pfizer sales colleagues are not permitted to assist hospitals with drafting or otherwise developing hospital clinical protocols or treatment standing orders. In certain circumstances, if available, Pfizer colleagues may utilize RC-approved materials to engage with HCP about the importance of developing a protocol or to advocate for the inclusion of a Pfizer product in a protocol within an approved indication or disease area.
	May I use a hospital protocol in detailing sessions?
	Only if the Review Committee has approved the use of such hospital protocol. You may <b>not</b> distribute a protocol and it may not be used or discussed outside of the originating institution.





## Other Things You Need to Know

### ***Educational Items to HCPs***

The PhRMA Code prohibits Pfizer from offering non-educational items to HCPs or members of their staff, even if the items are practice related and of minimal value (such as pens, pads, mugs, etc.). RC-approved educational items generally may be provided to HCPs and their staff as long as they are not otherwise prohibited under applicable state laws or VA/DoD restrictions. For more information about state laws, see Orange Guide Ch. 17: State Laws: HCP and State Employee Restrictions, and for more information about interactions with HCPs employed by the federal government such as the VA and DoD, see Orange Guide Ch. 4: Federal Employee Interactions and Lobbying. Additionally, a detailed [Q&A on the PhRMA Code is available on Global Policy Xchange on GCO On Demand](#). If you have any questions about the PhRMA Code, you can send your question to [StateHealthcareLawCompliance@pfizer.com](mailto:StateHealthcareLawCompliance@pfizer.com). Remember that the value of most educational items provided to HCPs is subject to public disclosure under our HCP disclosure policy as discussed in Orange Guide Chapter 18: Meals, Educational Items, Greenstone Giveaways, and HCP Payment Disclosure.

### **Out-of-Pocket Gifts for HCPs**

	Can I pay for a gift for an HCP out of my own pocket if I do not expense it?
	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 may appear to be an attempt to illegally influence prescribing in violation of the Anti-Kickback Statute. Remember that The Summary of Pfizer Policies on Business Conduct (the <a href="#">“Blue Book”</a> ) and <a href="#">Corporate Policy 203: Conflicts of Interest</a> require you to avoid even the appearance of a conflict of interest.

## Interactions with Field Medical Colleagues

### ***Interacting with Field Medical Director (FMD) Colleagues***

Field Medical Directors (FMDs) are field-based medical colleagues who are part of the Business Unit medical team. These colleagues have therapeutic area expertise and primarily serve the medical needs of individual HCPs, including investigators and other experts, within an assigned geography. Their communications with these HCPs include engaging in Pfizer-initiated non-promotional medical communications using materials approved by the relevant Medical Review Committee (MRC), responding to unsolicited medical requests they receive or that are escalated to them by the USMI, and discussing



service-based activities such as Pfizer sponsored/collaborative research, and/or consultancies. The FMD role is governed by the [Green Guide](#).

### ***Principles Governing FMD and Field Commercial Colleague Interactions***

The FMD role has been specifically tailored to focus on non-promotional medical activities designed to inform HCPs and other key customers about relevant medical information and the safe and appropriate use of Pfizer products. The objective of these interactions must not be sales focused (e.g., not done with a goal of obtaining prescriptions for a Pfizer product). There are limited instances when FMDs may engage in activities governed by promotional standards, such as conducting speaker training or participating in formulary presentations.

Internal interactions between FMDs and Field Commercial Colleagues as well as external interactions among FMDs, Field Commercial Colleagues, and HCPs must be carefully managed to ensure that FMD non-promotional activities are planned and executed appropriately.

### ***Internal Interactions between FMDs and Field Commercial Colleagues***

FMDs may interact with Field Commercial Colleagues in order to ensure appropriate, efficient and informed interactions with customers, as outlined in this section.

### ***Medical Objectives and Customer Insights***

Field Medical activities are aligned with BU Medical objectives, not sales targets or financial objectives. FMDs are not permitted to engage with Field Commercial Colleagues for the purpose of jointly determining medical objectives; however, they are permitted to seek limited input from Field Commercial Colleagues on medical priorities for HCPs in aggregate (not regarding any particular HCP).

FMD Colleagues may share customer insights with Field Commercial Colleagues, but such insights must be in aggregate to a territory, account, specialty, medical group, or academic center and not specific to any particular HCP's prescribing of Pfizer products or unsolicited medical requests. FMDs are not permitted to share insights regarding off-label use of Pfizer products, unapproved products, or information about responses provided to HCPs who have made unsolicited medical requests for information. They are also not permitted to share detailed work plans or provide information to Field Commercial Colleagues about ongoing clinical trials, consultancies, or other medical service-based activities. Accordingly, Field Commercial Colleagues must not request this type of information.

### ***FMD HCP Contact Lists***

The FMDs are permitted to share the names of HCPs on their contact list with Field Commercial Colleagues. However, FMDs and Field Commercial Colleagues must call on HCPs separately and independently unless otherwise permitted to hold a joint meeting, as described in this Chapter. Field Commercial Colleagues



may offer suggestions to FMDs about adding HCPs to their contact list; however, the FMDs will apply pre-determined medical criteria and make an independent judgment regarding whether any HCPs are appropriate to add to the list.

### ***FMD Attendance at Field Commercial Meetings***

On a limited basis and when there is a legitimate business rationale, Field Commercial Colleagues may invite FMDs to participate in internal business meetings such as district, regional, or national sales meetings (e.g., POA meetings). FMDs may also be invited to organized customer planning meetings.

Examples of appropriate reasons to request FMD participation at Field Commercial business meetings include for the FMD to:

- Conduct product or disease training, using RC-approved materials;
- Provide general information about medical objectives or an overview of Medical Review Committee (MRC) approved topic(s) or materials:
  - FMDs are not permitted to discuss the details of MRC-approved content or share actual MRC-approved materials with Field Commercial Colleagues. Field Commercial Colleagues must not ask for this information or seek to influence the way in which medical content is developed or delivered to HCPs or other customers.
- Share aggregated customer insights, information about geography or regional level dynamics, or to seek feedback. For example, information can be shared about gaps in HCP understanding about a disease or treatment. Customer information discussed must be in aggregate and not specific to any particular HCP or other customer's prescribing/utilization of Pfizer products or medical inquiries.
  - Field Commercial Colleagues are not permitted to ask FMDs to share any type of off-label information about a Pfizer product or information about unapproved Pfizer products.
  - Field Commercial Colleagues are not permitted share HCP-specific prescribing habits and to seek assistance from FMDs with overcoming barriers to HCP prescribing/utilization of Pfizer products.
  - Field Commercial Colleagues are not permitted to request information from FMDs about the substance of responses provided to customers who have made unsolicited medical requests for information.
  - FMD may seek to understand the business goals and objectives for an organized customer account so that they can develop fully-informed medical strategies, but they must not take directions from account management colleagues regarding medical activities.



### ***Organized Customer Planning and Coordination***

Medical Outcomes Colleagues (e.g., Medical Outcomes Specialists (MOS)) are the primary Field Medical Colleagues who serve the medical needs of managed care and other organized customers. For organized customers that have assigned Medical Outcomes Colleagues, those colleagues will coordinate when an FMD's assistance is needed with a particular organized customer. If an organized customer does not have an assigned Medical Outcomes Colleague, Field Commercial Colleagues may work directly with an FMD to discuss field medical support for the organized customer. The guidance governing Field Commercial Colleague interactions with Medical Outcomes Colleagues is contained in Chapter 5 on Interactions with Health Systems and Medical Groups.

### ***Medical Outcomes Colleague Attendance at Field Commercial Meetings***

On a limited basis, Field Commercial Colleagues may invite Medical Outcomes Colleagues to participate in internal business meetings such as district, regional, or national field commercial meetings (e.g., POA meetings). Medical Outcomes Colleagues may be invited to organized customer planning meetings as members of the Integrated Account Team. For more information on this topic, please see chapter 5 of the Orange Guide.

### ***General Requests for Field Medical Contact Information***

In response to general requests for a Pfizer Medical contact, Field Commercial Colleagues may provide HCPs with a copy of the approved Medical Resources brochure, which is intended to inform them about various Pfizer Medical Resources and how to access them. This brochure includes contact information to enable the HCP to contact USMI or an FMD directly. FMDs may e-mail a PDF of their individualized brochure to the relevant field sales manager or Field Commercial Colleague. If the Field Commercial Colleague chooses to e-mail the Medical Resource brochure to an HCP they should do so in a brief e-mail and not copy the FMD. Field Commercial Colleagues must follow the process below for submitting UMRs in response to any specific requests for clinical content relating to unapproved products, unapproved indications, or any other clinical content the Field Commercial Colleague is not permitted to discuss Unsolicited Medical Requests.

Field Commercial Colleagues must only refer UMRs to USMI as described below. Colleagues using Veeva CRM must submit UMRs using their tablet or other approved device. For non-Veeva users, or if Veeva is not available, you may direct the HCP to call USMI at 1-800-438-1985. If an HCP informs a Field Commercial Colleague that (s)he has not received a response to a previously submitted UMR or is not satisfied with a response received by USMI, the colleague may provide the appropriate FMD's contact information to the HCP so that *the HCP* can contact the FMD directly. In the event of an urgent safety question, Field Commercial colleagues can also provide the HCP with the assigned FMD's contact



information in addition to submitting the UMR to USMI. You may not otherwise facilitate any USMI/FMD request in response to UMRs.

### ***HCP Requests to Discuss Research***

Field Commercial Colleagues may refer HCP inquiries regarding potential involvement in Pfizer clinical research to an FMD if the HCP has specifically inquired about research opportunities with Pfizer. The decision to engage with the HCP is within the complete discretion of the FMD, and Field Commercial Colleagues must not attempt to influence this decision. FMDs are not permitted to engage in detailed discussion with Field Commercial Colleagues about ongoing clinical trials or other research-related activities; Field Commercial Colleagues must not request this type of information from FMDs.

### ***Requests for FMD to Provide Supplemental Speaker Training***

Field Commercial Colleagues are permitted to contact an FMD if a contracted promotional HCP speaker asks to meet with a Pfizer Medical Colleague to discuss RC-approved speaker program content or has a question related to the content. The FMD colleague should first confirm with the speaker that such a request has been made, and then may proceed to discuss promotional content and questions with the HCP. If the speaker's question is a UMR (not specifically related to his/her role as a promotional speaker), the Field Commercial Colleague must refer the question to USMI, as described in this Chapter.

If a Field Commercial Colleague, after holding a speaker program, thinks a speaker needs assistance from an FMD or BU Medical Colleague, in order to effectively or compliantly deliver approved speaker program content, the Field Commercial Colleague may contact the FMD or a BU Medical Colleague to request follow-up with the speaker. As a reminder, any speaker violation of Pfizer policy must be reported during the close out of the program.

### ***Planning for Joint External Meetings***

Where external joint meetings among FMDs, Field Commercial Colleagues, and HCPs or other customers are permitted, Field Commercial Colleagues may meet internally with FMDs to plan for these meetings (e.g., to share logistical information and meeting agendas). FMDs and Field Commercial Colleagues are also permitted to contact each other to request a one-time HCP introduction, as described below, or to discuss logistical information about offices/accounts or resolve scheduling issues.





### External Interactions between FMDs, Field Commercial Colleagues, and HCPs

In general, FMD and Field Commercial Colleagues must engage with HCPs separately and independently when conducting their respective activities. However, FMD and Field Commercial Colleagues may meet together with HCPs or other customers in limited circumstances described further in Chapter 18.

#### ***Introductory Meetings***

A Field Commercial Colleague is permitted to ask an FMD Colleague to make a one-time in-person introduction to an HCP and an FMD is permitted to ask a Field Commercial Colleague to do the same. The purpose of such meetings must be for introduction only and must not be used to hold a substantive joint meeting with the customer unless it is otherwise permitted.

The Field Commercial Colleague must not give an HCP a promotional presentation in the presence of an FMD, and FMDs are not permitted to engage in medical communications in the presence of Field Commercial Colleagues unless the material has been specifically approved by MRC for presentation in these circumstances.

In instances where an HCP or other customer limits the meeting time dedicated to industry, FMDs and Field Commercial Colleagues may schedule one Pfizer meeting with the customer but should then conduct consecutive independent discussions with the customer (outside the presence of the other) unless otherwise permitted to hold a joint meeting.

### Organized Customer Meetings and Formulary Committee Presentations

Medical Outcomes Colleagues, who work regularly with organized customers, are usually the Pfizer Field Medical Colleagues who represent Pfizer Medical at meetings with organized customers as well as Pfizer-initiated Formulary Committee presentations. However, when specific product and/or deep therapeutic area expertise is needed, the Medical Outcomes Colleague may contact an FMD to join these meetings. Field Commercial Colleagues should coordinate requests for FMD participation in organized customer meetings or Pfizer-initiated Formulary Committee presentations through the Medical Outcomes Colleague assigned to the organized customer, if one is assigned. If no Medical Outcomes Colleague is assigned to the organized customer, Field Commercial Colleagues are permitted to work directly with the FMD to coordinate such meetings. For further guidance related to joint external organized customer meetings, see Chapter 5 on Interactions with Health Systems and Medical Groups.



### ***Interacting with Medical Outcomes Colleagues***

For additional information about appropriate interactions with Medical Outcomes Colleagues (e.g., the MOS), see Orange Guide Chapter 5.

#### **Communicating Clinical Trial Results**



If I suspect that an HCP would be interested in learning about results from a clinical trial looking at a new use for one of Pfizer's products, am I allowed to ask an FMD Colleague to speak to that physician about the trial results?



No. No colleague, including FMD and MOS Colleagues, may communicate the results of an unapproved or off-label study to an HCP at the request of a commercial colleague, nor may they encourage the HCP to ask about unapproved uses. Pfizer Medical Colleagues can provide off-label information to a HCP in response to a specific **unsolicited** question seeking such information, as set forth in the [Green Guide](#). You may never solicit questions about unapproved products or uses, whether explicitly or implicitly. Any unsolicited request for off-label information received by a commercial colleague must be referred to USMI and follow the process as explained in this Chapter.

### **Exhibits and Displays**

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

All sales-funded exhibit and display requests must be reviewed and approved by your Manager and submitted to your designated Program Activity Coordinator (PAC) for processing and approval through Ariba. You should submit requests to the PAC at least four weeks prior to the date of the event. It is not permissible to participate in an exhibit or display if you have not received prior approval. In evaluating an exhibit or display request, Pfizer will ensure it is paying fair market value for the opportunity. If other companies are displaying their products, you should confirm whether such other exhibitors are being charged comparable amounts for the same type of space (it is also acceptable if all exhibitors are being charged the same fee, but Pfizer has negotiated to pay a discounted rate). Often the event brochure will

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list the levels of exhibit and display opportunities and describe the space and services that are being purchased at each level. This type of brochure should accompany your exhibit or display request because it helps to validate the fair market value of the exhibit opportunity. Some factors to consider when evaluating whether there is fair market value for an exhibit or display opportunity include the following:

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

#### Paying for Display Space at a Private Practice Event

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I received an invitation from one of my specialty practice groups to pay a display fee to set up an exhibit at the practice's business meeting. Can we pay for the display?

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Generally, no. Payments to private practice groups are subject to increased scrutiny and are generally impermissible, particularly at events exclusively for members of the practice or events which are aimed at benefiting the practice's business. However, there may be exceptions to this rule that you should discuss with your manager or team attorney. For example, payment might be permissible in a situation where a private practice group is relatively large and other pharmaceutical companies will be providing an exhibit. Similarly, payment might be permissible if an event involves the participation of a larger community of physicians (such as one providing continuing education credit).

#### Call Notes

"Call notes" are written records documenting specific detailing interactions with an HCP or a member of the HCP's staff. Sales Colleagues are not required to keep "call notes" documenting their details with HCPs. If Sales Colleagues do want to keep call notes, the call notes can only be kept in Veeva CRM. Call notes documented in Veeva CRM must be written in such a way that the context is clear and not misleading to an outside reader and that they could not be interpreted to suggest that you made any inappropriate promotional statements or engaged in inappropriate activities.



In certain instances, there may be a legitimate business need for Sales Colleagues to share call notes with colleagues who do not otherwise have access to Veeva CRM. In other instances, it may also be necessary for colleagues to share summaries of information contained in call notes with other colleagues, such as their managers. In all such instances, call notes must be appropriately documented in Veeva CRM before sharing written records (including summaries) that document specific detailing interactions with HCPs. Whenever possible, please refer colleagues directly to call notes in Veeva CRM. If sharing outside of Veeva CRM is required, please ensure that the substantive content of any written records to be shared is consistent with the information that is recorded in Veeva CRM. Importantly, you may not use any unapproved cloud-sharing/storage application, e.g., Google Docs, Dropbox, Evernote, or any other approved sharing applications, to communicate or share information with colleagues. See [Corporate Policy 403 – Acceptable Use of Information Systems](#) for additional information.

### Reporting Adverse Events and Other Product Safety Information

Safety reporting is an important responsibility at Pfizer. As Field Commercial Colleagues, you may become aware of Product Safety Information through a variety of ways such as routine work activities (e.g., written or verbal communication with HCPs, consumers and/or patients), Pfizer initiated programs (e.g., market research, patient support programs, Pfizer sponsored digital media (such as those that contain open text field), non-Pfizer media sources (e.g., TV, newspapers, magazines, internet sites and social media), conversations that take place in casual social settings or work related meetings (e.g. Speaker Programs and detailing).

Please ensure that you follow Pfizer's corporate policy on reporting Product Safety Information, [Corporate Policy 903, Your Responsibility to Report Information about the Safety, Quality, and Performance of Pfizer Products](#).

Product Safety Information includes any information about the safety, quality, and performance of Pfizer products, which include includes any non-prescription or prescription drug, biologic, biosimilar, medical device, including medical device combination products, vaccine, cosmetic, or food and dietary supplements.. There are four categories of Product Safety Information, listed below:



TYPES OF INFORMATION THAT SHOULD BE REPORTED		
	Description	Examples
<b>1. Adverse Events</b>	Any untoward medical occurrence in an individual administered a Pfizer product, all reports of Adverse Events should be forwarded, regardless of the seriousness of the event, whether or not there is a causal relationship with the Pfizer product and regardless of the event being mentioned in the product label/instructions.	<ul style="list-style-type: none"><li>• Abnormal test findings</li><li>• Clinically significant signs and symptoms</li><li>• Changes in physical examination findings</li><li>• Progression/worsening of underlying disease</li><li>• Lack of efficacy for a Pfizer product</li><li>• Drug abuse or dependency</li><li>• Death</li></ul>
<b>2. Unexpected Therapeutic Effect</b>	A beneficial therapeutic effect of a product aside from the use for which it had been given.	Patient takes a product for high cholesterol and notices decreased insomnia.
<b>3. Product / Medical Device Complaints</b>	<p>Product Complaint: any written, electronic, or oral communication of dissatisfaction relative to the quality or physical properties, condition, package insert, and/or packaging of a product.</p> <p>Medical Device Complaint: any written, electronic, or oral communication of dissatisfaction relative to the appearance, identity, quality, durability, reliability, safety, effectiveness, instructions for use, or performance of a medical device or a product with a medical device component, including Pfizer sponsored medical software products that are regulated as medical devices (e.g. mobile apps, website functionality, etc.).</p>	<ul style="list-style-type: none"><li>• Blister pack arrived empty</li><li>• Vial is leaking liquid</li><li>• Syringe is jammed</li><li>• Product is/may be counterfeit</li></ul>
<b>4. Circumstances That May Lead To Adverse Events</b>	Certain situations should also be forwarded whether or not there are any associated adverse events. They include: drug misuse; extravasation, drug overdose; exposure during pregnancy or breastfeeding; medication errors; occupational exposure; and off-label use.	<ul style="list-style-type: none"><li>• Occupational Exposure: A hospital maintenance worker accidentally splashes a Pfizer medicinal solution in his eye while cleaning up</li><li>• Off-label use: Prescribed Revatio for a child with hypertension (only approved for adults)</li></ul>



\* **The above are examples only. Please refer to [Corporate Policy 903](#) for more details regarding reportable product safety information.**

If you become aware of reportable safety information, you must report it to the appropriate Pfizer contact within **24 hours of receipt**. All reports of safety information should be forwarded regardless of the seriousness of the event, whether or not there is a causal relationship with the Pfizer product and whether or not the event is mentioned in the product label/instructions. For product complaints **only**, please submit the report by phone at **800-438-1985**. For all other reportable safety information, submit the report by phone at **800-438-1985**, or e-mail to: [USA.AEReporting@pfizer.com](mailto:USA.AEReporting@pfizer.com), through MYRA (My Reporting App) on your mobile device or Veeva CRM from your iPad. Please include as much information as possible in your report, including the HCP's name and contact information along with details of the event and patient's details (e.g. age, gender or gestation period, for pregnancy reports). Please not delay submission of your report even if you have only limited information available. Remember that if you have any uncertainty about whether the information is reportable, you should submit the report. For further information about your safety reporting responsibilities, visit [Handling Suspected Adverse Events](#) on the MyPfizerNet Compliance page, [Corporate Policy 903](#) on Policy Source, or the [Pharmacovigilance and Cosmetics Reporting Site](#). Other resources are available on this site, including the Your Reporting Responsibilities Training as well as contacts for submission of questions.

### ***Preceptorships and Other Training for Field Commercial Colleagues***

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

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

A "preceptorship" refers to a group learning situation where a group of colleagues meet to hear presentations from one or more HCPs or observe patient care situations over the course of a day. The need for these events should be limited, and these events should occur infrequently.

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



Preceptorships may only be organized by colleagues who are District Manager level and above (“Project Managers”). Project Managers must complete the appropriate documentation located under the “HCP Engagements” tab on [Global Policy Xchange on GCO On Demand](#). Project Managers are required to obtain Legal approval for preceptorship engagements and must document the key learnings from the engagement and how the learnings will be incorporated into future business activities.

Occasionally, Sales Colleagues (Regional Manager level and higher) may engage HCPs to provide educational presentations at Pfizer meetings for the purpose of training colleagues.

The organizer of the training must review the content of the presentation and ensure the following conditions are met when any HCP is engaged to train colleagues:

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

Refer to the HCP Engagement tab on [Global Policy Xchange on GCO On Demand](#) for the procedures and policies that apply to these types of arrangements. You should always consult with your manager and obtain the approval of your team attorney before engaging in these activities.

### **Detailing Activities in Connection with Customer and Other Third Party Meetings**

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

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



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

- A representative may only provide a meal at an in-office or in-hospital setting,\* unless a Centris speaker program is being conducted, in which case the program must comply with the rules set forth in Orange Guide Chapter 9: Speaker Programs for HCPs.
- All Pfizer policies and processes regarding detailing must be adhered to—for example, you should use Veeva CRM to record all attendees at a product detail (regardless of whether a meal was provided).
- You must make a good faith effort to avoid presenting product information to HCPs who are excluded for the product you are promoting, or HCPs whom you believe are unlikely to prescribe the product for on-label use.
- You must make it clear to the customer or organization that Pfizer is not a “sponsor” of its business meeting. Explain that Pfizer is engaging in a separate promotional activity with attendees of the meeting. Identify to the audience a clear start and end to the Pfizer promotional activities to avoid the misperception that Pfizer is supporting any part of the meeting itself.
- You must not distribute invitations, or any other written material created by the host organization, unless the material has been RC-approved.
- If you provide a meal,\* it must be offered as part of the detail and incidental to the program. It is improper to provide frequent, regular, or recurring meals. For additional information on appropriate provision of meals, see Orange Guide Chapter 18: Meals, Educational Items, Greenstone Giveaways, and HCP Payment Disclosure.
- Pfizer cannot split the cost of a meal with the host of a third-party meeting. However, you may engage in promotion during a meal that is provided and paid for entirely by a third party, as long as you make clear that Pfizer is not responsible for providing the meal. Meals provided by third parties will not be reported as part of Pfizer’s payment disclosure policy.
- You must avoid being present during any discussion of any Pfizer product that you anticipate will be inconsistent with that product’s labeling. In the context of journal club meetings or similar presentations, a Sales Colleague must make every effort to identify the agenda topics. Colleagues may detail before or after such a presentation only if the agenda topics for the program do not appear to contain off-label information respective to a product supported by the Sales Colleague.

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

**\* Remember that you cannot provide any food or other financial support in connection with an accredited continuing medical education activity (ACCME, ACPE, or ANCC).** Even if you are offered

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time to promote while providing a meal to attendees at an accredited medical education conference, you must decline that opportunity since any type of financial support for accredited continuing education, including payment for event expenses or meals, can only be funded through an independent professional education grant. Requests for these grants should be sent by the requestor through Pfizer's Independent Grants for Learning & Change website. For more information, see Orange Guide Chapter 3: Support of External Organizations.

#### Detailing at Journal Club Meetings

	<p>I've been invited to make a promotional presentation at a journal club meeting held at a local hospital. Is it permissible for me to make a promotional presentation? And if so, can I provide a modest meal?</p>
	<p>Sales Colleagues may provide a promotional presentation. However, you should not attend or provide content or logistical support for any portions of a third-party meeting that are accredited for CME. Additional information about Pfizer's policies for attending CME-accredited events is located in the below section (Attendance at Continuing Medical Education Events – Grand Rounds/Tumor Boards) and on the <a href="#">MyPfizerNet Compliance page</a>.</p> <p>You may provide a meal as part of the presentation only if no part of the meeting involves CME and you comply with all applicable Pfizer policies, including:</p> <ol style="list-style-type: none"><li>1. Ensuring that the audience is appropriate and does not contain HCPs who practice in excluded specialties;</li><li>2. Ensuring that you have a legitimate opportunity to present information about Pfizer products;</li><li>3. Ensuring that any meals are offered during the presentation and are incidental to the program;</li><li>4. Appropriately recording all attendees in Veeva CRM and all expenditures in PT&amp;E;</li><li>5. Segregating the Pfizer promotional presentation from the rest of the meeting; and</li><li>6. Ensuring that all relevant state restrictions on the provision of meals and other items are followed (see Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions).</li></ol> <p>If you are unsure whether the promotional opportunity is appropriate, contact your manager or team attorney.</p>



## Attendance at Continuing Medical Education Events

### ***Grand Rounds/Tumor Boards***

Grand rounds (and tumor boards) are specific types of third-party educational meetings that typically occur in the institutional setting. They are an important teaching tool for doctors, residents, and medical students. The format usually entails a presentation of medical information and a discussion led by a speaker. The objective of these meetings is to educate HCPs on evolving areas of clinical practice. Many institutions (e.g., teaching hospitals) provide routine (weekly/monthly) grand rounds, which tend to be open to the entire medical professional community. A large percentage of grand rounds involve continuing medical education (CME) credits for the attending HCPs.

With prior manager approval and adherence to the Grand Rounds Exception Policy (available on the Grand Rounds/Tumor Board SharePoint site), Sales Colleagues are permitted to attend CME-related grand rounds in order to further their education in a relevant therapeutic area. Grand rounds attendance must not be used as a means to gain access to information about off-label uses of a product the Sales Colleague supports.

Please note that if a grand rounds event is non-CME, then Sales Colleagues are expected to adhere to the Orange Guide's policy on Third Party Meetings set forth in this Chapter and the additional restrictions in this section do not apply. Additionally, for widely attended CME-related events that are not classified as Grand Rounds or Tumor Board, please adhere to the guidance provided in the Medical Congresses/Conventions section below.

Each Sales Colleague may attend no more than twenty-four (24) grand rounds/tumor board programs per year. In addition, of those twenty-four (24) maximum allowed grand rounds/tumor board programs, no more than twelve (12) of them may occur with an individual institution within a calendar year.

Some of the key additional requirements for Sales Colleague attendance at grand rounds, as set out in the Grand Rounds Exception Policy, include:

- Prior to attendance, a Sales Colleague must make every effort to identify the agenda topics for the program they wish to attend; attendance at the program is permissible only if the majority of the agenda topics for the program do not appear to contain off-label information respective to a product supported by the Sales Colleague. In addition, if the agenda topics are not off-label, but lack relevance to the Sales Colleague's respective therapeutic area, then the manager should assess whether there is a sufficient business need for the Sales Colleague to attend the event.



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- Prior written approval from the attendee's manager (via the Grand Rounds/Tumor Board SharePoint site) is required, with e-mail requests and approvals generated by the applicable SharePoint system;
  - Oncology: <http://ecf.pfizer.com/sites/OncFF/>
  - Vaccines: <http://ecf12.pfizer.com/sites/VaccineGrandRounds/SitePages/Home.aspx>
- Sales Colleagues must not engage in sales or promotional activities while in the space or place of the grand rounds program or in conjunction with such program.
- Sales Colleagues may not provide any meals at the host facility or in connection with the grand rounds program at any point during the day of the event.
- Attending Sales Colleagues must comply with rules of the sponsoring institution.
- No Pfizer ID badges are to be worn unless required by the institution.
- Sales Colleagues must provide written certification of attendance to their manager within seven days following the event (via the Grand Rounds/Tumor Board SharePoint site).
- Regarding patient data, Sales Colleagues must avoid accessing Protected Health Information (PHI), such as a patient's name, date of birth, or social security number, during their attendance at Grand Rounds programs. Sales Colleagues must avoid attending any program where they know that PHI will be made accessible. If a Sales Colleagues comes into contact with PHI at any program: (1) he or she must inform his or her manager promptly, and the manager must notify the RBD and team attorney promptly to set up a discussion as to whether any additional action is warranted; (2) he or she must not document or reproduce the PHI in any media or form; and (3) he or she must strictly maintain the confidentiality of such information in accordance with Pfizer's policy of safeguarding the privacy of PHI. Unless approved by the RBD, the manager should not approve further attendance by any Sales Colleague at a program at which PHI has been made available to attendees. For more information on Pfizer's policies for protecting patient privacy, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.
- Within three calendar days after attending a program, the Sales Colleague must inform his or her manager if there were any areas of non-compliance with this policy. In such case, the manager must notify the RBD, and either the BU Compliance Counsel or team attorney promptly to set up a discussion as to whether any additional action is warranted. For more information on Pfizer's policies for protecting patient privacy, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.
- Sales Colleagues must not discuss or utilize any off-label information learned during their attendance at the grand rounds program and must avoid attending any program where they know is likely to involve substantial discussion of investigational Pfizer compounds or topics that are inconsistent with labeling for an approved Pfizer product; and



- Sales Colleagues must ensure that any promotional efforts following their attendance at a grand rounds event will be consistent with all RC-approved messaging regarding their responsible Pfizer products.
- Safety reporting: Sales Colleagues are responsible for reporting any reportable safety information learned during the Grand Rounds programs as discussed in this Chapter and in [Corporate Policy 903](#).

Please contact your team attorney if you have any questions concerning this policy.

### ***Medical Congresses / Conventions / Widely Attended CME Events***

CME lectures often take place during conventions, symposia, or congresses. Sales Colleagues' attendance at such CME-accredited programs can present legal, perception and other risks. Therefore, in the case of widely attended medical congresses or conventions (where such events are open to external invitees from other institutions), Sales Colleagues may attend CME-accredited lectures subject to the following:

- Manager approval must be obtained;
- Attendance must be occasional;
- Sales Colleagues may not attend CME-related Congress, Symposia, or large Convention events that are likely to involve substantial discussion of investigational Pfizer compounds or topics that are inconsistent with labeling for an approved Pfizer product (e.g., if there are 3 topics listed on a program agenda, and only 1 of them involves off-label information about the Sales Colleague's product, the Sales Colleague may attend the program because the majority of the topics do not involve relevant off-label information);
- Sales Colleagues must not engage in promotional activity at the CME event;
- Sales Colleagues must avoid initiating conversations with prescribers and should not discuss Pfizer products if approached by an HCP while at the CME event; and
- Sales Colleagues must ensure that any promotional efforts following attendance at the CME event will be consistent with all RC-approved messaging (e.g., you must not discuss or utilize any off-label information learned during your attendance).

While the above guidance must be followed when attending these Congress/Symposia type CME events, such attendance does not need to be entered into the CME SharePoint site for Grand Rounds/Tumor Boards.

Please contact your team attorney if you have any questions concerning this policy.



### For More Information

- For more information on the acceptable use of information systems, see [Corporate Policy 403, Acceptable Use of Information Systems](#).
- For more information on safety reporting, see [Corporate Policy 903, Your Responsibility to Report Information about the Safety, Quality, and Performance of Pfizer Products](#).
- For more information on Pfizer's policies for protecting patient privacy, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.
- For more information on interacting with consumers and employees, see Orange Guide Chapter 16: Consumer, Patient, and Employee Interactions.
- For information on relevant state law restrictions, see Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions.
- For more information on providing meals to HCPs, Interactions related to Greenstone and Pfizer Injectables and Pfizer's HCP Disclosure Policy, see Orange Guide Chapter 18: Meals, Educational Items, Greenstone Giveaways, and HCP Payment Disclosure.
- For Q&A on the PhRMA Code, see the [Global Policy Xchange on GCO On Demand](#).
- For more information on interacting with MOS and/or FMD Colleagues, see the [Green Guide: Governance for Medical Activities](#).
- For more information on documentation to be completed for preceptorships, see the [HCP Engagements Tab](#) on the Global Policy Xchange on GCO On Demand. Refer any questions to your manager or team attorney.



## **CHAPTER #3 – SUPPORT OF EXTERNAL ORGANIZATIONS**



Chapter

#3

SUPPORT OF EXTERNAL  
ORGANIZATIONS

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## Chapter #3 Support of External Organizations

### Introduction

Pfizer is often asked to provide funding or other support to external organizations including for-profit and not-for-profit entities. Pfizer provides external funding through sponsorships and charitable contributions. Pfizer also supports joint collaborations 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 and perception 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 provided by colleagues through collaborations with external organizations, be reviewed and approved by the applicable Review Committee.

Pfizer must also comply with certain reporting and disclosure requirements of the Sunshine Act and State Laws. Included in scope for reporting are any payments or transfers of value that are made directly or indirectly to a covered recipients as defined under the Sunshine Act. A payment or transfer of value is considered indirect if it is known that the organization receiving the funding will be conveying a benefit to a covered recipient even if Pfizer does not direct or influence the selection of the recipient or have knowledge of the identity of the recipient.

If Pfizer has agreed to an organization's use of funds that includes a payment or transfer of value to covered recipients in any form of direct, indirect, or in-kind payment or transfer of value, then the Pfizer project manager is responsible to collect all relevant information for each physician and/or teaching hospital required for disclosure using the Sunshine Data Template available at <http://ecfd.pfizer.com/sites/sunshinetracker/default.aspx>.

The Centers for Medicare and Medicaid Services (CMS) discloses the data on a publicly available [website](#). CMS discloses calendar year data on June 30<sup>th</sup> of the following year. Please refer to **Orange Guide Chapter 18: Meals, Educational Items, Greenstone Giveaways, and HCP Payment Disclosure** for more information on our disclosure obligations under the Sunshine Act.





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

#### **Key Points to Ensure Compliance**

- Understand the policies that apply to your group.
- Funding to not-for-profit organizations by U.S.-based (and non-U.S. based when charged to U.S. cost centers) colleagues within Pfizer Biopharmaceutical Group, Upjohn (excluding Upjohn R&D colleagues), collectively Business Units or BUs, Worldwide Medical & Safety (comprised of legacy Pfizer Medical division and Safety group), Chief Business Office (CBO), and Corporate Affairs 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](mailto:USFundingRequest@Pfizer.com). For specific questions relating to funding by Corporate Affairs, e-mail [PolicyFRC@Pfizer.com](mailto:PolicyFRC@Pfizer.com).
- Funding to external organizations by U.S.-based colleagues in WRDM (excluding Worldwide Medical & Safety (WMS)), Global Product Development (GPD) (collectively, "R&D colleagues") must follow R&D SOP 202.
- Pfizer colleagues in other divisions must follow [Corporate Procedure 801](#) and also the review, approval and documentation requirements applicable to their division.
- Funding under this Chapter is not intended to provide support for Independent Medical Education activities or research activities such as Investigator Sponsored Research (ISR) and Clinical Research Collaborations (CRCs).
- Understand the types of activities your group is permitted to fund by reviewing the relevant SOP or reaching out to the supporting teams identified in the relevant SOP.
- For U.S.-based (and non-U.S. based when charged to a U.S. cost center) colleagues in the BUs, WMS, CBO, and Corporate Affairs, the following table summarizes permitted funding by group:



Type of Funding	Sales	Non-Sales (including PCA and Account Managers)	Corporate Affairs	BU Medical, WMS, and CBO	Global Medical Grants (GMG)
<b>Non-Healthcare Charitable Contribution</b>		Yes*	Yes	Yes	
<b>Healthcare Charitable Contribution</b>					Yes
<b>Policy Focused Healthcare Charitable Contribution</b>			Yes		
<b>Special Event</b>			Yes		
<b>Sponsorship</b>	Yes, but DBM and above only	Yes	Yes	Yes	
<b>Collaboration</b>	Yes, but DBM and above only	Yes	Yes	Yes	Yes
<b>Fellowship</b>				Yes**	
<b>Independent Charity Patient Assistance Programs</b>			Only certain Colleagues within Global Health & Patient Access (legacy Corporate Responsibility)		



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\* To remain consistent with, and for purposes of this chart found in the [SOP on Funding Requests for Not-for-Profit Organizations](#), "PCA" and Account Managers includes all Account Management roles e.g. Account Directors, Key Account Managers (KAMs), HIT Specialists and Vaccine Account Management roles. PCA & Account Management colleagues must consult their Team Attorney before proceeding to support a Non-Healthcare Charitable Contribution. \*\*Patient & Health Impact (PHI) colleagues involved in designing and conducting research related to health economics and real world data are the only CBO colleagues permitted to fund Fellowships.



### ***Key Points to Ensure Compliance***

- Field Commercial Colleagues, as defined in Chapter 1 of this Guide, may fund sponsorships that provide an appropriate “tangible benefit” (as defined later in this Chapter) to Pfizer. For BU Sales Colleagues, these sponsorships may only be provided at the DBM level or higher.
- A 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.
- 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 and ensure that it is a type of request they are permitted to fund, under relevant SOPs.
- Never offer or provide funding: (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 grant funding or donations unless approved in advance by Legal.
- 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 inappropriate promotion of Pfizer products or where there is a likelihood that treatment options will not be presented in a fair and balanced manner.
- Never sign an agreement or contract until the funding request is fully approved.
- Never make a verbal or written commitment until the funding request is fully approved.

## **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 prior to making any commitment of funding.

#### ***Sponsorships and Charitable Contributions: WRDM and GPD***

Funding and non-financial support in the form of volunteering, membership and board membership to external organizations by U.S. WRDM (excluding WMS) and GPD colleagues (collectively, “R&D colleagues”) must follow R&D SOP 202 and R&D SOP 203. Guidance and support can be found on [R&D's Compliance CNTR](#).

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#### ***Sponsorships and Charitable Contributions: BUs, CBO, WMS, and Corporate Affairs***

The remainder of this section describes the policy that applies to U.S.-based (and non-U.S. based when charged to U.S. cost centers) colleagues in the BUs, including Field Commercial Colleagues, WMS, CBO, and Corporate Affairs. Colleagues in these divisions should refer to the [SOP on Funding Requests for Not-for-Profit Organizations](#) (“External 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 BU Leadership and the Medical Lead for each BU. Those activities are addressed in the External 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 represents the type of opportunity that they can appropriately fund. Such guidance can be found in the [External Funding SOP](#).



#### **“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 External 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 most 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.

**A funding request characterized as a sponsorship 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 PCA\*) 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.**

\* To remain consistent with the [SOP on Funding Requests for Not-for-Profit Organizations](#), “PCA” includes Account Managers, including but not limited to Account Directors, Key Account Managers (KAMs), Oncology KAMs, HIT Specialists, and Vaccine Account Managers (VAMs).





Tangible Benefit Examples*	Fair Recognition Examples (Not Considered A Tangible Benefit)
<ul style="list-style-type: none"><li>• An activity provides a Tangible Benefit where Pfizer is a direct recipient of the activity output (e.g., funding the development of literature that will then be used by Pfizer) or where Pfizer has any input with respect to the execution or content of the activity (e.g., providing strategic direction or message development).</li><li>• Distribution of branded materials or dissemination of information on specific products.</li><li>• Promotional placement of <b>product</b> logos on a podium or in literature aimed at HCPs or patients.</li><li>• Opportunity to promote Pfizer products (e.g., via branded materials or a booth at an exhibition).</li><li>• Opportunity to promote Pfizer's programs or services (e.g., Pfizer RxPathways).</li><li>• Providing or selecting a speaker (including for a policy topic).</li><li>• Opportunity to promote Pfizer unbranded programs (such as smoking cessation which may have related branded or unbranded materials).</li><li>• Opportunity to promote specific businesses, portfolios, or franchises within Pfizer (e.g., Pfizer Oncology, Pfizer Women's Health, Pfizer Vaccines), provided that such promotion involves activities beyond mere promotional placement of its name/logo, such as the ability to distribute materials or information related to such business, portfolio, or franchise and/or products within such business, portfolio, or franchise.</li></ul>	<ul style="list-style-type: none"><li>• Placement of a Pfizer corporate logo by itself on a podium, in literature, or on a purchased table at an event.</li><li>• Honorable mentions and announcement of thanks, written or verbal.</li><li>• Tickets to an event.</li><li>• Recognition in conference brochure/program (such as listing as Gold Sponsor).</li></ul>

\* Subject to meeting all relevant review committee approval requirements.



If a not-for-profit sponsorship opportunity satisfies the above key characteristics, U.S.-based (and non-U.S. based when charged to U.S. cost centers) colleagues in BUs, WMS, CBO, and Corporate Affairs may submit a funding request using the Funding Request Form (FRF) available at <https://aribaprime.pfizer.com/Sourcing/Main>. Sponsorship opportunities involving for-profit organizations are evaluated under similar rules but must be submitted for Legal approval directly and not through the Ariba ACM /FRF system.

#### Evaluate Substantive Nature of Funding Request

	Can a colleague in a BU, WMS, CBO, or Corporate Affairs, fund a sponsorship as long as the tangible benefit criteria is met?
	Not necessarily. When evaluating the substantive nature of a funding request for a sponsorship, colleagues must differentiate the tangible benefit offered from the activity/event. For example, at times organizations may offer exhibit space in return for providing support for a medical education conference. While the exhibit space is considered a tangible benefit, only GMG is permitted to support the medical education conference through an independent medical education (IME) grant. In order to fund a sponsorship for the exhibit space, the funding request must clearly outline support is being provided for the exhibit space and not for the medical education conference.

#### Submission of Funding Requests by Sales Colleagues

**Sponsorships may be funded only by Sales 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 Ariba ACM. 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 must complete the Funding Request training module in order to gain access to the FRF in Ariba. All funding requests are subject to review and approval by the appropriate Legal Division colleague, unless otherwise noted. Contact [USFundingRequest@Pfizer.com](mailto:USFundingRequest@Pfizer.com) for more information about training.





### **Charitable Contributions**

Generally, charitable contributions are expenditures that are intended to fund a qualified 501(c)(3) organization in the United States (or non-U.S.-based not-for-profit entity equivalently recognized by the respective country's local government) for its 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 who May Provide Funding:** U.S.-based (and non-U.S. based when charged to U.S. cost centers) colleagues in the following Pfizer divisions: BU non-Sales Functions (including PCA), Corporate Affairs, CBO, and WMS. For purposes of the External Funding [SOP](#), PCA includes Account Managers, as defined above.
- **Approval Process:** Requests for non-healthcare charitable contributions may be submitted using the Funding Request Form at <https://aribaprime.pfizer.com/Sourcing/Main>. All such requests are subject to review and approval by Legal.

**Healthcare charitable contributions (non-policy focused)** are charitable contributions to healthcare-related organizations or non-healthcare related organizations for healthcare-related programs. Field Commercial Colleagues may not fund healthcare charitable contributions. GMG 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., transportation costs); and/or organizations whose general mission is to benefit specific patient groups. If the target audience of a patient/community education program also includes HCPs, the request may not be supported as a charitable contribution—the request must be processed as an Independent Medical Education (IME) grant (refer to the chapter titled “Independent Medical Grants”).



- **Examples:** Contribution to the Arthritis Foundation for patient education on lifestyle changes that can help them manage their condition; contribution to CancerCare for improved access to care—transportation to/from medical appointments for patients with breast cancer.
- **Colleagues who May Provide Funding:** GMG
- **Approval Process:** Requests for (non-policy-focused) healthcare charitable contributions that meet the criteria above must be submitted directly by the 501(c)(3) not-for-profit organization to GMG via Pfizer's online [Grant Management System \(GMS\)](#). Colleagues may not submit requests to GMG on an organization's behalf. This website includes a list of criteria that any request must meet to be eligible for GMG charitable funding. Funding from GMG may not be used to support food or beverages for learners/participants. GMG will review submissions for completeness, alignment with clinical areas of interest, compliance with Pfizer policies, and other requirements. Requestors will receive an e-mail notification when the request is approved or denied.

**Policy-focused healthcare charitable contributions** are contributions to 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 continuing medical education/continuing education (CME/CE) or disease state, medical, or clinically-focused activities).

- **Example:** Charitable contribution to the Georgia Medical Society for education of members on healthcare reform.
- **Colleagues who May Provide Funding:** Corporate Affairs.
- **Approval Process:** Requests must be submitted by appropriate colleagues using the [Funding Request Form](#). All such requests are subject to review and approval by Legal.

**"Special Events"** are contributions to 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 who May Provide Funding:** Corporate Affairs.
- **Approval Process:** All requests must be submitted by appropriate colleagues using the Funding Request Form through [Ariba-ACM](#). All such requests are subject to review and approval by Legal.
- **Internal Coordination:** Involvement of BU colleagues in policy-focused healthcare charitable contributions and Special Events must be strictly limited. Certain designated BU colleagues are





permitted to present therapeutic area strategies and priorities to Corporate Affairs so that Corporate Affairs 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, Corporate Affairs may invite colleagues to participate only if there is no branded or promotional interaction with the organization, and discussions with attendees must not involve Pfizer brands or products. Colleagues are not permitted to invite HCPs to these events.



Key Characteristics: Sponsorships vs. Charitable Contributions		
Characteristic	Sponsorship	Charitable Contributions
Promotional in nature	Yes	No
Payee must be a not-for-profit organization (501(c)(3) or similar designation)	Yes (except for Exhibit and Displays)	Yes (but only 501(c)(3) organizations are eligible)
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 SOP

	Where can Pfizer colleagues in the BUs, WMS, CBO, and Corporate Affairs get help and information on Pfizer's policy regarding funding to not-for-profit organizations?
	Funding requests must be initiated at <a href="#">Ariba-ACM</a> under the Create menu, select "Funding Request Project". Additional resources are also available at <a href="#">CO PolicyXchange</a> under the "Funding Requests" tab. Global Policy Xchange on GCO On Demand also includes a funding request "wizard" and other tools that can help you determine whether a proposed funding activity is permissible for you to support. You can direct any questions about the process to <a href="mailto:USFundingRequest@Pfizer.com">USFundingRequest@Pfizer.com</a> .

#### Purchase of a single ticket to a Gala/Fundraiser



	The External Funding SOP prohibits Field Commercial 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?
	Yes. The SOP 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 must operate within the spirit of these guidelines and not purchase individual tickets in a manner that result in the purchase of a whole table in order to circumvent the SOP.

#### Sponsorship Request related to For-Profit Organizations



	Does the External Funding SOP apply to funding requests from for-profit organizations?
	No. These requests are evaluated under similar standards but are not covered by the External Funding SOP and should not be processed using the Funding Request Form (FRF) in Ariba-ACM. Colleagues should obtain approval from Legal and determine the appropriate process (e.g., purchase order (PO) or ePay).



### Sales-Funded Exhibit and Display Requests

	Are Exhibit and Display Fees made payable to not-for-profit organizations covered by the External Funding SOP?
	Sales-funded Exhibits and Displays are subject to a different SOP – <a href="#">ED SOP2-01</a> available on Global Policy Xchange on GCO On Demand under the Funding Requests tab which is separate from the External Funding SOP. You should submit Exhibit and Display requests through Ariba ACM using the Funding Request Form (FRF) which will be routed to your program activity coordinator for review and follow the applicable policies (available in <a href="#">Global Policy Xchange on GCO On Demand</a> under the “Funding Requests” tab). However, if an Exhibit and Display request is part of a larger promotional sponsorship package that includes other benefits (in addition to an exhibit and display space), then the <a href="#">External Funding SOP</a> should be followed.

### Appropriate Pfizer Foundation Referrals

	Can a customer's request for a charitable contribution be forwarded to the Pfizer Foundation for consideration?
	No. The Pfizer Foundation is an independent, tax exempt organization established by Pfizer Inc. and does not accept unsolicited funding requests. 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 Healthy Families, Healthy Futures program.

## Collaborations

Another way that Pfizer supports external organizations is by participating in collaborations or joining coalitions to advance shared objectives (this chapter does not include guidance regarding Clinical Research Collaborations). Colleagues must follow the review, approval, and documentation requirements applicable to their division. The requirements for BUs, WMS, CBO, and Corporate Affairs 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 specified shared objectives, where all parties participate as equal partners. Pfizer must not only support the organization with funding (in cash or in-kind resources or expertise) but must also make a substantial intellectual contribution to the project. “Substantial intellectual contribution” means conceiving and designing a project, acquiring data, or analyzing and interpreting data.

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If the organization creates materials that are published, this must occur in conjunction with Pfizer. In a Collaboration, Pfizer is involved with the creation of the output, provides feedback on suggested publications, and has the right to use the materials being created. For BU colleagues, all materials developed for distribution must go through a Pfizer RC evaluation to check the content for factual accuracy and compliance with applicable laws, regulations and Pfizer policies.

Pfizer's involvement in a Collaboration must be disclosed clearly in all resulting materials in a manner that does not imply that the materials were funded through an unrestricted grant or Charitable Contribution. Such disclosure should state "Developed in collaboration with Pfizer" or similar terms.

- **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 who May Provide Funding:** U.S.-based (and non-U.S. based when charged to U.S. cost centers) colleagues in the BUs, WMS, CBO, and Corporate Affairs.
- **Approval Process:** Colleagues should discuss all pertinent facts about a collaboration with Legal prior to submitting the Funding Request Project for approval. After consulting with Legal, requests to participate in a collaboration must be submitted by appropriate colleagues by creating a Funding Request Project in Ariba-ACM, which are subject to formal review and approval by Legal.
- One type of collaboration involves Pfizer working with two or more separate entities to achieve a common objective (e.g., public policy development). This type of collaboration is commonly known as a coalition. Pfizer's membership in a coalition may involve monetary funding or a donation in-kind of resources or expertise but must always include Pfizer's involvement in the development of the mission and goals and the advancement of the aims of the collective group. Due to a high degree of legal risk in healthcare-related coalitions, the majority of the group's members must be non-commercial, non-manufacturer organizations and they should be the partners who have ultimate control over the coalition and its messaging, subject to Pfizer's rights to review the content for factual accuracy and to ensure compliance with applicable laws, regulations, and Pfizer policies.

#### ***Collaborations – Tangible Benefit and Disclosure of Pfizer Involvement***

Given the nature of Pfizer's involvement in collaborations, including the provision of strategic input and often the rights to use the output of the activities, **this category must 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 must also be appropriately disclosed in all resulting materials in a manner that does not imply that funding was provided via an unrestricted grant or charitable contribution (e.g., "Developed in partnership with Pfizer" rather than "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. WMS and BU Medical are permitted to fund awards, fellowships, and scholarships. Certain PHI colleagues are also permitted to fund fellowships. The requirements and process in this section relate to the US External Funding SOP. R&D colleagues should refer to R&D SOP 202 for requirements related to Fellowship funding.

**Awards** are programs developed with an independent professional group to provide funds or other recognition to an individual demonstrating professional excellence in the field of medical science or healthcare leadership or an outstanding commitment to public health or patient care. **Fellowships** are generally funds paid to 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 research or 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 carefully selected educational conferences; or (2) support clinical or research fellowships.

- **Colleagues who May Provide Funding:** Awards, scholarships, and fellowships are permitted to be funded only by **WMS** and **BU Medical** colleagues. PHI colleagues involved in designing and conducting research related to health economics and real world data are the only CBO colleagues permitted to fund fellowships.
- **Approval Process:** All such funding requests are subject to review and approval by the Policy Funding Review Committee (PFRC).
- **Requirements:** Pfizer funding of awards, scholarships, and fellowships is permissible only under the following circumstances:
  - The selection of awardees is independent of direct and indirect Pfizer influence, which includes direct selection of awardees as well as 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;
  - Pfizer receives an unsolicited request from an organization to fund a fellowship program that already exists, or is being developed, and will be operated by, the organization; and

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- Such awards, scholarships, and fellowships comply with applicable state laws and regulations.

In addition, awards, scholarships, and fellowships must be provided directly to requesting organizations (e.g., academic medical center; professional association) that independently select final individual awardees. It is permissible to assemble and retain a selection committee to evaluate requesting organizations when such expertise is required; provided that such requesting organizations independently select the individual student or HCP ultimately to receive the award, scholarship, or fellowship. 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 requesting organization's existing, routine, or ordinary business expenses. Fellowships must be paid directly to the awardee's institution and cannot be paid directly to the awardee. In addition, Pfizer can provide fellowships only to support the research activities of awardees 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 awardee will devote to non-billable teaching and research. Also, funding cannot be used to cover the salaries of other individuals assisting the awardee.

## Non-Financial Support

### ***Personal Volunteering***

With the exception of manager-approved team building activities or site-led hands-on volunteer activities, volunteering activities by Pfizer colleagues must be done during a colleague's personal time. Please review CP801 to review guidance on volunteering. Personal volunteering should not be linked to commercial goals or objectives or otherwise be part of promotional activities or business plans.

This prohibition, however, does not apply to activities approved by the relevant BU or division that are undertaken with organizations to promote Pfizer's products or advance Pfizer's business interests appropriately. For example, an Account Manager can join an 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, trustee 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"), [Corporate Policy 203: Conflicts of Interest](#), and other applicable Pfizer policies that address conflicts of interest.

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**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.**

While Pfizer encourages you to be active in the community in which you live and work, some activities, such as serving on a board of directors or trustees, advisory board or committee, may present a conflict of interest in some situations. Colleagues must ensure that such activities do not present a conflict of interest or create the appearance of one, pursuant to [Corporate Policy 203: Conflicts of Interest](#). With limited exception (as described in CP203), before accepting a role with an outside organization, inform your manager to determine if any specific review or approvals are required. In some situations, consultation with Legal and Compliance may be appropriate and additional approvals required.

Accordingly, every colleague who participates as a regular member, officer, trustee 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 obtain approval from Corporate Responsibility prior to making a financial commitment. In addition:

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 or 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 or 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: Interactions with HCPs and [ED SOP2-01 – Exhibits and Displays Standard Operating Procedure](#) available in Global Policy Xchange on GCO On Demand under "Funding Requests".
- SOP on [Funding Requests for Not-for-Profit Organizations](#) applies to U.S.-based (and non-U.S. based when using U.S. cost centers) colleagues in the BUs, WMS, CBO, and Corporate Affairs. For questions relating to this SOP, e-mail [USFundingRequest@Pfizer.com](mailto:USFundingRequest@Pfizer.com). For specific questions relating to funding by Corporate Affairs, e-mail [PolicyFRC@Pfizer.com](mailto:PolicyFRC@Pfizer.com).
- For other general information and training materials regarding Funding Requests, consult the Funding Requests tab on [GCO PolicyXchange](#).
- For questions regarding (non-policy-focused) healthcare charitable contributions, e-mail [healthcharitables@Pfizer.com](mailto:healthcharitables@Pfizer.com) or visit [www.pfizer.com/healthcharitables](http://www.pfizer.com/healthcharitables).



## Orange Guide – Chapter 3: Support of External Organizations

- For questions regarding Special Events, policy-focused healthcare charitable contributions, awards, scholarships, or fellowships, e-mail [PolicyFRC@pfizer.com](mailto:PolicyFRC@pfizer.com).
- R&D colleagues must refer to [R&D's Compliance CNTR](#) for guidance and support.
- Please refer to Orange Guide Chapter 18: Meals, Educational Items, Greenstone Giveaways, and HCP Payment Disclosure for more information on our funding disclosure obligations under the Sunshine Act.
- For more information on the Pfizer Foundation, refer to <https://www.pfizer.com/purpose/responsibility/the-pfizer-foundation>.
- For information about Pfizer's disclosure of external funding activities, please visit <https://www.pfizer.com/purpose/transparency/transparency-in-grants>.
- For information regarding Pfizer's policies related to donations to, and interactions with, Independent Charity Patient Assistance Programs (ICPAPs) organizations, as it relates to Pfizer Colleagues is described in more detail in [Corporate Policy and Procedure #803](#).
- Refer other questions to your Legal support.



## **CHAPTER #4 – FEDERAL EMPLOYEE INTERACTIONS AND LOBBYING**



Chapter

#4

FEDERAL EMPLOYEE INTERACTIONS  
AND LOBBYING

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## Chapter #4 Federal Employee Interactions and Lobbying

### Introduction

This Chapter summarizes: (a) the important rules you must understand and follow when engaging in promotional and non-promotional activities with U.S. federal government agencies, including the Department of Veterans Affairs (VA), the Department of Defense (DoD), the Department of Health and Human Services (DHHS), and federal government employees; and (b) certain key Pfizer policies regarding lobbying registration and disclosure. This Chapter is relevant to any colleague who (1) interacts with federal government employees, including healthcare professionals (HCPs) and formulary decision-makers, or (2) 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 governing interactions with federal employees and lobbying activities involving federal or state government officials and public employees. Non-compliance with these policies puts the Company at risk and can subject colleagues to internal disciplinary action, up to and including termination, and external civil and criminal sanctions.**

### 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 more commonplace. Pfizer's customers include federal government agencies and institutions, including the VA and its hospitals, the DoD and its medical facilities, and the DHHS, including the Indian Health Service (IHS) and the Centers for Disease Control and Prevention (CDC). Pfizer sales colleagues may interact with HCPs and other employees who work for these government agencies and institutions on a full- or part-time basis or otherwise qualify as federal government employees. Account managers may also interact with federal government employees who make decisions on formularies and purchasing.

**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).

**Centers for Disease Control and Prevention (CDC)**

Federal agency that is responsible for the of promotion health and quality of life by preventing and controlling disease, injury, and disability.

**Indian Health Service (IHS)**

Federal agency that is responsible for providing federal health services to American Indians and Alaska Natives.

Promotional activities that are permissible when conducted with HCPs who are not federal government employees may be prohibited when these same activities are conducted with HCPs who are federal government employees. Interactions with federal employees are governed by the Standards of Ethical Conduct established by the Office of Government Ethics (OGE), other government-wide OGE regulations, agency-specific regulations and policies, and institution and site-specific policies and procedures. Interactions with VA employees are further restricted by the more specific rules contained in [Veterans Health Administration \(VHA\) handbook 1004.07](#)

(“Financial Relationships Between VHA Healthcare Professionals and Industry”), [VHA Directive 1108.10](#) “Promotion of Drugs and Drug-related Supplies by Pharmaceutical Company Representatives”, and 38 C.F.R. 1.220, On-site Activities by Pharmaceutical Company Representatives at VA Medical Facilities.

## Promotional Activities

***Impact of Formulary Status on Ability to Promote***

Sales colleagues must comply with federal agency, institution, and local site policies regarding drug promotion, including those that regulate promotion based on formulary status. In some cases, local regulations will prohibit any discussion of products that are either not on the institution’s formulary or are on the formulary with restrictions. In all cases, you must accurately and clearly represent the formulary status of the product being discussed.



At VA facilities and other VA points of care, promotion of formulary and non-formulary drugs, including those with established [Criteria-For-Use](#) (CFU) is permitted only under limited circumstances. CFU means clinical criteria developed by the Department of Veterans Affairs (VA) at a National level that describe how certain drugs may be used. VA's CFU are available to the public at [www.pbm.va.gov](http://www.pbm.va.gov). Exceptions may be applied at the local level for operational reasons. In all cases, the Veterans Integrated Service Network (VISN) Director, the facility Chief of Pharmacy, or his or her designee must provide approval of the promotional activity. Key VA-specific rules are set forth below.

**VA-Specific Promotional Rules:** VA National Formulary (VANF) and Non-VANF drugs and drug-related supplies may be promoted in VA medical centers (including Community-Based Outpatient Clinics (CBOCs) and other VA medical facilities) provided that all of the following conditions are met:

- (1) The promotion has been approved by the VA medical facility's Chief of Pharmacy Services, or designee;
- (2) The promotion is consistent with the existing Pharmacy Benefits Management (PBM) Criteria-for-Use guidance;
  - **NOTE:** Sales representatives may access information regarding VA Criteria-for-Use *from the PBM Web site at:* [www.pbm.va.gov](http://www.pbm.va.gov).
- (3) The drugs or drug-related supplies are discussed, displayed, and represented accurately;
- (4) The promotion has significant educational value and does not inappropriately divert VA staff from other activities they would otherwise perform during duty hours, including patient care and other educational activities; and
- (5) The drug or drug-related supply has not been classified by VA as non-promotable.

38 C.F.R. 1.220 On-site Activities by Pharmaceutical Company Representatives at VA Medical Facilities.

Non-VANF drugs and drug-related supplies where PBM Criteria-for-Use have not been developed, may be promoted in VA medical centers (including CBOCs and other VA medical facilities) provided that all of the following conditions are met:

- (1) The promotion is specifically permitted by the VA medical facility's Chief of Pharmacy Services, or designee;
- (2) Drugs or drug-related supplies are discussed, displayed, and represented accurately;
- (3) The promotion has significant educational value and does not inappropriately divert VA staff from other activities they would otherwise perform during duty hours, including patient care and other educational activities; and







- (4) The drug or drug-related supply has not been classified by VA as non-promotable. **NOTE:** *The PBM maintains a National listing of formulary medications that are not to be promoted or detailed by sales representatives on the PBM intranet (<http://vawww.pbm.va.gov>) and internet ([www.pbm.va.gov](http://www.pbm.va.gov)) Web sites.*

38 C.F.R. 1.220 On-site Activities by Pharmaceutical Company Representatives at VA Medical Facilities.

**Products with Criteria-for-Use:** It is possible that product-specific information and recommendations in the CFU may be inconsistent with product labeling. Therefore, sales colleagues can discuss CFU product-specific recommendations and clinical recommendations only if approved by the relevant brand RC. It is important to highlight, when having such discussions, that the CFU was independently developed by the VA and that Pfizer does not necessarily endorse them. In the event that the CFU is inconsistent with product labeling, for example, when they recommend use of a Pfizer product over a competitor when there is no head to head data, or when the use is recommended in a patient population that is different from that in the label, the brand RC may consider allowing sales colleagues to refer HCPs to the VA website for review of the CFU or leaving a copy behind, without discussing them. If copies of CFU are approved by the brand RC as a leave-behind, they should be distributed separately from any promotional materials and include prominent disclaimers that the CFU was independently developed by the VA, that Pfizer does not endorse the CFU or recommend using the product as described in the CFU and attach a copy of the approved product labeling.

In all cases where there is any question as to whether promotional materials are consistent with Pfizer policies, your team attorney must be consulted **before** providing those promotional materials to the customer.

#### Products with Criteria-for-Use

	The VA provider mentioned to me he tried prescribing Product X but was told he must first try Product Y. What should I do?
	VA establishes CFUs that are similar to prior-authorizations per its VANF process. These may require trial through VANF drugs, generics, or certain circumstances to exist. The specific VA product CFU cannot be discussed by representatives unless permitted by the brand RC. Representatives may acknowledge in general the existence of a CFU and refer the provider to their internal website or pharmacy for more information.





### **Site Visits/Providing Promotional Materials/Educational Materials**

You must make an appointment prior to visiting VA Facilities for the purpose of promotional activity. Use and reference to promotional materials can be driven by facility-specific policy. VA policy, for example, requires that promotional materials referenced on a VA site must be approved by the VA medical facility's Chief of Pharmacy Services or his or her designee. Also, it does not permit company representatives to leave promotional materials in patient areas. At DoD facilities you should follow the process of each facility regarding appointments and promotional activity.

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, VA facilities do not permit marketing to students (including residents), and do not permit waiting in patient-care areas or paging employees via a public address/paging system.

- Any promotional programs or educational materials that sales colleagues wish to use or circulate at VA facilities must be RC-approved and submitted to the Facility Chief of Pharmacy Services at least 60 days prior to your educational program or meeting for review and approval. No materials may be used without obtaining such approval. Additionally, without permission from the VA Pharmacy Benefits Management Service, patient education materials may not contain the name or logo of the manufacturer or promote a specific medication.

#### **VA Appointment Requirement**

	Do sales colleagues have to make an appointment before calling on HCPs who work at VA facilities?
	Yes. Additionally, once on-site you may only detail HCPs with whom you have made an appointment.

### **Starters**



Many federal government institutions, such as VA clinics and hospitals, may prohibit pharmaceutical companies from leaving starters, samples, or free goods. You must always learn the sample policies and procedures of any institution that you call on and follow those rules. If there is any question as to whether these policies and procedures might conflict with Pfizer policy or the Prescription Drug Marketing Act (PDMA), you must consult your team attorney **before** leaving starters with that customer.

Federal rules and policies regarding sampling/starters/donations must be followed in all cases where samples are provided to or in federal facilities. Accordingly, starters cannot be left for federal employees at the federal institution at which the employee works even in cases where the starters are intended for use outside of the government (e.g., in private practice settings).



The VA has documented procedures, policies, and regulations regarding the donation of drug samples by pharmaceutical representatives at VA medical facilities. All drug donations must be approved in advance by the VA Medical Facility Director. Additionally, all usage information about the product must be forwarded to the VA Pharmacy Executive or Formulary Committee. If donated products are intended to be used solely to allow VA clinicians to gain familiarity with the products, such use must be pre-approved by the VISN Pharmacist Executive and/or VISN Formulary Committee. After approval, all samples must be delivered to the Office of the Chief of Pharmacy Services for proper storage, documentation, and dispensing. In general, donated drugs should not be labeled as “sample”. However, on rare occasion, the VA will make exceptions to this rule if it is in the best interest of the patient (e.g., product shortage). 38 C.F.R. 1.220 On-site Activities by Pharmaceutical Company Representatives at VA Medical Facilities.

#### Providing Starters to the VA

	I've been told by an HCP at a VA facility that pharmaceutical companies cannot leave starters with the VA. Is this correct?
	VA policy permits “free goods” to be donated to the VA, but only after pre-approval by the VA Medical Facility Director. And, the product must be delivered to the Office of the Chief of Pharmacy Services for proper storage, documentation, and dispensing. The distribution of starters directly to VA HCPs is inconsistent with the VA’s policy.

### Gifts to Federal Employees

#### General Rules

Like the PhRMA Code’s guidelines on gifts to HCPs, the federal government places restrictions on the acceptance of gifts by its employees, including HCPs. Under the overarching federal gift rules, a federal government employee may not accept any single gift (which can include anything of value, such as meals, travel, lodging, entertainment) that has a retail or market value of more than \$20, nor can a federal government employee accept gifts with an aggregate value of more than \$50 annually from a single “source,” e.g., a single company, like Pfizer. As discussed in this section, there are additional rules that further limit these general restrictions.

**To help ensure that Pfizer maintains compliance with the federal rules, the only “gifts” that colleagues can provide to federal government employees (including HCPs) are Pfizer-approved educational items and modest refreshments (without alcoholic beverages) under the circumstances outlined in this Chapter. As a reminder meals at VA facilities are prohibited.**



Further, any gifts, including refreshments, provided to federal government employees 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 Pfizer sales colleague or by contacting [PTI@Pfizer.com](mailto:PTI@Pfizer.com). For additional information on Pfizer's HCP Payment Disclosure Policy, see Chapter 18: Meals, Educational Items, Greenstone Giveaways, and HCP Payment Disclosure.

### **Educational Items**

There is an exception to the general gift restrictions that allows a federal government employee to accept unsolicited gifts of informational materials with a value of \$100 or less from a single source in a calendar year. To qualify, the materials must be: (i) educational or instructive in nature; (ii) not primarily created for entertainment, display, or decoration; and (iii) contain information that relates in whole or in part to the following categories: (A) the employee's official duties or position, profession, or field of study; (B) a general subject matter area, industry, or economic sector affected by or involved in the programs or operations of the agency; or (C) another topic of interest to the agency or its mission. A federal government employee may exceed the \$100 limit with prior written authorization from his or her Designated Agency Ethics Official (DAEO) before providing informational materials to a federal government employee, you must contact Pfizer ethics counsel for prior approval.

### **Refreshments**

As outlined above, federal law and Pfizer policy place limits and/or restrictions on the offering of food, meals, and refreshments to federal employees. These must be followed by all Pfizer colleagues.

**Modest Refreshments:** Modest refreshments (such as coffee and donuts, not including alcoholic beverages) in some cases can be offered to federal government employees when incidental to a scheduled meeting or legitimate educational interchange not otherwise prohibited by the facility or local rules. In these cases, modest refreshments are not considered "gifts" and do not count toward the \$50 annual cap for each federal government employee. Also, offering even modest refreshments on a regular, repeated, or routine basis is not allowed, and alcohol is always prohibited.

**Site-Specific Rules/VA On-Site Prohibition:** *The VA prohibits pharmaceutical representatives from providing meals or refreshments of any type or value to VA staff (including volunteers) or non-VA staff while on-site at a VA facility (hospital, office, other agency offices).* Other federal government agencies, including DoD and IHS, have their own rules concerning interactions on-site at their facilities. Pfizer sales colleagues must review the local site rules of all federal healthcare facilities that they visit to determine whether in-office or in-hospital meals and/or refreshment are permissible.

When meals are permitted, you also must comply strictly with the following limitations:



- You must obtain confirmation from the federal employee that he or she is permitted to accept the in-office or in hospital meal under all applicable laws and rules, including any local site rules.
- You may not offer meals on a regular, repeated, or routine basis to any federal government employees, including any HCP or group of HCPs;
- Each meal must have a total value of \$20 or less;
- You must confirm that offering the meal will not cause Pfizer to exceed the \$50 ceiling on gifts to any federal employee (this ceiling applies to Pfizer as a whole and not to specific Pfizer colleagues); and
- The meal must take place at the HCP's office or hospital when hosted by a Pfizer colleague.

#### ***Inviting Government Employees to Speak or Present at Events***

Pfizer colleagues must contact Pfizer ethics counsel for more information before scheduling an event or meeting at which a full- or part-time federal employee will speak or extending an invitation to any federal employee to attend an event.

**Speaker/Free Attendance:** Federal government employees, including HCPs, may accept an offer of free attendance to speak at a Pfizer-sponsored event and may accept meals provided at the event that are provided to all participating speakers on the same day. Pfizer policy requires obtaining approval by the DAEO of any such engagement in writing. However, federal government employees are generally prohibited from accepting compensation for speaking engagements that relate to their official duties. This includes receiving compensation to speak to other government employees on Pfizer's behalf.

In limited circumstances, federal government employees may be compensated to speak on matters that are **not** related to their official duties. The conflict-of-interest regulations require that any such engagement be pre-approved in writing by the federal government employee's DAEO. (Approval from other federal government employees who are not the DAEO is not sufficient.) In assessing such an engagement, the DAEO will consider whether the federal government employee:

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

Pfizer policy requires receipt of DAEO approval in writing prior to such speaking engagement or confirmation from the Government Employee, in writing, that they received approval from the DAEO.



***Inviting Government Employees to Attend Events (Non-Speakers/Presenters).***

On occasion, Pfizer may wish to invite federal government employees to events, including off-site educational speaker programs, as non-speakers. Under those circumstances, free attendance is considered a gift. Free attendance and meals provided to all attendees in a group setting may be allowed under an exception to the gift restriction that applies for “widely attended gatherings.” Importantly, to qualify for this exception, the federal government employee must receive prior written approval from his or her DAEO before accepting the invitation to attend. (Approval from other Federal Government Employees who are not the DAEO is not sufficient.) Pfizer policy thus requires receipt of DAEO approval or confirmation from the Federal Government Employee, in writing, that they received approval from the DAEO prior to Federal Government Employee attendance at this type of event and all invitations must be contingent upon receiving this approval.

Pfizer policy further requires that any meal being provided is 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 a federal government-employed HCP.

**Lunch and Learn**





A sales colleague would like to call on a HCP employed by the VA who has a busy schedule. Due to 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 in her office on alternating Tuesdays and bring a modest lunch for the HCP, such as a sandwich and soda?





No. VA Rules prohibit providing a meal to VA employees at VA facilities. Additionally, because the HCP is a federal government employee, even if the on-site meal prohibition did not apply, Pfizer prohibits colleagues from providing meals to federal government employees. Under the policy, colleagues may only provide modest refreshments without alcoholic beverages.





### Speaker Program Meals

	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 permitted, is it permissible for the DoD HCP to receive the same meal as the other attendees in the group setting if it’s more than \$20 in value? Or, is Pfizer required to provide a meal of \$20 or less in value?
	The Pfizer Colleague needs to confirm that the federal government employee has received DAEO approval in writing (approval by others within the agency will not be sufficient). If DAEO written approval has been obtained, the exception will be met and the meal provided at the event will not be considered a gift. The HCP thus can have the same meal as the other event attendees.

### Part-Time VA Employees



	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?
	Yes. 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.

### Compliance Responsibility

	If a HCP at a VA facility asks me to provide him with something that would be considered a gift, isn’t it the HCP’s responsibility to make sure that he or she is in compliance with applicable gift rules? How can Pfizer get in trouble?
	<p>It is your responsibility to make sure that you do not take action that causes the HCP to violate the gift rules. While the ethics rules place compliance requirements on the federal employee, under criminal law, private companies can be held accountable for their actions, including any that result in federal employee violations of ethics rules. Additionally, if Pfizer provides a gift to a federal HCP, it can trigger certain reporting obligations for the company. In addition, providing the gift may violate the local institution’s policies and result in Pfizer being excluded from the facility.</p> <p>Accordingly, at no time should you ever provide a federal government employee with any gift or meal, except as described in this Policy, even if the item has been approved for distribution to non-government HCPs or the item is requested by the federal government employee. 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.</p>



#### Engaging Part-Time Government Employees as Speakers

	May I engage an HCP who works part-time at a federal government institution to be a paid speaker at a Pfizer conference?
	You may only engage the HCP once he or she can provide a written approval from his/her DAEO authorizing the engagement. Additionally, all Pfizer policies related to engaging HCPs as speakers and properly conducting speaker programs must be followed. Please see chapter 9 of the Orange Guide.

#### 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 independent educational grants. Grant requestors must submit all requests for funding through [www.pfizer.com/independentgrants](http://www.pfizer.com/independentgrants). Requests will be reviewed according to Pfizer's standards for supporting independent medical education. For more information on Pfizer's educational grant process, refer to [GNT01-GSOP](#) "Independent Medical Grants" for further details.

#### Summary of Guidelines Regarding Federal Employee Interaction

##### General

- Do not provide anything of value to a federal government employee (including HCPs) other than Pfizer-approved educational items and modest refreshments (not including alcoholic beverages); additionally, on-site meals at VA facilities are strictly prohibited.
- Only provide federal government employees with educational materials that are pre-approved in accordance with this Chapter.
- Never provide free alcoholic beverages to federal government employees.
- On site at facilities of other federal government agencies, understand and comply with the applicable rules. For instance, if you are visiting a DoD or IHS facility, you are responsible for identifying any unique rules that apply to that facility and complying with them.
- Do not engage a federal government employee, including a HCP, to speak on Pfizer's behalf without evidence that the employee's DAEO has approved the engagement in writing or unless the Federal Government Employee has confirmed in writing that the engagement has been approved.
- Do not provide a federal government employee, including a HCP, free attendance to an event without evidence that the employee's DAEO has approved in writing the employee's attendance.





- Even if an item may be provided under the federal ethics rules and agency/facility-specific requirements, any such item, including refreshments, provided to a U.S.-licensed physician may be reportable under the relevant state laws and/or Sunshine Act.
- Additionally, always check the State Laws: *HCP and State Employee Restrictions* chapter for additional guidance.
- You must understand and comply with the sample policies of any institution that you call on, and to the extent that there is any question as to whether they might conflict with Pfizer policy or the PDMA, consult your team attorney.
- You must submit RC-approved educational materials to the Chief of Pharmacy Services at least 60 days prior to your educational program or meeting. Additionally, without permission from the VA Pharmacy Benefits Management Service, patient education materials may not contain the name or logo of the manufacturer or promote a specific medication.

***For DoD or IHS facilities, if provision of meals is permitted, 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;
- Meals must comply with the \$20 per occasion and \$50 per year limits discussed above; and
- The federal government employee must confirm in advance that he or she is permitted to accept an in-office or in-hospital meal under the Standards of Ethical Conduct and the local site rules.

#### ***Key Points to Ensure Compliance***

- Only RC-approved (and, in the case of the VA, approval by the VA medical facility's Chief of Pharmacy Services or designee) 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 state government official or his or her staff must be coordinated through the relevant GRD. Communications with federal government officials or staff must be coordinated through the Washington, D.C. Pfizer office.
- 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.



### ***Key Points to Ensure Compliance***

- 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 GRD 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.

## **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 disclose publicly its lobbying expenditures on a regular basis.

### ***Federal Lobbying***

The Federal Lobbying Disclosure Act (LDA), as amended by the Honest Leadership and Open Government Act (HLOGA), 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 advocacy 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 either through the Pfizer Grassroots program, the Washington, D.C. office, or a Pfizer State Government Relations Director (GRD), depending on the nature of the interaction.

Like the rules that govern your interactions with healthcare professionals, 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,



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.

### Who Is a “Lobbyist?”

Under 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 pertains only to Pfizer colleagues and not to 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 U.S. 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,” federal law requires Pfizer to report your time spent supporting the lobbying efforts of others within the Company.

### Calculating Lobbying Contacts





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?



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

	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?
	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. Pfizer is required to file quarterly reports that provide a list of the specific issues that were addressed by "lobbying activities" and an estimate of the total expenses incurred in connection with these 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;
- 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;
- Communicating with government officials as part of Pfizer's Grassroots advocacy program;
- 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 advocacy program works to inform and educate colleagues on public policy issues and provide colleagues the opportunity to engage in policy debates by making their voices heard in Washington, D.C. and state capitols across the country. There may be other activities developed by a State Action Team (formerly called 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 state government officials must be coordinated through a GRD. Interactions with federal government officials must be coordinated through the Washington, D.C. Pfizer office. 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 lobbying activities related to Pfizer business.
Report your 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 been engaged in federal “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 should fill out the form 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 online form is collected for the Company's quarterly federal LDA reports which are filed on April 20th, July 20th, October 20th, and January 20th 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 online form no later than one week after the close of the reporting period, or by April 7th, July 7th, October 7th, and January 7<sup>th</sup>, of that year.**

### Determining Time Engaged in Lobbying Activities



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?





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 activity 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, the Washington, D.C. Pfizer office, or your team attorney to verify whether your activities subject you to registration or reporting requirements.**



#### Leaving Educational Items with Public Employees

	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?
	Yes. Under Pfizer's HCP Payment Disclosure Policy, educational items valued \$10 or more must be disclosed and items valued less than \$10 may also be subject to disclosure so all items must be tracked for reporting purposes. Also, a reporting obligation may be triggered under applicable state law. Because state laws differ by state, it is imperative that you check with your team attorney before leaving any item with an HCP at a state prison.

#### HCPs Who Sit on State Formulary Committees

	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?
	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 team 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 Relations program which is active in almost all 50 states. As part of this effort, certain 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 (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 under which marketing activities involving Medicaid Pharmaceutical and Therapeutics Committee members may be considered 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 team attorney before engaging in any marketing interactions with state or local government employees.





### ***State Restrictions on Gifts to Legislators***

Many states place restrictions on gifts from the general public and lobbyists to legislators. These range from a general prohibition to specific dollar limits. The link below outlines some of these restrictions at <http://www.ncsl.org/research/ethics/50-state-table-gift-laws.aspx>. There are differences in what a lobbyist can provide to a legislator and what a legislator can receive from the public, a lobbyist or an outside interest. Consult your team attorney for specific restrictions.

### ***State Formularies***

Attempts to influence state formulary decisions are 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.

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

## **Campaign Contributions**

It is important to understand the difference between lobbying and grassroots advocacy efforts and campaign contributions. Lobbying and grassroots advocacy 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 committee that supports candidates who value biopharmaceutical innovation and are open to real dialogue on issues that affect patient access to medicines. For more information on the Pfizer PAC, please visit [http://sharepoint.pfizer.com/sites/USGovernmentRelations/SitePages/Home\\_New.aspx](http://sharepoint.pfizer.com/sites/USGovernmentRelations/SitePages/Home_New.aspx).

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

### For More Information

- Lobbying questions may be referred to the relevant GRD, the Washington, D.C. Pfizer office, or team attorney.
- For more information on state specific laws, see Chapter 17: State Laws: HCP and State Employee Restrictions.
- For more information on Pfizer's HCP Payment Disclosure Policy, see Chapter 18: Meals, Educational Items, Greenstone Giveaways, and HCP Payment Disclosure.
- For more information on Pfizer's educational grant process, refer to <http://ecf.pfizer.com/sites/eSOPPortal/Lists/Index/MEG.aspx> for MEG01-POL ("U.S. Medical Education Grants Policy") and MEG01-GSOP ("Processing of U.S. Medical Education Grants SOP").
- For more information about the Pfizer PAC, visit [http://sharepoint.pfizer.com/sites/USGovernmentRelations/SitePages/Home\\_New.aspx](http://sharepoint.pfizer.com/sites/USGovernmentRelations/SitePages/Home_New.aspx).
- Take the online training module ([training module for the online form](#)) on how to complete the federal Lobbying Disclosure form.
- Federal Employee Interaction questions may be referred to your lead BU National Account Manager or team attorney.
- For more information regarding on-site activities at VA facilities, see [March 2012 Legally Speaking](#) article found on the Compliance page of [MyPfizerNet](#).



## **CHAPTER #5 – INTERACTIONS WITH HEALTH SYSTEMS AND MEDICAL GROUPS**



Chapter

#5

INTERACTIONS WITH HEALTH SYSTEMS  
AND MEDICAL GROUPS

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## Chapter #5 Interactions with Health Systems and Medical Groups

### Introduction

Pfizer's customers are increasingly being organized into large healthcare delivery organizations such as large medical groups and integrated delivery networks or systems (collectively, "Health Systems"). It is important to understand that working with Health Systems can present unique risks if not done in the appropriate manner.

This Chapter summarizes key Pfizer policies regarding Field Commercial Colleagues interactions with Health Systems. The purpose of this Chapter is to provide guidance to those colleagues who interact with decision makers at these Health Systems at an account level rather than at the prescriber or individual HCP level. In particular, this Chapter focuses on Account Managers, including Key Account Managers (KAMs) and Account Directors (ADs) across all business units and regardless of title, and others, to the extent they engage a Health System at the account level. **Non-compliance with these policies puts Pfizer at risk and can subject colleagues to disciplinary action up to and including termination of employment.** *If the application of any policy is unclear to you, discuss the issue with your manager or your team attorney.*

- If a colleague gives – or could be perceived as giving – a Health System something of value as an inducement for prescribing or recommending a product, that could potentially implicate state and federal anti-kickback laws.
- If an offering of value to a Health System affects or could appear to affect the prices of Pfizer products that a Health System is purchasing, it could cause Pfizer to report inaccurately the price of its products in submissions it makes to the government under the Medicaid Drug Rebate Program and other health care programs.
- If a Field Commercial Colleague communicates with a Health System about a product, outcomes, or therapeutic area in a manner that could make express or implied claims that are not consistent with approved messaging, Pfizer could be exposed to liability for inappropriate messaging about our products.



### ***Key Points to Ensure Compliance***

- Do not discuss the formulary status of a Pfizer product or increased product utilization as part of a collaboration.
- When providing approved tools or resources, do so without any expectation of financial return to Pfizer.
- Never condition the offer or provision of a program on increased prescribing or improved formulary status.
- To avoid implicating pricing and potential kickback concerns, avoid combining different types of transactions. Do not discuss grants, service agreements, Organized Customer and Payer tools and resources, or other items of value in connection with formulary discussions. Do not link or reference the terms of Pfizer's commercial rebate agreement when negotiating a collaboration or a service agreement. If the Health System tries to link these topics inform them that Pfizer has a strict policy against doing so and immediately inform your team attorney.
- Do not attempt to leverage any additional (e.g., non-formulary) arrangements in order to secure preferential formulary status.
- Do not engage, attempt to influence, or get involved in medical activities that Field Medical colleagues such as Medical Outcomes Specialists (MOS) are responsible for, such as conducting a Customer Data Evaluation (CDE) for a Health System.
- Ensure that collaboration proposals and other projects are aligned with public health objectives that are of interest to Pfizer by consulting with the relevant internal stakeholders including Medical, the relevant brand team, the Customer Marketing-Payer and Channel Access group, and Legal.

### **Core Compliance Principles**

The Core Compliance Principles apply to engagements with Health Systems. As a reminder, those Core Compliance Principles are as follows:

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



The importance of using only approved materials and not engaging in actual or perceived quid pro quo in the context of engaging Health Systems is discussed in greater detail below. For further discussion of staying on-label and providing fair balance, please see Orange Guide Chapter 2: Interactions with HCPs.

### Approved Materials and Resources

The policies requiring that you only use approved materials and resources with HCPs described in Chapter 2 also apply to interactions with Health Systems. Although interactions with more senior personnel at Health Systems tend to be more “high-level,” the risks related to the material’s use are no less than the risks inherent in interactions with HCPs. Any materials used with Health Systems – for example, slide decks mentioning products or therapeutic areas, or summary or pitch documents – must be approved through the appropriate Pfizer channels.

“Approved materials” usually means approval by a Pfizer Review Committee (RC), particularly where the materials are branded or focus on a particular disease state. Depending on the item, however, approval by your team attorney may be sufficient. If you have any questions regarding the approval process, or whether a piece is approved, you should contact your team attorney who can help make that determination.

Key Points: Approved Materials	
Material	Approval Requirements
Product-specific material, not approved by an RC in part or in whole.	Requires the approval of the relevant product attorney (or specific product RC, as determined by the relevant product attorney).
Disease area materials, not approved by an RC in part or in whole.	Depends upon the content. Consult with your team attorney to help determine the appropriate approval process and who can facilitate coordination with product attorneys, as necessary.
Any modification of already approved materials.	Generally, must be brought back through the original approval process for review and approval. However, circumstances may warrant exceptions, so you should work with your team attorney.
Information that is publicly available.	Requires RC approval for external use.





Key Points: Approved Materials	
Material	Approval Requirements
E-mail or text to a Health System concerning logistical issues (such as to schedule or confirm an appointment) consistent with the guidelines in Orange Guide Chapter 2: Interactions with HCPs.	Approval not required.
Beyond logistical correspondence (consistent with Orange Guide Chapter 2: Interactions with HCPs), e-mail or text messages to a Health System mentioning a product or therapeutic area.	Requires the approval of the relevant product attorney (or specific product RC, as determined by the relevant product attorney). Approval is not required <b>so long as the correspondence does not mention a product or make substantive statements about the therapeutic area or disease state.</b> If you have questions or would like to request an exception, consult your team attorney.
Account manager e-mail of a contract containing the product name.	Approval of the e-mail is not required so long as the draft contract is approved for dissemination and there is no commentary that is or can be perceived as a product claim.
Customizable RC-approved template, with the ability to fill in blank fields with simple “plug in” information specific to the customer (e.g., customer name and address).	No additional legal approvals required to use with customer, as intended by RC. Consult with your team attorney if you are at all unsure.
Approved, entirely unmodified materials, that are Health System -specific.	Generally, must be approved for use with a different Health System. However, circumstances may warrant exceptions, so you should work with your team attorney.
Approved, entirely unmodified materials, that are not <a href="#">Health System</a> -specific.	Additional approvals are not required, but it is your responsibility to ensure that the materials were approved through the appropriate channels and remain current and approved for your intended use. Consult with your team attorney if you are unsure.



Once a piece or material is approved for one purpose, it is not necessarily approved for all purposes. For example, a proposal or deck approved by an RC for use with one Health System may not be approved for use with another Health System without further review. These materials and proposals are customized for the particular Health System and are reviewed with that Health System in mind. These decks sometimes contain Health System confidential information and therefore it would not be appropriate to use “as is” with another customer. If you are aware of a piece used with one Health System, or collaboration proposed to one Health System, and you think that piece or collaboration may possibly work for a different Health System, you must follow up with your team attorney for necessary revisions and approval. Similarly, slide decks approved for training or other internal use must receive approval specifically for use externally with Health Systems or other third parties.

Even when materials are approved for use, they are not necessarily approved to be left behind with a Health System. If you intend to leave behind approved materials, such as copies of a slide deck, be certain the materials were approved not just to show or present but also to leave behind.

#### E-mailing a Health System about a Collaboration



I had a meeting with a Health System about potential smoking cessation collaboration and would like to follow-up by e-mail to answer some questions that the Health System had. Can I send an e-mail with responses?



It depends. The use of e-mail with Health System must be limited. As explained in Orange Guide Chapter 2: Interactions with HCPs, an e-mail that mentions a product name cannot contain a reference to the relevant disease state or therapeutic area. If you are working on an unbranded collaboration project, you can send an e-mail to the Health System that mentions the relevant therapeutic area or disease state as long as the content cannot be perceived as making any product claim.

#### Disease State Discussions with Health System



After preliminary needs assessment meetings, the Pfizer team would like to present to a Health System a list of areas of mutual interest for potential collaboration. One potential opportunity is in a disease state where Pfizer has a prominent product. How much can be said about the disease state and can Pfizer mention its product in the presentation? Will the presentation need to be approved?



The particular disease state and the Pfizer product in that disease state will dictate how much can be said. In certain cases, where a risk of off-label use exists, or where Pfizer's product is the only available product for the disease state, Pfizer's disease



### Disease State Discussions with Health System

state discussion must be consistent with the label for the specific Pfizer product. In other cases, the disease state discussion possibly could be broader, as long as there is no implication that use of the Pfizer product could result in broader benefits than those mentioned in the product's label.

In most cases, discussions of potential disease state collaboration should not involve any discussion of a particular Pfizer product. Typically, the brand team with a product in the relevant therapeutic area will have materials approved for discussions that follow an initial needs assessment. If you are looking to engage the Health System in a discussion around a disease state where there are no currently available approved materials, consult with your team attorney to help determine the appropriate approval process and who can facilitate coordination with product attorneys, as necessary.

Note that before presenting to the Health System, proposals related to a disease area should be appropriately vetted with the relevant internal stakeholders in order to help ensure that all relevant Pfizer stakeholders are aligned with respect to strategies in disease areas in which we promote. Such stakeholders may include the respective brand team(s), Customer Marketing- Payer and Channel Access group, Medical, Legal, and the Intake Committee.

### Product Messaging Risks

When discussing a Pfizer product with a Health System, any statement a colleague makes can expose the company to a risk of inappropriate promotion. Even when a colleague does not mention Pfizer products by name and only talks “above brand,” i.e., just about disease states, there may still be risk of being perceived as promoting Pfizer products inappropriately. For example, discussing with a Health System disease area where Pfizer does not yet have an approved product, or therapeutic areas that are different or broader than those where Pfizer has approved products, may present a risk of inappropriate promotion.

Do not discuss with a Health System a product or disease state unless you have completed the required training on that product or disease state. If you discuss a product or disease state you are not familiar with, you risk inadvertently making (or implying) a statement that is not consistent with Pfizer's approved messaging.

### Appropriate Product Discussions




Xalkori is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive, as detected by an FDA-approved test. Does that mean that Oncology Field

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### Appropriate Product Discussions

	Commercial Colleagues, when discussing disease state, can only discuss ALK-positive NSCLC?
	It depends. To the extent the colleague is discussing use of Xalkori in any way, the colleague must be careful to only discuss ALK-positive NSCLC. However, to the extent a colleague is discussing a population in a Health System with NSCLC generally to understand the Health System's treatment needs, they would not be required to discuss only the patients who are ALK-positive since that is not known about the population. However, any proposed collaboration or project must be discussed with, and approved by, your team attorney.

### Collaborations

A **collaboration** is an activity or project undertaken by Pfizer with one or more organizations to advance public health goals of interest to both Pfizer and the organization(s). It is different from a traditional service arrangement, where Pfizer might pay a Health System a fair market value fee to perform a service on behalf of Pfizer. In a collaboration, it is important that both Pfizer and the Health System make relatively equal contributions towards the identified, shared public health objective. Pfizer may provide funds, resources, or expertise to the collaboration. Often, 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 Health System or Pfizer, or both, may retain ultimate control of the goals, activities, and messaging, always subject to Pfizer's right to review (via RC, where applicable) any materials for accuracy and compliance with relevant laws and regulations, as well as Pfizer policies and procedures.

For Account Managers, it is important to recognize that some collaboration concepts may be defined by Pfizer policies as studies which require independent medical oversight. Drawing this distinction may be necessary in the context of a collaboration with an Account that seeks to measure the impact of an intervention, including a non-drug intervention, such as patient counseling or adherence materials. Because the conduct and publication of a study can expose Pfizer to risk, studies must be done in compliance with applicable Pfizer SOPs, such as CMCD CT24-GSOP Non-Interventional Studies, CMCD CT25-GSOP Pfizer Non-Sponsored Research, CMCD CT44-GSOP Clinical and Research Collaborations and CMCD 45-GSOP Pragmatic Clinical Trials. Therefore, it is critical that Account Managers involve the appropriate Field Based Medical Colleagues such as MOSs to lead the assessment any time a Health System engagement seeks to collect and examine both existing as well as to-be-collected data from a Health System. The MOS will seek to determine whether the proposed engagement may be considered a study under Pfizer policies and next steps required to be in compliance with such policies.



#### Collaborating around Disease States Not linked to a Pfizer Product



In a meeting regarding a potential collaboration, a Health System raises the possibility of an obesity project. Since Pfizer doesn't have a product in this disease state, can we engage in this discussion?



It depends. Collaborations with Health System must align with the public health goals as well as the business objectives of both the Health System and Pfizer. In certain circumstances collaborations in disease areas where we do not currently have a product may provide public health objectives that are aligned with Pfizer's interests, such as reducing the risk of co-morbid conditions. In these cases, an obesity project may align with Pfizer's business objectives and public health goals; however, each project will need to be assessed on a case-by-case basis. It is critical that you consult with your team attorney in the concept stage of the process to ensure that the project is appropriate.

In any collaboration, always involve your team attorney early in the concept stage and throughout the process until its conclusion. Account Managers must consult the Organized Customer Collaborations Process Guideline available on the KAM SharePoint site from your team attorney.

#### ***When is a Project Considered a Collaboration and Requires a Collaboration Agreement?***

Projects with Health Systems vary in size and complexity. Some projects consist of the deployment of an approved Pfizer tool without any customization, while others involve the use of multiple tools, sometimes combined with more involved participation from cross-functional Pfizer colleagues. Collaborations with Health Systems must advance public health goals and provide specific, appropriate, and commensurate business value to both the Health System and Pfizer. When a project with a Health System is deemed to be a collaboration under the factors and definitions outlined in this chapter, a Collaboration Agreement must be executed with the Health System. Even if a project is not a collaboration, a different type of agreement may still be required, such as a Service Agreement or Data Use Agreement. See Orange Guide Chapter 15: Service Agreements and Other Non-Discount Arrangements with Accounts for more information on these types of agreements.

Consult with your team attorney throughout the process, first to determine whether a Health System interaction is a project or a collaboration and next to draft and approve any necessary and appropriate agreement. Among the factors to consider in evaluating whether a potential project is a collaboration are the following:



- **Complexity and customization** – Generally speaking, the more a project involves customized solutions rather than off-the-shelf tools, the more likely the project will rise to the level of a collaboration.
- **Provision of Pfizer Tools** –Provision of individual “off-the-shelf” tools to a Health System in accordance with company policies does not rise to the level of a collaboration. However, use of multiple Pfizer tools or the need to customize existing Pfizer tools may necessitate a Collaboration Agreement. Colleagues should take care to ensure that the use of multiple or customized tools is warranted for the project, as excessive or inappropriate use of these tools could create potential kickback risk for Pfizer. Be sure to consult with your team attorney.
- **Length of the project** – The longer a project is expected to take, the more likely it will rise to the level of a collaboration requiring a collaboration agreement. Longer projects may be more complex and are more likely to involve the sharing of data and/or the creation of a publication.
- **Data from the Health System** – if the joint project is going to generate data that would be of interest to Pfizer, then some kind of contract is necessary. Whether that would be a Collaboration Agreement or, alternatively, a Data Use Agreement, will depend on, among other things, how the data is generated. If the data is generated as a result of the use of tools and services provided by a Pfizer commercial colleague, then a Collaboration Agreement may be appropriate. If, on the other hand, the data is requested by a Medical colleague and is collected by the Health System using routine methods, another type of agreement may be more appropriate. Be sure to work with your medical account team colleague to determine whether Pfizer policies governing the conduct of studies apply.
- **Other Deliverables from the Health System** –Sometimes, Pfizer may negotiate to have the Health System develop certain materials or undertake certain activities (e.g., mailings to their HCP employees) as part of a project. In order to secure these or other Health System obligations, a Collaboration Agreement may be necessary. (Depending on the details, a Service Agreement may be more appropriate. Be sure to discuss with your team attorney.)
- **Protecting Pfizer's Interests** – A Collaboration Agreement is a contract that will define the rights and responsibilities of each party on a variety of topics related to the joint engagement, including publications, intellectual property, contributions, and involvement in the making of certain decisions. Depending on the nature of Pfizer's rights and responsibilities, and the rights and responsibilities of the other party, Pfizer may decide that a Collaboration Agreement is necessary to protect its interests. In particular, intellectual property issues, including the creation of new intellectual property as an output of the undertaking with the Health System, may add a layer of complexity to the contract. The need for enhanced intellectual property language in the Agreement may require additional time to review and also may make it more difficult to secure the approval of the Health System. Be sure to discuss with your team attorney.

Please consult your team attorney regarding your specific scenario as there are multiple factors to weigh before the final determination of whether a Health System engagement is a project or collaboration, and

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whether an agreement is required (i.e., Collaboration Agreement, Service Agreement, or Data Use Agreement).

#### Is this a Collaboration?

	As part of my work with a Health System, I will facilitate two off-the-shelf, RC -approved workshops and share related patient education materials. Is a collaboration agreement required?
	No. The work you describe is a project not requiring a collaboration agreement. The resources have not been tailored for the Health System, the timeline is defined and short, and the nature of the interaction is transactional rather than complex. However, to the extent there are implementation guidelines and guidance on the use of those materials, you must follow that guidance.
	I am discussing a project with a Health System that may include Electronic Medical Record and workflow changes, educational staff training, development of an adherence platform, and creation of a joint Steering Committee with Pfizer participation. The Health System is willing to create and share a related dashboard report around specific data points with Pfizer. Is a collaboration agreement required?
	Yes, you have described a collaboration, which would require a collaboration agreement. Pfizer would have an extended involvement in the execution of the project, by participating on the Steering Committee and any assistance with the EMR and workflow changes. The Health System also has committed to provide certain deliverables to Pfizer, which should be memorialized in an agreement to ensure accountability and protect Pfizer's interests.
	I would like to work with an integrated delivery network to put together a mailing to a selected group of patients. Do I need a collaboration agreement?
	Not necessarily. Depending on the scope of the undertaking, as well as whether there are other related efforts that may require a contract, you may be able to handle the mailing by using a Service Agreement rather than a Collaboration Agreement. Be sure to discuss with your team attorney before you start drafting, as a number of additional issues may need to be taken into account (e.g., patient privacy, consent, and potential kickback issues).

#### **Intake Committee and the Collaboration Evaluation Process**

To help ensure compliance with all relevant policies and mitigate potential risks, an *Organized Customer Collaboration Evaluation Form* and *Intake Committee* process has been designed to review potential collaboration concepts. The Intake Committee consists of representatives from Legal, KAM Enablement, Field Based Medical, and Regional Customer Marketing. The Intake Committee is responsible for review

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and approval of collaboration agreements as well as service agreements with certain types of third parties or organized customers such as Integrated Delivery Networks (IDN), Accountable Care Organizations (ACOs), and large group practices. Seeking input from brand teams, HEOR colleagues in Patient and Health Impact, and other functions as needed, the Intake Committee determines steps required to comply with Pfizer policies. The Intake Committee also maintains a repository of agreements and shares best practices on an ongoing basis. Colleagues also are encouraged to bring their proposals before the Intake Committee for a concept review, especially where the content of the proposed collaboration involves novel or unusual terms. Members of the Intake Committee also have access to a Fair Market Value (FMV) assessment tool to assist in determining the value of certain frequently provided activities or activities with like components that Pfizer may contribute to a collaboration. The tool helps provide a consistent and formatted methodology to the calculation of value that Pfizer may provide to a collaboration. Account Management and Field-based Medical Colleagues who contributed to the development of the tool are available to assist with use of the tool.

Check with your team attorney to determine whether you will require review by the Intake Committee before proceeding with your project. For more details about the development, evaluation, and implementation of collaboration agreements, please review the Organized Customer Collaborations Process Guidelines.

### ***Appropriate Value***

In working with a Health System on a collaboration or other transaction, you must ensure that Pfizer will receive appropriate value from the transaction. The value Pfizer receives must be obvious, tangible, measurable, and must be commensurate with the value provided by Pfizer under the collaboration. If an equal exchange of value between Pfizer and the customer does not exist, Pfizer could be viewed as providing a payment or value to influence a customer improperly. In addition, all collaborations must be fully documented via a collaboration agreement.



In determining the value to Pfizer, there are certain things we can “offer” or “ask” for as part of the negotiation. You must work with your team attorney to help ensure the appropriateness of your offers and requests. It is not appropriate to discuss the formulary status of a Pfizer product or ask for increased product utilization as part of a collaboration. Improving Pfizer’s relationship with the Health System, increasing access to key decision makers at a Health System, and the expectation of increased volume of prescriptions of Pfizer products also would **not** be appropriate “value” to Pfizer.

In assessing Pfizer’s contributions in a collaboration versus the Health System’s contribution, you must take into account the intangibles provided to the Health System that may be considered valuable. For example, advice or counseling provided by a Pfizer colleague to a Health System related to its EMR system, depending upon the details of that assistance, could be perceived as value in the form of consulting services for which the Health System normally would pay a third party vendor. If not appropriately accounted for in the collaboration, such services may elevate anti-kickback and other risks.







### Receiving Appropriate Value for a Collaboration



	<p>I have a Health System that is far below state and national averages in cardiac-related patient outcome measures. Non-valvular atrial fibrillation (NVAf) patients are emerging as a high-risk patient base that requires care across multiple settings. Pfizer currently has tools and resources that can be used by HCPs for screening and managing this population, and Pfizer has experts who can train HCPs on how to better discuss NVAf and educate patients. Finally, Pfizer's MOS Colleagues will be able to work with the Health System using approved medical tools to measure the impact of implementing a comprehensive NVAf program using these resources. The Health System is interested in implementing this initially in 10 practices and then in a larger scale roll-out to all 75 practices. The Health System will be responsible for developing and implementing all training and communications. The Health System will pay the costs of the roll-out. Is this proposed collaboration appropriate for Pfizer to engage in?</p>
	<p>On its face, provided that the total value provided by the Health System is equal or approximately equal in value to the total value provided by Pfizer, it may be appropriate for Pfizer to engage in this collaboration. Providing assistance to the Health System that would aid in improving the diagnosis, management, treatment, and outcomes of NVAf patients not only benefits the Health System, it benefits public health and the overall healthcare system. The collaboration would educate and help patients better adhere to medicines in a disease state in which Pfizer currently has interest. Additionally, Pfizer could potentially obtain useful data from this collaboration as to the effectiveness of implementing these types of programs to allow Pfizer to evaluate whether the program could be replicated for other Health System and to provide insights to management of patients in this high-risk disease area. Consult with your team attorney in the concept state to ensure that the project is appropriate and whether the concept should be brought to Intake Committee for further guidance.</p>

### Receiving Appropriate Value for a Collaboration (continued)

	<p>Accountable care organizations (ACOs) are looked upon as a way to facilitate a more coordinated, efficient, and higher quality care for patients. Can I help my Health System meet the requirements of an ACO?</p>
	<p>If the primary objective of the proposed collaboration is to help the Health System become an ACO, then it is unlikely that Pfizer can engage in such collaboration. Part of the FMV assessment of Pfizer's contributions is that it must not only be fairly equal</p>



#### Receiving Appropriate Value for a Collaboration (continued)


	to Health System's contributions, but Pfizer must get an appropriate value from the collaboration. A collaboration that is aimed at helping a Health System become an ACO on its face does not appear to have any tangible, appropriate value to Pfizer and only benefits the Health System, even though the project appears to support a public health interest objective.
	In a collaboration, if Pfizer's contribution is \$25,000 and the Health System is not contributing cash but is providing services valued at \$25,000, is that okay?
	First and foremost, you must work closely with your team attorney to assess the value of contributions within a Collaboration agreement. In the above scenario, the proposal may be okay so long as Pfizer's contribution is not considered payment for the services. Your team attorney will be able to help you work through all the nuances to make a determination if there is equal contribution on both sides.

#### Metrics and Reimbursement

Do not make commitments or provide guarantees around metrics. At times, when presenting a potential collaboration with customers, it may be necessary for Field Commercial Colleagues to present, with appropriate approvals, potential cost savings or other benefits around the particular projects. Such metrics must be based only upon **credible and reliable** available information and may include only high level data shared with Pfizer by the Health System. Always ensure that the information and data used externally are not subject to confidentiality or restrictions on use. The basis and source of such metrics always must be disclosed to the customer. In presenting such information, you must expressly state that such information must not be construed as a guarantee around cost savings and that such assessment should be conducted separately by the Health System.


A Health System's primary goal in any collaboration should not be to increase its reimbursement from its payers. In some circumstances, higher reimbursements may be a byproduct of corresponding improvements in quality of care (e.g., through associated quality metrics) or associated with improvements in a broader public health goal. Collaborations that are primarily intended to increase a customer's reimbursement from its payers are not appropriate.

#### Presenting Financial Metrics to a Customer



	A Health System wants to know how a screening/disease identification collaboration on which we are working together to improve quality of care might help improve their economic performance in either additional care identified (new patients) or costs
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### Presenting Financial Metrics to a Customer

	averted (e.g., reduced unnecessary re-admissions). Can we assist in projecting what potential financial impact this work may have for them?
	In presenting a proposed collaboration to a Health System, the account team may, as a general matter, present general financial metrics from the proposed initiative based upon publicly available, credible information. The collaboration and any associated financial metrics should be focused on the improvement in quality of care and benefit to the overall health care system. Any projections as to economic performance must be consistent with these objectives. You should always use credible sources that have been approved for such use, and never provide any guarantees around achieving such financial goals. You must always include appropriate disclaimers when presenting financial metrics. Remember, presentations must be approved in advance before use with Health Systems. You should work closely with your medical counterpart and consult with your team attorney for necessary approvals, including appropriate use of the data.

### Reimbursement



	A During a needs assessment meeting, a representative from a Health System states that the group would like to increase its reimbursement for certain diagnostic tests and would like to know if Pfizer can assist in educating the Health System's providers on the best practices for coding and billing for such tests. Is this an appropriate activity for a collaboration with this Health System?
	No, this is not an appropriate activity. Pfizer cannot provide assistance for the purpose of increasing the Health System's reimbursement. Although the appropriate use of some diagnostic tests could potentially increase the appropriate diagnosis (and treatment) of certain medical conditions, Pfizer may not commit resources to a collaboration that is focused on reimbursement of items or services for a Health System.

### Use of Publicly Available Information

	What qualifies as credible and reliable publicly available information?
	That depends. In deciding whether something is credible and reliable determine whether the information is generally accepted by experts in the field. Generally,



#### Use of Publicly Available Information

	medical journals, governmental (e.g., CMS) websites as well as the particular Health System website are examples of credible and reliable sources. You should work with your medical counterpart and team attorney who can assist in making a determination.
	If Pfizer does not commit resources to the specific aspects of the collaboration that are focused on coding, billing, and reimbursement, can Pfizer participate in other aspects of this potential collaboration with the Health System that are focused on related quality measures?
	It depends. The overall goal of any collaboration must be to address a public health goal. Even if the Health System's contribution to the collaboration is focused on activities that are intended to address a public health goal, the overall results of the collaboration must also be expected to result in the advancement of such goal.


#### Offering Pfizer Tools & Resources

Occasionally Pfizer offers to Health Systems certain free quality-based programs and unbranded tools and resources designed to educate Health System, benefit patients, improve patient outcomes, and/or generally to promote quality health care. These are referred to as Organized Customer and Payer Resources ("OCP Resources").

Many of these programs can be found on the Pfizer intranet site at [PROMOSprime](#). In offering OCP Resources to a Health System, colleagues must not engage - or appear to be engaging - in quid pro quo. For more information on the requirements around who can offer OCP Resources, the situations in which Pfizer can offer these tools and resources, and the associated review requirements, please consult Orange Guide Chapter 14: Organized Customer and Payer Tools and Resources.

When offering or providing approved tools or resources, do not condition the offer or provision of a program on increased prescribing or improved formulary status.

#### Use of Quality Programs

	A Health System is trying to attain NCQA PCMH accreditation. Can I offer a menu of six or seven PCA Quality Programs solely to aid them in meeting the accreditation standards?
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### Use of Quality Programs

	No. Pfizer's policy does not permit providing Quality Programs to Health Systems primarily for the Health System to meet its NCQA accreditation. The decision to provide each Quality Program must be based on Pfizer's goals of improving health outcomes, patient awareness, wellness, disease prevention, and high quality health care. If you have any questions, consult with your team attorney.
	Can Quality Programs be used to get access or to assist in building relationships with a Health System? What about <a href="#">PROMOSprime</a> and other OCP Resources?
	No. The use of Quality Programs or other tools to gain access or for relationship building purposes can raise red flags under anti-kickback laws. These tools and resources must be offered to Health Systems with the same intent for which they are created: to promote wellness, disease prevention, patient awareness, and high quality health care.

### Sunshine Act

In addition to existing payment disclosure obligations, Pfizer must comply with certain reporting and disclosure requirements of the Sunshine Act. Included in scope for reporting are any payments or transfers of value that are made directly or indirectly to a covered recipient, defined as a U.S. licensed physician or a teaching hospital. A payment or transfer of value is considered indirect if it is known that the organization receiving the funding will be conveying a benefit to a covered recipient even if Pfizer does not direct or influence the selection of the recipient or have knowledge of the identity of the recipient.

If Pfizer has agreed to an organization's use of funds that includes a payment or transfer of value to a covered recipient in any form of direct, indirect, or in-kind payment or transfer of value, then the Pfizer project manager is responsible to collect all relevant information for each physician and/or teaching hospital required for disclosure using the [Sunshine Data Template](#).

### Avoid Combining Types of Transactions



As the lines between customer types (payers, prescribers, purchasers, etc.) have begun to blur, it is important to ensure separation among Field Commercial Colleague roles to avoid the actual or perceived commingling of transactions which could raise anti-kickback and pricing concerns. Even if the risks are not apparent, always consult your team attorney **before** undertaking any activities that are functionally aligned to other roles within the organization. For example, what is appropriate for an Account Manager may not be appropriate for certain sales roles. Further, when engaging with a Health System, particular initiatives



must be pursued by themselves and must not be predicated on other programs or additional performance of any kind. When different transactions are commingled inappropriately –for example, OCP Resources offered not for their own approved purposes but rather to secure formulary placement – there can be a risk that the value to the Health System of that separate, non-rebate related arrangement would need to be considered and included as a discount to the Health System for purposes of price reporting under the Medicaid Drug Rebate Statute for a drug. Therefore, avoid combining certain types of transactions to avoid implicating pricing or anti-kickback concerns. For example:

- Do not attempt to leverage any additional (e.g., non-formulary) arrangements in order to secure preferential formulary status;
- Do not discuss grants, service agreements, Organized Customer and Payer tools and resources, or other items of value in connection with formulary discussions;
- Do not link or reference the terms of Pfizer's discount or rebate agreements when negotiating a collaboration; and
- Do not discuss the formulary status of a Pfizer product or ask for increased product utilization as part of a collaboration.

#### Discussing Payer Rebates

	<p>One of my customers is a Health System that manages its own formulary and is owned by or affiliated with a payer. Pfizer's product does not have favorable access at the Health System. I would like to engage in discussions with this Health System about the clinical benefits of a product and the potential benefits to their patients. Can I discuss rebates received by the affiliated payer customer under contract with Pfizer? Can I provide tools or engage in adherence arrangements in conjunction with or in exchange for formulary access?</p>
	<p>No. Pfizer colleagues must not discuss rebates received by a Health System affiliated with a payer or any other customer with another Health System as that would violate contractual confidentiality obligations Pfizer has with those customers. Even though one Health System is affiliated with the payer customer, Pfizer's contract is with the payer and discussions related to the terms of those contracts must remain confidential. Additionally, Pfizer colleagues must not provide tools or engage in adherence arrangements in conjunction with or in exchange for formulary access. Comingling other arrangements with formulary discussions elevates risk under the anti-kickback statute and raises the risk that separate, non-rebate arrangements might need to be considered for purposes of price reporting.</p>



## Medical Activities

### ***Interacting with Medical Outcomes Colleagues***

Medical Outcomes Colleagues such as the Medical Outcomes Specialist (MOS) are field-based medical colleagues who are part of the Business Unit Medical function. These colleagues have expertise in pharmacoeconomics and population health, responsible for medical engagements with Health Systems such as IDNs, ACOs, and large group practices. Their activities with these Health Systems may include but are not limited to presenting and discussing approved disease-state, clinical, and pharmacoeconomic information related to Pfizer products, collaborating with Health Systems to advance the quality of patient care, working with electronic clinical data including extraction and management, information technology, and clinical content within electronic applications, informing formulary decision making, and conducting customer data evaluations (CDEs) using approved templates. Medical Outcomes engagements are governed by the [Green Guide](#).

## Principles Governing Medical Outcomes and Field Commercial Colleague Interactions

Field Medical, such as Medical Outcomes, roles are non-promotional roles that are focused on the medical needs of managed care and Health Systems, including IDNs and large group practices. *The objective of field medical interactions must be non-promotionally focused (e.g., not done with a goal of obtaining prescriptions for a Pfizer product).* There are limited instances when both the MOS and Field Medical Director (FMD) may engage in activities governed by promotional standards, such as giving payer value proposition/formulary presentations or certain RC-approved presentations.

Internal interactions between Medical Outcomes Colleagues and Field Commercial Colleagues as well as external interactions among Medical Outcomes Colleagues, Field Commercial Colleagues, and Health Systems must be carefully managed to ensure that Medical Outcomes Colleagues' non-promotional activities are planned and executed appropriately.

### ***Internal Interactions between Medical Outcomes and Field Commercial Colleagues***

Medical Outcomes Colleagues may interact with Field Commercial Colleagues in order to ensure appropriate, efficient and informed interactions with Health System, as outlined in this section. It is expected that Medical Outcomes Colleagues, in their role as the medical lead working as part of an Health System integrated account team, have reason to interact more frequently with Account Management Colleagues for purposes of internal account team coordination. Given this dynamic, as well as the fact that the Medical Outcomes Colleagues engage in more limited proactive and responsive medical communications compared with FMDs, there is more flexibility in the level of appropriate internal interaction which can take



place between Medical Outcomes Colleagues and Account Management Colleagues, as reflected in this section.

### ***Medical Objectives, Account Plans, and Customer Insights***

Field Medical activities must be aligned with BU Medical objectives, not sales targets or financial objectives. Medical Outcomes Colleagues may provide input in the key account prioritization process or the overall Pfizer account plan for a Health System. Medical objectives may be documented in the overall account plan but must be separate from any commercial objectives and prominently marked as medical objectives. All medical objectives must be independently designed and drafted by the Field Medical Colleague and not Account Management Colleagues. Medical activities must not be directly tied to commercial account metrics.

Medical Outcomes Colleagues may share Health System insights with Field Commercial Colleagues, but such insights must be in aggregate to a territory, account, specialty, Health System and not specific to any HCP's prescribing of Pfizer products or unsolicited medical requests. Medical Outcomes Colleagues are not permitted to share insights regarding unapproved uses of Pfizer products, unapproved products, or information about responses provided to HCPs who have made unsolicited medical requests for information. Field Commercial Colleagues must not request this type of information.

### ***Medical Outcomes Customer Accounts***

Medical Outcomes Colleagues are permitted to share their assigned customer account lists with Account Management Colleagues. Account Management Colleagues may offer suggestions to Medical Outcomes about adding accounts to their target list; however, the Medical Outcomes Colleagues will apply pre-determined medical criteria and make an independent determination regarding whether the account is targeted.

### ***Medical Outcomes Colleague Attendance at Field Commercial Meetings***

On a limited basis, Field Commercial Colleagues may invite Medical Outcomes Colleagues to participate in internal business meetings such as district, regional, or national field commercial meetings (e.g., POA meetings). Medical Outcomes Colleagues may be invited to Health System planning meetings as members of the Integrated Account Team.

Examples of appropriate reasons to request Medical Outcomes participation at Field Commercial business meetings include for the Medical Outcomes Colleague to:

- Conduct product or disease training, using RC-approved materials;
- Provide general information about medical objectives or an overview of Medical Review Committee (MRC) approved topic(s) or materials;





- Medical Outcomes Colleagues are not permitted to discuss the details of MRC-approved content or share actual MRC-approved materials with Field Commercial Colleagues. Field Commercial Colleagues must not ask for this information or seek to influence the way in which medical content is developed or delivered to HCPs or other customers.
- Share aggregated Health System insights, information about geography or regional level dynamics, or to seek feedback. For example, information can be shared about gaps in HCP understanding about a disease or treatment. Health System information discussed must be in aggregate and not specific to any particular HCP or Health System's prescribing/utilization of Pfizer products or medical inquiries.
  - Field Commercial Colleagues are not permitted to ask Medical Outcomes Colleagues to share any type of off-label information for a Pfizer product or information about unapproved Pfizer products;
  - Field Commercial Colleagues are not permitted to seek assistance from Medical Outcomes Colleagues with overcoming barriers to Health System prescribing/utilization of Pfizer products; and
  - Field Commercial Colleagues are not permitted to request information from Medical Outcomes Colleagues about the substance of responses provided to HCPs who have made unsolicited medical requests for information.

#### ***Organized Customer Planning and Coordination***

Medical Outcomes Colleagues are usually the primary Field Medical Colleagues who serve the medical needs of Health Systems. For Health Systems that have assigned Medical Outcomes Colleagues, those colleagues will make determinations about when FMDs are needed to assist. If a Health System does not have an assigned Medical Outcomes Colleague, Account Management Colleagues are permitted to work directly with FMDs to discuss field medical support for a particular Health System. However, it is recommended that MOS Colleagues are engaged first for all medical needs as the Integrated Account team medical lead.

Account Management Colleagues may meet with Medical Outcomes Colleagues (or FMDs if an Outcomes Colleague is not assigned) regarding the following:

- Account prioritization and planning;
- Customer needs assessments;
- Large project or collaboration agreement development and planning;
- Non-product medical activities such as disease presentations, health trend/channel presentations, and quality of care presentations; and



- Account level dynamics such as utilization of products in a specific therapeutic area, quality metric gaps or goals, key events (e.g., placement of new products on formulary), and other information relevant to respective medical and commercial account objectives (e.g., benefit design, adherence rates).

Health System planning and coordination discussions must focus on the exchange of information needed to achieve independent commercial and medical objectives. Account Management Colleagues must not attempt to direct or determine medical activities. Field Medical Colleagues must not be invited to join internal business meetings when the focus is traditional managed care contract negotiation, rebates, or other issues relating to pricing of Pfizer products.

### ***Customer Data Evaluation (CDE) Discussions***

Customer Data Evaluations (CDEs) are conducted most often by Medical Outcomes Colleagues such as the MOS. CDEs involve examination of data provided to Pfizer by a Health System, such as a managed care organization, hospital, or large medical group in order to help the Health System make informed decisions related to quality of care, health outcomes and/or economics, or drug acquisition/selection.

If asked by a Medical Outcomes Colleague, Account Management Colleagues may provide input in order to identify Health Systems for which a CDE project may be useful to the Health System and patients. Likewise, if a Health System expresses an interest in working with Pfizer to evaluate its data, Account Management Colleagues are permitted to contact the Medical Outcomes Colleague to relay the Health System's interest. However, Medical Outcomes Colleagues must make an independent medical determination as to whether an evaluation is ultimately to be conducted and Account Management Colleagues must not attempt to influence the decision. All CDEs must be conducted by the Medical Outcomes Colleague independently and without the involvement of Field Commercial Colleagues.

Medical Outcomes Colleagues are permitted to share certain CDE Executive Summaries with Account Management Colleagues after obtaining approval; however, detailed CDE results may not be shared and Field Commercial Colleagues must not request this information.

### ***Unsolicited Medical Requests (UMRs)***

Field Commercial Colleagues must refer all UMRs to Pfizer's Medical Information department, as described in Chapter 2, and must not contact Medical Outcomes Colleagues to respond to UMRs, including requests from Health System accounts.

Account Management Colleagues who receive a formulary presentation request from a Health System that has dedicated Medical Outcomes support are permitted to forward the request directly to the Medical Outcomes Colleague assigned to the Health System. Account Management Colleagues who receive a product UMR from a Health System that has dedicated Field Medical support are permitted to provide the Field Medical Colleague's contact information to the Health System so that the Health System can contact



the Field Medical colleague directly with questions. Account Management Colleagues are not permitted to forward the question themselves; the Health System must initiate contact with the appropriate Field Medical Colleague.

### ***Organized Customer Requests to Discuss Research***

Field Commercial Colleagues may refer Health System inquiries regarding potential involvement in Pfizer non-interventional research to a Medical Outcomes Colleague, who will evaluate the request together with the appropriate FMD. The decision to engage with the Health System rests solely with the Medical Colleagues, and Field Commercial Colleagues must not attempt to influence this decision. Medical Outcomes Colleagues are not permitted to engage in detailed discussion with Field Commercial Colleagues about ongoing research-related activities; Field Commercial Colleagues must not request this type of information.

### ***Planning for Joint External Meetings***

Where external joint meetings among Medical Outcomes, Field Commercial Colleagues, and Health Systems are permitted, Field Commercial Colleagues may meet internally with Medical Outcomes Colleagues to plan for these meetings (e.g., to share logistical information, meeting agendas). Medical Outcomes and Field Commercial Colleagues are also permitted to contact each other to request a one-time introduction to a Health System or to discuss logistical information about offices/accounts or resolve scheduling issues.

## **External Interactions between Medical Outcomes, Field Commercial Colleagues, and Organized**

### ***Introductory Meetings***

A Field Commercial Colleague is permitted to ask a Medical Outcomes Colleague to make a one-time in-person introduction to a Health System and a Medical Outcomes Colleague is permitted to ask a Field Commercial Colleague to do the same. The purpose of such meetings must be for introduction only and must not be used to hold a substantive joint meeting with the Health System unless it is otherwise permitted. The Field Commercial Colleague must not give the Health System a promotional presentation in the presence of the Medical Outcomes Colleague, and Medical Outcomes Colleagues are not permitted to engage in medical communications in the presence of Field Commercial Colleagues unless the material has been MRC-approved for presentation in these circumstances.

In instances where an HCP or Health System limits the meeting time dedicated to industry, Medical Outcomes Colleagues and Field Commercial Colleagues may schedule one Pfizer meeting with the Health System but should then conduct consecutive independent discussions with the Health System (outside the presence of the other) unless otherwise permitted to hold a joint meeting.



### ***Organized Customer Meetings***

Medical Outcomes Colleagues, who work regularly with Health Systems, are usually the Pfizer Field Medical Colleagues who represent BU Medical at meetings with Health Systems. However, when specific product and/or therapeutic area expertise is needed, the Medical Outcomes Colleague may contact an FMD to join these meetings. Field Commercial Colleagues should coordinate requests for FMD participation in Health System meetings through the Medical Outcomes Colleague assigned to the Health System, if one is assigned. If no Medical Outcomes Colleague is assigned to the Health System, Field Commercial Colleagues are permitted to work directly with the FMD to discuss field medical support for the organized customer as appropriate.

Medical Outcomes Colleagues are permitted to join Account Management Colleagues at needs assessment meetings with Health Systems, where the intent of the meeting is to explore potential collaborations or projects between Pfizer and the Health System. It is also permissible for Medical Outcomes Colleagues to join Account Management Colleagues at periodic meetings with Health Systems to discuss the status of collaboration activities conducted pursuant to an agreement under which both medical and commercial activities are being executed. Aside from these periodic meetings, Medical Outcomes Colleagues must conduct separate meetings with the Health System in order to plan and execute their medical activities.

### ***Formulary Committee Presentations***

Pfizer-initiated Formulary Committee presentations are primarily conducted by Medical Outcomes Colleagues. However, when specific product and/or therapeutic area expertise is needed, the Medical Outcomes Colleague may contact an FMD to assist with the presentation. Field Commercial Colleagues should coordinate requests for FMD participation in Health System meetings through the Medical Outcomes Colleague assigned to the customer, if one is assigned. If no Medical Outcomes Colleague is assigned to the Health System, Field Commercial Colleagues are permitted to work directly with the FMD to coordinate Formulary Committee presentations.

Formulary Committee presentations, when initiated by Pfizer, are governed by promotional standards even when delivered by Field Medical Colleagues. Account Management Colleagues are permitted to attend Pfizer-initiated Formulary Committee presentations given by Field Medical Colleagues. *However*, if a Formulary Committee requests in advance that certain information be provided during a formulary presentation and that information is off-label or unapproved for promotional use, account management and other Field Commercial Colleagues are *not* permitted to attend these Formulary Committee presentations given by Field Medical Colleagues Non-Product Presentations

Medical Outcomes Colleagues occasionally deliver certain non-product presentations to Health Systems categorized as Skilled Based Learning (SBL) resources. Depending on the nature of the content, the RC



or MRC determines the appropriate customer audience and, may set restrictions on which Pfizer colleagues may attend the presentation. For example, the RC or MRC may prohibit attendance by Sales Colleagues or may place other restrictions on the attendance of Field Commercial Colleagues. Consult the implementation guidance provided by the relevant RC or MRC that approved the content to determine if your attendance is permissible. Please check with your Medical Outcomes Specialist if you are unsure if your attendance is permitted or if you are unable to locate the relevant implementation guidance (e.g. certain MRC-approved content can only be accessed by Medical Colleagues).



### ***Customer Data Evaluation (CDE) Development and Presentations***

Field Commercial Colleagues, including Account Management Colleagues, are not permitted to attend meetings with Health Systems when the subject of the meeting includes detailed discussion of CDEs (e.g., development of the data analysis plan, implementation plans, or detailed results). Account Management Colleagues may attend meetings with Health Systems where a Medical Outcomes Colleague presents a high level description of a proposed CDE or an Executive Summary of a completed CDE if approved in advance by the Medical Outcomes Colleague's Team Leader.

### ***Interacting with Field Medical Director (FMD) Colleagues***



For additional information about appropriate interactions with Field Medical Director Colleagues see Orange Guide Chapter 2: Interactions with HCPs.

### **Medical and Commercial Interactions**

	<p>I am a KAM, and one of my Health System customers has provided me with spreadsheets that contain data on a particular disease state related to that Health System, which includes an affiliated hospital. The Health System wants me to assist in analyzing the data in order to assist them in better understanding the impact this disease has on hospital admissions. Some of this data is high level, such as total number of hospital admissions with a specific disease broken down by various common demographic categories: gender, age cohorts, etc. One spreadsheet inadvertently contains a list of specific patients, which does not include patient names but does include length of admission, diagnosis, etc. Can I, as a KAM, receive this data from the Health System and what analysis can I perform with it?</p>
	<p>Generally, no. In every situation where the Health System wishes to provide patient data for analysis, the Field Commercial Colleague should refer their MOS Colleague directly to the Health System to determine what sort of data analysis may be appropriate. While in some situations commercial field-based colleagues may perform high level analysis based on publicly available information, such situations are limited and need the approval of the team attorney. Under no circumstance may any Pfizer colleague receive patient specific information unless appropriate authorizations are in place and even then only Pfizer Medical Colleagues will be able to receive such</p>



#### Medical and Commercial Interactions

	information. In the event you find yourself in possession of such information in error, consult your team attorney immediately. Please consult Orange Guide Chapter 8: Privacy – Protecting Personal Information for more information on the appropriate use of patient information.
	A Health System customer wants assistance in development of an IDN specific guideline and treatment pathway around a specific disease state. Can Pfizer Field Medical and Field Commercial Colleagues work with the Health System on this project?
	If there are branded or unbranded RC-approved resources of such as an independent third-party developed criteria or recommendations for treatment of a disease state, consistent with product labeling, you may utilize them with the Health System. However, if the goal of the project is to support the development of treatment guidelines, consult your team attorney on how best to proceed.

#### For More Information

- For more information on interacting with Field Medical Colleagues including both MOS and FMDs, see [The Green Guide: Governance for External Medical Activities](#).
- For more information about collaborations and collaboration agreements involving Key Account Managers, including how to get them approved and prepared, GIP KAMs may proceed to their respective SharePoint site and see the [Organized Customer Collaborations Process Guidelines](#). All other Account Managers should proceed to the respective link on the Customer Resource Center.
- Please refer to Orange Guide Chapter 18: Meals, Educational Items, Greenstone Giveaways, and HCP Payment Disclosure for more information on our disclosure obligations under the Sunshine Act and certain state laws.
- For information on the appropriate use of patient information, please see Orange Guide Chapter 8: Privacy – Protecting Personal Information.
- For additional guidance on OCP Tools and Resources see Orange Guide Chapter 14: Organized Customer and Payer Tools and Resources or visit [PROMOSprime](#).
- Refer any questions to your manager or team attorney.



## **CHAPTER #6 – CLINICAL RESEARCH AND CLINICAL RESEARCH COLLABORATIONS**



**Chapter**

**#6**

**CLINICAL RESEARCH AND CLINICAL  
RESEARCH COLLABORATIONS**

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## Chapter #6 Clinical Research and Clinical Research Collaborations

### Supporting Legitimate Medical Research

Pfizer engages with scientists, academics, Healthcare Professionals (“HCPs”), academic and research organizations as well as government agencies to conduct research and development, including *in vitro* experiments (discovery), *in vivo* studies (pre-clinical animal) and human clinical studies. Research sponsored by Pfizer, as well as research sponsored by others, that Pfizer supports, can generate important information about Pfizer compounds and products and lead to improvements in clinical care, the development of new treatments, and better healthcare delivery.

Clinical studies for which Pfizer is the regulatory sponsor are those studies where Pfizer (or a party acting on Pfizer's behalf) designs, conducts and oversees the study. Pfizer engages Contract Research Organizations (“CROs”), academic or research organizations and other types of vendors to execute clinical study protocols. As regulatory sponsor of a clinical study, Pfizer is responsible for compliance with the regulatory obligations applicable to such research and development activities.

Pfizer may also collaborate with institutions on studies that may be initiated by Pfizer or by another party, in a co-development partnership or a relationship called a Clinical Research Collaboration (CRC) results from these studies may be used for regulatory submissions, data generation (i.e., publication) or for Pfizer internal research purposes.

For many HCPs, conducting industry-funded medical research may be a significant source of income; this may also apply to customer groups (Accounts). If done for inappropriate reasons, selecting an Account to conduct research and development or an HCP to be a researcher who carries out a clinical trial or other clinical research (“**Clinical Investigator**”) as part of a Pfizer-sponsored study, collaboration, or ISR grant, may raise significant legal issues.

### Types of Funding or Support

Pfizer will only fund and support legitimate medical research. This means the research must seek to answer a genuine scientific or clinical question through validated scientific clinical and research methodologies. The Clinical Investigator must be qualified to conduct the intended research and be selected on the basis of their applicable experience and training. Researchers are compensated for the fair market value of the services provided to Pfizer. Further, the research must be conducted in compliance with recognized scientific and ethical standards, as well as applicable laws and regulations. Pfizer must **never** support an HCP's scientific or medical research to:



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

As with other financial transactions between Pfizer and HCPs or Accounts, attempting to influence prescribing behavior or improve Pfizer's relationship with the recipient by providing money for research may violate federal or state anti-kickback laws. The impact on an HCP's prescribing behavior or an Account's purchase or recommendation of a Pfizer product must not be taken into consideration when deciding whether to engage an HCP as an investigator or fund or support independent medical research by an HCP or Account. In addition, both the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals (PhRMA Code) and the U.S. Department of Health and Human Services Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers forbid the use of "token" consulting arrangements. Examples of prohibited arrangements include payments to Clinical Investigators to encourage the use of a Pfizer product or to reward a Clinical Investigator for previous use of a Pfizer product, rather than to address a genuine scientific issue or obtain meaningful clinical information. Pfizer policies and procedures help ensure that Pfizer-sponsored clinical research and CRCs, comply with applicable healthcare laws, regulatory requirements, ethical standards, and industry guidelines.

**Non-compliance with policies applicable to clinical research activities puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination of employment.**

#### ***Pfizer-Sponsored Trials***



**Pfizer-sponsored trials** are clinical studies that are designed, conducted, supervised and funded by Pfizer and for which Pfizer holds regulatory responsibility. Pfizer compensates Clinical Investigators for providing protocol-required services for Pfizer-sponsored trials. Compensation must be fair, reasonable and equitable to fair market value, explicitly identified in the investigator contract and linked to their performing specific and necessary protocol-required services (e.g. medical procedures, collection of data). The informed consent form must also specify that the investigator is being compensated by Pfizer.

HCPs sometimes ask colleagues how they can be engaged as Clinical Investigators. Pfizer's decision whether to engage an HCP as a Clinical Investigator must be made without regard to the HCP's prescribing potential or history, or relationship with Pfizer. You may never commit to engaging an HCP as an investigator or make any other promises relating to the engagement of an HCP as an investigator. All decisions about Clinical Investigators must be made by the relevant Pfizer medical, research or development organization.



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

#### Clinical Studies and Prescribing Habits

	A very influential HCP is reluctant to prescribe a certain Pfizer product. Can I recommend to my Field Medical Director (FMD) that this HCP be selected as an investigator in an upcoming clinical trial for that product, so that she can gain additional first-hand experience regarding the product's use?
	No. You may not recommend a HCP as an investigator if a purpose for choosing the HCP is to influence prescribing habits. Clinical Investigators must be selected solely on the basis of their research experience and clinical training, not their past, current or potential future prescribing habits.

#### Requests for Study Product or Pure Substance

A request for study product or pure substance (for pre-clinical studies) to support legitimate medical research should be referred to the [GMGS web portal](#) or see Chapter 22: Independent Medical Grants. Starters (samples) may never be used for clinical trials and it would be inappropriate for you to try to obtain or promise samples for any research purposes.

##### Key Points to Ensure Compliance

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



### ***Clinical Research Collaborations (CRCs)***

CRCs are engagements under which Pfizer collaborates with an external party to perform research and/or clinical activities. CRCs can be initiated by Pfizer (i.e., Pfizer approaches an external party to propose a collaboration) or initiated by an external party (i.e., an external party approaches Pfizer to propose a collaboration). CRCs are managed by the Worldwide Medical & Safety (“WMS”) CRCs Group.

CRCs are subject to the requirements of [CT44-GSOP: Clinical Research Collaborations](#). A Clinical Research Collaboration “CRC” is defined as clinical research that is being conducted and sponsored by an external party, in which Pfizer intends to collaborate on certain aspects of the proposed research including but not limited to:

- Study design;
- Data analysis;
- Publication authorship; and
- Oversight of research conduct.

Pfizer may provide financial and/or non-financial benefit to the external party (e.g., in-kind support, intellectual property rights, data, pure compound, investigational product, device, etc.) to support the clinical research study.

The study data generated from the clinical research study may be used by Pfizer for certain activities including but not limited to:

- Internal research purposes or decision making;
- To support regulatory activities such as applications to regulatory agencies or post marketing commitments, etc.;
- Obtain and maintain access to a medicine in a national/local health system or a national/local formulary (e.g., recommendation of the CDC’s Advisory Committee on Immunization Practices, ACIP); and
- Generate publications.

It is important for Account Managers and others to understand that a customer engagement or customer collaboration may actually be or become a study to which Pfizer Clinical Trial policies apply. This most often occurs in the context of a collaboration with a customer that seeks to measure the impact on patients of an intervention, including a non-drug intervention, such as patient counseling or adherence materials. Because the conduct of a study can expose Pfizer to risk, studies must be done in compliance with applicable Pfizer Clinical Trial policies, such as [CT44-GSOP](#). It is critical that Account Managers work closely with Field-Based Medical colleagues, such as Medical Outcome Specialists (MOSs) and Field



Medical Directors (FMDs), any time a customer engagement project involves examining existing or anticipated customer data. Your Field-Based Medical colleagues will assist you in determining whether the proposed engagement is a clinical study under Pfizer policies and, if so, in complying with those policies.

#### **Collaborator**

The external party (or parties) supporting, conducting or procuring the research and/or clinical development activities agreed to under a collaboration agreement such as a CRC or business development deal. By way of example, Pfizer may partner with a Collaborator to design, conduct, monitor or supervise a clinical research collaboration. The Collaborator generally conducts the research activities following its own policies and procedures, unless otherwise agreed to by Pfizer and the Collaborator.

#### **“Compassionate Access” Requests**

From time to time, you may receive requests from HCPs to provide one of Pfizer's investigational drugs for a seriously ill patient. Such requests on behalf of patients are called “compassionate access” requests.

If anyone asks you about compassionate use of a Pfizer product, refer the inquiry promptly to Pfizer Medical Information or direct them to PfizerCAREs ([Pfizer's Compassionate Access Request system](#)) or PfizerCAREs mailbox at [PfizerCAREs@pfizer.com](mailto:PfizerCAREs@pfizer.com). Remember, you must never discuss unapproved products or indications with HCPs. More information may be found [here](#).

#### **Responding to Requests from HCPs Regarding Medical Research**



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

##### ***Responding to Requests to be a Clinical Investigator***



Not all interested HCPs will qualify to be Clinical Investigators. In addition to requiring appropriate expertise and training, being a Clinical Investigator may require having access to office space to accommodate research subjects, retaining study monitors and other personnel, acquiring additional equipment, and securing storage for both drugs and files. The HCP will also need to have knowledge of informed consent and patient protection issues and be trained in Good Clinical Practice (GCP).



#### Referring HCPs as Potential Clinical Investigators for Pfizer-Sponsored Studies

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

#### Collaboration with Physicians on Questionnaires and Surveys

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

#### No Assistance with Patient Recruitment

It is not appropriate for members of Pfizer marketing or sales functions to assist Clinical Investigators in recruiting subjects for Pfizer-sponsored studies nor for any Pfizer colleagues to assist in recruitment of subjects for CRCs. Similarly, it is not permissible to offer additional compensation to an investigator in order to offset higher than expected recruitment costs. Any requests for additional funding must be made directly to the Pfizer Medical contact for the study.

#### For More Information

- For more information on SOPs please refer to the [eSOP portal](#).



## Orange Guide – Chapter 6: Clinical Research and Clinical Research Collaborations

- For any questions about compassionate use of a Pfizer product refer the inquiry promptly to Pfizer Medical Information or direct them to PfizerCAREs ([Pfizer's Compassionate Access Request system](#)) or the PfizerCAREs mailbox at [PfizerCAREs@pfizer.com](mailto:PfizerCAREs@pfizer.com).
- For any questions about Clinical Research Collaborations, direct them to the [CR-Collaborations@pfizer.com](mailto:CR-Collaborations@pfizer.com) mailbox.
- Questions may be referred to a Medical colleague, your manager, or Pfizer Legal counsel.



## **CHAPTER #7 – P&T COMMITTEE INTERACTIONS**





Chapter

#7

P&T COMMITTEE INTERACTIONS

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## Chapter #7 P&T Committee Interactions

### P&T Committees

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

P&T Committees typically make formulary decisions based upon assessments of safety, efficacy, tolerability and, increasingly, cost-effectiveness. In some cases, organizations with P&T Committees may be acting on behalf of Medicaid, Medicare Part D, or other government healthcare programs. P&T Committee members are charged with an important responsibility and therefore are expected to avoid both actual and perceived conflicts of interest when making formulary decisions.

Field Commercial Colleagues as well as Field Medical Colleagues, as those terms are defined in Chapter 1 of this Guide, interact with P&T Committee Members in a variety of ways. Field Commercial and Field Medical Colleagues may attend or present at P&T Committee meetings where formulary decisions are considered. Account Managers may also work with P&T Committee members outside of such meetings to educate them about our products. Field Commercial Colleagues may detail a P&T Committee member in the member's capacity as a practicing HCP. This chapter provides guidance to Field Commercial Colleagues regarding their interactions with P&T Committees and their members and working with Field Medical Colleagues in presentations to P&T Committees.

It is Pfizer policy not to engage in any activity that could be construed as improperly influencing the independent judgment of a P&T Committee member. In fact, consistent with the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals ("PhRMA Code"), any HCP hired by Pfizer as a speaker or consultant who also serves as a member of a P&T Committee must disclose to the Committee the existence and nature of his or her relationship with Pfizer. This requirement generally extends for at least two years beyond the termination of any speaker or consulting arrangement.

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



### ***Key Points to Ensure Compliance***

- Field Commercial Colleagues should interact with P&T Committee members the same way they interact with other HCPs - by following the four Core Compliance Principles.
- Field Commercial Colleagues who interact with a P&T Committee member should treat them the same as they treat any other HCP; call on a P&T Committee member as a normal part of business. Do not treat a P&T Committee member any differently during a pending formulary decision than at any other time.
  - Do not show HCPs "special treatment" because of their status on a P&T Committee.
  - Notify your manager promptly if a Committee member requests "special treatment."
  - The mere increase of detailing or interactions during a pending formulary decision in and of itself generally is not considered "special treatment," so long as the purpose is to provide relevant, on-label information. However, increasing the number of meals provided in connection with the increase in detailing or calls is not permitted.
- Do not engage in any activity that could be construed as improperly influencing the independent judgment of a P&T Committee member.
- Do not link any financial transactions (other than disclosed rebate or discount arrangements, if and as appropriate) or anything else of value to formulary decisions or formulary placement of a Pfizer product.
- Direct all questions about **off-label information** to Pfizer Medical Information. If such a request is submitted to you in connection with an upcoming P&T Committee formulary review, you may also contact a Field Medical Colleague or Medical Outcome Specialist (MOS), depending on the question, to ask that he or she present and respond to the Committee, if appropriate.
- During P&T Committee presentations where both Medical and Field Commercial Colleagues are present, Field Commercial Colleagues are prohibited from participating in any discussion of unapproved or off-label information.



## Field Commercial Colleague Interactions with P&T

### Day-to-Day Interactions

Field Commercial Colleagues may come in contact with P&T Committee members as part of their normal Pfizer activities. These day-to-day interactions with P&T Committee members are governed by the same policies that govern interactions with other HCPs. The four Core Compliance Principles will guide Field Commercial Colleagues in these interactions:

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

Field Commercial Colleagues who interact with HCPs who may also be P&T Committee members must:

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

### Questions From a P&T Committee Member About Their Status





If a HCP asks if I know whether he or she is a P&T Committee member, what should I say?





Always answer truthfully. While P&T Committee members often do not wish to be identified as such, answering honestly is the best way for you to demonstrate the core value of integrity with the HCP.





#### Buying Lunch for a P&T Committee Member

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

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

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

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

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



## Generating Support for Formulary Placement

When advocating for formulary placement of Pfizer products, it is permissible to ask P&T Committee members and other influential HCPs for their support. Account Managers and Sales Colleagues can work together to identify HCPs who may be willing to advocate for access to Pfizer products. Remember that any discussions with potential advocates must be focused on the strength and weight of the scientific, medical, and clinical evidence for the products and are at all times governed by Pfizer's policies on product promotion, including the four Core Compliance Principles.

Colleagues may engage in certain activities in an effort to generate support for formulary placement of Pfizer products; however, nothing of value can be promised or given to an HCP or P&T Committee member in return for their testimony or support. Examples of permitted activities include:

### Generating Support for Formulary Decisions



May I tell other (non-P&T Committee member) HCPs about upcoming formulary decisions involving Pfizer products? May I encourage HCPs to contact Committee members or to attend Committee meetings to voice their support for our products?



Yes. Colleagues can ask HCPs who support the use of a Pfizer product to express their opinions to P&T Committee members. Although colleagues cannot create talking points or write letters for an HCP who would like to advocate for a Pfizer product, you may discuss the product's safety and efficacy using RC-approved messaging and provide the HCP with RC-approved materials.

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

- Inviting a P&T Committee member to become a speaker, consultant, or member of an advisory board if the invitation is even partially motivated by a desire to influence an upcoming formulary decision;
- Writing letters or creating talking points for use by an HCP or P&T Committee member who would like to advocate for a Pfizer product;
- Taking a P&T Committee member out to a meal that is extravagant or otherwise not in compliance with the PhRMA Code;
- Providing any payment (such as an exhibit/display fee or speaker fee) to a P&T Committee member or their institution if the payment is even partially motivated by a desire to influence an upcoming formulary decision;
- Providing any unapproved item to a P&T Committee member; and



- Linking financial support from Pfizer, either directly or indirectly, with influence over that P&T Committee member's exercise of judgment in serving on their P&T Committee.

#### Discussion of Extraneous Financial Transactions

To avoid violating the anti-kickback laws, Pfizer strictly prohibits linking financial transactions (other than disclosed rebate or discount arrangements) or anything else of value to P&T Committee decisions. Outside of certain limited exceptions, anti-kickback laws prohibit manufacturers from providing anything of value in order to influence formulary decisions. Any separate financial arrangements could also affect Pfizer's government pricing obligations under federal and state law.

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

#### Responding to Requests for Funding by P&T Committee Members



What if, while I am giving a presentation on a Pfizer product under formulary review, a P&T Committee member asks for a grant or charitable contribution? Should I schedule a separate meeting to explain Pfizer's process for considering these requests?



You must never affirmatively raise the topic of providing a grant or charitable contribution to a P&T Committee member. However, if the member makes a specific unsolicited inquiry about grants or charitable contributions you should address it briefly, so long as you do the following:

- State that, at the conclusion of your product discussion, you can provide information about the procedures for submitting a request to Pfizer;
- State that a decision to provide the requested funds will in no way be influenced by the P&T Committee member's status in making formulary decisions; and
- Explain that the decision on whether to provide requested funds will be made by an independent multi-disciplinary group and will not be impacted by the pending formulary decision.



## Formal Product Presentations to P&T Committees

### ***Who May Present?***

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

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

### ***What Information May Colleagues Present?***

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

#### ***If Pfizer Requested the Opportunity to Present Information***

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

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



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





provide a brief answer that is truthful, not misleading, based on substantial scientific evidence, and non-promotional in tone; and then continue with the original presentation). Field Commercial Colleagues may remain in the meeting during this time, but if a more extensive answer or discussion is needed to respond to the customer's request, the Medical Colleague should submit an unsolicited medical request or speak to the customer after the meeting out of the presence of Field Commercial Colleagues as appropriate.

#### P&T Committee Standing Requests for Off-Label Information

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

#### *If the P&T Committee Requested that Pfizer Provide Information*

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

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

MOS Colleagues may respond to requests for unapproved but on-label information (e.g., where no RC-approved materials exist to use in a response). Because of their background and training, they may also respond to requests for pharmacoeconomic or outcomes information if they have materials approved for



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such responses. A FMD may respond to requests for both unapproved and off-label information. In the absence of a specific request for such information about our products, no colleague may present unapproved or off-label information about Pfizer products to a P&T Committee or one of its members.

#### Joint Sales and Medical P&T Presentations

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

#### For More Information

- Questions may be referred to your manager or team attorney.
- For medical inquiries, contact Pfizer Medical Information at 1-800-438-1985.



## **CHAPTER #8 – PRIVACY: PROTECTING PERSONAL INFORMATION**



Chapter

#8

PRIVACY: PROTECTING PERSONAL  
INFORMATION

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## Chapter #8 Privacy: Protecting Personal Information

### Privacy

This Chapter highlights certain key Pfizer policies regarding the protection of Personal Information. Personal Information is any information that links, relates or is linkable to an identifiable individual or household or can be used to identify a person or household, either directly or indirectly (e.g., by combining different sets of indirect identifiers). Examples include a person's name, physical and e-mail addresses, phone numbers, identification numbers, preferences, unique online identifiers or IP addresses. Examples of activities involving collection or access to Personal Information of others (both HCPs and patients) include health screenings, surveys, clinical outcomes research, and mentorships as well as managing Personal Information in your possession—such as on your computer.

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

We are all familiar with the notion of privacy from our own daily lives. Privacy is often described as an individual's desire to keep his/her Personal Information confidential and, by extension, to determine when, how and to what extent any Personal Information is used and shared with others. Some Personal Information identifies who we are and where and how we live; other Personal Information is medical in nature; other forms of Personal Information relate to finances, political affiliations, and philosophical beliefs. Pfizer's corporate policies require that the confidentiality and security of Personal Information be maintained in accordance with state and federal law.

### Patients' Privacy and Personal Information

"Personal Information" includes any information that alone or in combination with other data can be used to identify or link to a person or household such as name or initials, address, phone number, e-mail address, or IP address. "Sensitive Personal Information" ("SPI") is a subset of Personal Information that is generally considered to include more private details about an individual and may trigger additional requirements under the law. Sensitive Personal Information may include geolocation data, financial information, national identifiers such as social security number, information about an individual's race, ethnicity, religion, sex life/sexual orientation, and information about a person's physical or mental health (e.g., a person's medical history, physical or mental condition, diagnosis or treatment protocol), or under certain state laws biometric data.



### **Governing Laws and Pfizer Policies**

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 United States may have privacy implications for complying with the laws of other countries. Consult your team attorney or the [Global Privacy Office \(GPO\)](#) if a proposed activity presents potential privacy implications for individuals outside of the United States or involves the transmission of Personal Information collected in one country to another country. **A privacy implication includes** any collection, use, transfer, storage, or deletion of personal information of any kind. It is important to note that merely accessing Personal Information about an individual in another country via your computer or a database is likely considered an international transfer of personal information.

The goal of data privacy laws is to ensure that companies like Pfizer handle Personal Information in a way that is transparent, fair and reasonable. For example, when an individual chooses to share such information with a person or entity they trust, regardless of the circumstances under which Personal Information is shared, he or she generally expects that the person or entity to use that information for limited purposes, hold that information in confidence, and keep it reasonably protected. 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 also recognizes that in many countries this is more than an expectation but rather an individual fundamental right. 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 \(CP\) #404: Protecting the Privacy of Personal Information](#).

The California Consumer Privacy Act "CCPA" went into effect on January 1, 2020 and is the closest thing to a GDPR style comprehensive privacy law in the United States. If you are working with California residents, you should consult with your legal counsel on how this law may apply to you.

#### **Key Points to Ensure Compliance**

- Always disclose that you are a Pfizer employee when interacting with patients. For example, wear your Pfizer branded name tag at all times when, attending a consumer health fair or during a mentorship or preceptorship.
- [Corporate Policy 404, - Protecting the Privacy of Personal Information](#) requires all Pfizer colleagues to employ appropriate safeguards designed to protect Personal Information they have access to, including the Personal Information of customers or patients.



### ***Key Points to Ensure Compliance***

- Do not request or collect Sensitive Personal Information for any reason unless there is a clear business need for such Sensitive Personal Information and you have specific approval from your team attorney to do so.
- Avoid situations likely to lead to the inadvertent disclosure of Personal Information, including Sensitive Personal Information, such as being present at or near private conversations between HCPs and patients. Limit use of free form fields and situations that may lead to social media sharing of personal information.
- If you become aware that Pfizer, a business partner or a service provider has received Sensitive Personal Information or more extensive Personal Information than intended, expected, or necessary for the business purpose, immediately notify your team attorney.
- When setting up a mentorship or preceptorship, Pfizer colleagues must remind HCPs serving as mentors or preceptors that they have a legal obligation to obtain their patients' written authorization before Pfizer colleagues may be allowed to observe any consultation, examination, or treatment of any patient or have access to information about their health or medical condition.
- Pfizer usually does not perform work on behalf of an HCP, Health Plan, or other "covered entity" under HIPAA. Therefore, it is not appropriate for any field-based colleague to enter into a Business Associate Agreement. If you are asked to sign a Business Associate Agreement, you may instead offer either the Pfizer Privacy Pledge or Patient Health Information Confidentiality Agreement template found on [MyPfieldNet](#), as appropriate. If this does not satisfy the party making the request, you must consult with your team attorney.
- HCPs are permitted to disclose protected health information about their patients to persons "subject to the jurisdiction of the FDA" for activities related to the quality, safety, or effectiveness of an FDA regulated product or activity for which the person has responsibility. Continue to follow the process established for collecting information about and reporting these events pursuant to [Corporate Policy 903 – Your Responsibility to Report Information about Safety, Quality or Performance of Pfizer Products](#).
- Do not sign any non-Pfizer Confidentiality Agreement without consulting with with your team attorney.



### **Key Points to Ensure Compliance**

- Do not discuss with an HCP the fact that you may know their prescribing practices based on their prescriber data.
- Do not share an HCP's prescriber data with anyone outside of Pfizer.
- Pfizer colleagues should not engage health fair attendees in discussions about their specific health status, symptoms, diagnosis, or treatment. Refer attendees who raise these topics to their treating HCP.
- Employ the same safeguards to protect the confidentiality of prescriber data as you would any other Personal Information. As a general rule, prescriber data should be collected and used only for internal business purposes and not in discussions with Pfizer's customers (including the HCPs themselves) or external third parties.
- Personal Information should generally only be processed in a manner that is transparent and within the reasonable expectations of the patient / individual.
- Any suspected breach of security of Personal Information or Sensitive Personal Information must be immediately reported as "Incidents" pursuant to [Corporate Policy 411 – Information Incident Response Policy](#). Pfizer colleagues should avoid using the term "breach" when reporting a suspected incidents involving Personal Information. Do not use the word "breach" in email subject lines. A "Breach" is a legal definition that varies by jurisdiction and only determined by legal counsel. Lost or stolen computers or other devices containing Pfizer data must be reported to the user's local Service Desk / Help Desk - the worldwide list of contact telephone numbers is available online at <http://ITSupport.pfizer.com>.
- Any other incidents of potential unauthorized access to Pfizer data must be reported as soon as possible to the Global Security Operations Center at 212-733-7900 or [GSOCwatchroom@pfizer.com](mailto:GSOCwatchroom@pfizer.com). You may also report incidents to your team attorney.

### **Laws Protecting Personal Data**

One of the most important federal healthcare laws in the area of privacy is called the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (**HITECH Act**) (collectively, **HIPAA**). HIPAA imposes strict limitations on the use and disclosure of Sensitive Personal Information pertaining to health data (called "protected health information" (PHI) under HIPAA), by "covered entities" and their "business associates." It is important to

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note that Pfizer is not a covered entity under HIPAA, and it usually does not function as a business associate on behalf of covered entities. However, HIPAA is relevant to our business because Pfizer does business with many covered entities and business associates such as HCPs, HCOs and other Organized Customers, including hospitals, health plans, and the vendors who provide services to them.

The collection and use of Personal Information is also regulated by other federal and state laws and regulations, including state health privacy laws or state security breach notification laws that apply in the event that certain personal information is lost or improperly accessed and used.

### Business Associate Agreements and Confidentiality Agreements

Sometimes a customer that is a covered entity such as an HCP or Organized Customer may incorrectly request that you sign a HIPAA Business Associate Agreement (BAA). A BAA is an agreement that is entered into between a “covered entity” (e.g., an HCP or a health insurer) and a “business associate,” which generally is defined as an entity or person who performs work for or on behalf of a covered entity with respect to protected health information (certain types of vendors are automatically considered “business associates”). **Pfizer generally does not perform this type of work on behalf of covered entities. Consequently, it would not be appropriate for Pfizer Field Commercial Colleagues to enter into a BAA individually or on Pfizer’s behalf.**

A confidentiality agreement will usually meet the needs of the covered entities mistakenly requesting BAAs. To address such requests, Pfizer has developed two Pfizer template forms, either of which you are permitted to offer to the HCP as assurance of your intent to keep Personal Information and Sensitive Personal Information (including protected health information) confidential.

The Privacy Pledge and Patient Health Information Confidentiality Agreement can be downloaded from [MyPfildNet](#).

#### Business Associate Agreements





What should I do if a HCP insists that I sign a Business Associate Agreement before I enter the patient clinic? Can I sign the Business Associate Agreement to avoid being shut out?



No. You must not sign a Business Associate Agreement, even if required by an HCP in order to be allowed access to a facility. You may offer to sign the Pfizer Privacy Pledge or Patient Health Information Confidentiality Agreement template found on [MyPfildNet](#). Providing a copy of one of these documents with your signature is usually sufficient 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 who may be able to provide assistance to you.



### Signing Customer Confidentiality Agreements

	If an HCP insists that I sign a facility's Confidentiality Agreement, even after I sign and show the HCP Pfizer's Privacy Pledge and Patient Health Information Confidentiality Agreement, can I sign what the HCP wants me to sign?
	Maybe. Sometimes these agreements are acceptable to sign, but you may never do so unless your team attorney has first reviewed and approved the agreement.

## Steps to Protect Patient Privacy

### ***Data Minimization***

It is important to avoid access to, collection, retention, and use (collectively “processing”) of Personal Information unless and as long as there is a legitimate business need for doing so. Processing Personal Information, which includes both collection and use of the information, imposes legal obligations on Pfizer including an obligation to keep that information confidential and secure. Disclosure of certain types of Personal Information, even if accidental, can expose Pfizer to legal liability, create a risk of fraud or even identity theft for the information owner, and erode confidence in Pfizer and its commitment to privacy and information security.

**Except as expressly authorized by your manager or team attorney, you must avoid collecting, maintaining, or using Sensitive Personal Information.** If you inadvertently come into contact with Sensitive Personal Information or are asked to collect it, you should contact your team attorney immediately to discuss Pfizer's policies on safeguarding such information.

### ***Avoid Intentional and Inadvertent Disclosure of Sensitive Personal Information***

HCPs and Organized Customers such as, health plans, hospitals, and other Pfizer customers are subject to many restrictions regarding the use and disclosure of Sensitive Personal Information about their patients and members. With certain exceptions, they are not permitted to disclose a patient's or member's Sensitive Personal Information to a third party, such as Pfizer, unless they receive prior written authorization from the patient or member. You must avoid situations in which you may be exposed to Sensitive Personal Information without an individual's written authorization or applicable consent. In the event a Pfizer customer or other person working on behalf of a customer or covered entity exposes you to Sensitive Personal Information without having obtained the required authorization, you should not document or reproduce the information in any form. You must strictly maintain the confidentiality of such information in accordance with Pfizer's policies. Even if an individual has authorized the use or disclosure of Sensitive Personal Information, such as during a mentorship, you must still abide by the rules discussed in this Chapter and consult your team attorney, as needed, to ensure compliance with Pfizer policies and



applicable laws regarding the use, disclosure, and destruction of any Sensitive Personal Information to which you are exposed.

### ***Seek Only Aggregated or De-Identified Data***

Under limited and specific circumstances, and in consultation with your team attorney, it may be appropriate for colleagues to receive certain “aggregated” or “de-identified” patient information from a HCP, Organized Customer (e.g., health plan or hospital), or other third party. “**Aggregated**” data is information about multiple individuals that is compiled and does not allow for the re-identification of any one individual. “**De-identified**” data is data that cannot be attributed to any specific individual or used to identify any individual and usually has been stripped of certain key identifiers which, either alone or in combination with other available information, could link the information with a specific individual or be used to identify a specific individual (including the individual’s name, elements of the individual’s address, date of birth or death, telephone number, patient identification number, treatment dates, and social security number, among others). HIPAA regulations and certain state privacy laws include strict standards for what qualifies as “de-identified.” Accordingly, you must consult your team attorney before assuming information has been properly “de-identified.”

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

### ***Obtain Patient Consent (via Written Authorization) Where Appropriate***

In certain circumstances, it may be appropriate or even necessary for Pfizer to receive Sensitive Personal Information from patients or consumers as part of certain approved activities. You must ensure that the appropriate patient consent (a written HIPAA authorization) has been obtained by the HCP or Organized Customer prior to:

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



The signed authorization form should be maintained as part of the patient's medical record by the HCP, and a copy should be given to the patient by the HCP. There is no need or reason for you to have a copy of the form, so you should not collect or retain a signed copy of the form. Consult your team attorney or the Global Privacy Office to determine whether an authorization is necessary and whether the template available contains the appropriate legally required terms.

### ***Report Data Incidents***

If you unintentionally gain access to or if you become aware of any compromise of or potential unauthorized access to or use of Pfizer data, including Personal Information, you must promptly report the incident to Pfizer's Global Security Operations Center (GSOC) (212-733-7900 or [GSOCwatchroom@pfizer.com](mailto:GSOCwatchroom@pfizer.com)) pursuant to [Corporate Policy 411 – Information Incident Response Policy](#). Additionally, you should also notify your team attorney. Lost or stolen computers or other devices containing Pfizer data must be reported to your local Service Desk / Help Desk the worldwide list of contact telephone numbers is available online at <http://ITSupport.pfizer.com>. Pfizer colleagues should avoid using the term "breach" when reporting a suspected incidents involving Personal Information.

### ***Mentorships and Preceptorships***

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

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

When setting up a mentorship or preceptorship, colleagues must remind HCPs serving as mentors or preceptors that they have a legal obligation to obtain their patient's written authorization before colleagues may be allowed to observe any consultation, examination, or treatment. Pfizer has created a Patient Authorization template, available on [MyPfizerNet](#) under Mentorship Guidelines that may be provided to HCPs for use in obtaining a patient's permission, as described above.

Because patient privacy issues are often implicated when Pfizer employees are permitted to observe treatment or consultation sessions with patients and HCPs, colleagues must identify themselves as Pfizer employees and must wear their Pfizer name tags at all times, so that patients are fully aware of and understand the colleagues' role.





### **Adverse Event Reporting**

HCPs are permitted to share PHI about their patients without a business associate agreement or patient authorization in limited circumstances. HCPs are permitted to disclose PHI to persons “subject to the jurisdiction of the FDA” for activities related to the quality, safety, or effectiveness of an FDA regulated product or activity for which the person has responsibility. Therefore, if an HCP reports an adverse event or other safety or product information, continue to follow the process established for collecting information about and reporting these events pursuant to [Corporate Policy 903 – Your Responsibility to Report Information about Safety, Quality or Performance of Pfizer Products](#).

For additional rules regarding the appropriate use of mentorships and preceptorships, please see Orange Guide Chapter 2: Interactions with HCPs. If you have any questions about Pfizer’s Patient Authorization language, please contact your team attorney.

### **Consent Forms and Mentorships**

	Does a patient have to sign a written authorization form before I can observe an examination or treatment as part of a mentorship, or is oral permission sufficient?
	<p>Oral permission is not acceptable. As a convenience to your HCP mentor, you can download a template Patient Authorization Form from <a href="#">MyPfieldNet</a> for the HCP to use. Ultimately, it is the responsibility of the HCP to obtain the appropriate written authorization from the patient.</p> <p>Remember, you must also wear your Pfizer name tag at all times.</p>

## **Handling Patients' Personal Data**

### **Pfizer-Sponsored Third-Party Communications to Patients**



Occasionally, and subject to strict limitations and legal review, Pfizer may pay for certain communications to be made to patients. For example, such communications may include managed care organizations or retail pharmacies sending Pfizer-approved disease management or educational materials or medication compliance mailings to inform or remind patients of the schedule to fill or refill a prescription for a chronic medication. Payments must be made in accordance with applicable state and federal laws and must be documented in a written Service Agreement between Pfizer and the managed care organization or pharmacy or intermediary service provider. Your team attorney must approve the particular business arrangement/sponsorship as well as the Service Agreement. See Chapter 15 for additional information on Service Agreements.



The Service Agreement is designed to ensure protection of patients' privacy as well as compliance with applicable laws and Company policy. Please note that Pfizer will not receive any patient names, addresses, or other Sensitive Personal Information.

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



#### Chart Reviews

	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?
	No. It is Pfizer policy that colleagues should never conduct a chart review. In addition, as discussed earlier, field-based colleagues must not sign Business Associate Agreements under any circumstance. If the confidentiality agreements referenced above do not satisfy the party requesting a BAA, you must consult your team attorney.

#### Consumer Health Fairs and Screenings

Consumer health fairs and screenings may raise patient privacy concerns since Personal Information is often obtained in the presence of sales representatives or other Pfizer colleagues attending the health fair. Pfizer colleagues should not engage health fair attendees in discussions about their specific health status, symptoms, diagnosis, or treatment. These discussions should occur between the patient and an appropriate HCP. Should a patient attempt to initiate such a discussion, the Pfizer colleague should make clear that he or she is not an HCP and is not providing medical advice and should redirect the patient to an HCP at the fair or to his or her treating HCP.

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

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



## REMEMBER

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

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

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

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

## Securing Consent and Personal Information from Consumers

Pfizer does not use Personal Information to communicate directly with patients unless the patient has consented (either implicitly or explicitly to receiving such communications).

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

- Disease management program enrollment forms;
- Coupons and rebate offers;
- Literature requests;
- Loyalty programs; and
- Health screenings.

These guidelines apply only when consumers are asked to provide Personal Information, such as name, address, e-mail address, or a phone or fax number. Pfizer may not discriminate against or exclude consumers from participating in programs based on the fact that consumers do not opt-in or opt-out of providing their Personal Information. The same applies to the subsequent selling of the consumer's Personal Information. Offering financial or other valuable incentives in exchange for data may be allowed in limited circumstances where the financial incentive is a result of data monetization and stands in relation to such and is part of an "enhanced" program offering. When a Pfizer program requires a consumer to provide Personal Information as a term or condition of use of or access to the "enhanced" program, a simple, timely, cost-free mechanism (toll-free number or prepaid mail-in form) must also be provided that



allows the consumer to discontinue or “opt out” of the program at any time. Before engaging in any loyalty or rewards, or other incentive programs, you must consult with your team attorney.

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

### Handling HCP Personal Information

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

As a general policy, Pfizer restricts access to Personal Information to individuals who “need to know” the information as related to their job duties. In general, most Pfizer colleagues, including Sales Colleagues, do not need access to Personal Information about HCPs, their employees, or the employees of Pfizer customers like Health Plans or GPO’s 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).

#### ***Proper Use of HCP Prescriber Data***

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

You may engage in an on-label discussion directly with the HCP to solicit and learn information about his or her clinical approach and use of specific products in order to tailor your promotional presentation; however, you may not directly convey the data you possess on his or her prescribing nor may you use prescribing data to directly or implicitly exert pressure or coerce HCPs to prescribe a particular product. You are also prohibited from sharing an HCP’s prescriber data with other individuals and entities outside of





Pfizer as that would compromise its confidentiality. HCP prescriber data must only be used for legitimate business purposes, such as the development of your team's promotional strategy. Access to HCP Prescriber Data must be limited to individuals with a legitimate business need. In developing and distributing reports that contain HCP prescriber data, colleagues should provide instructions to recipients that in reviewing the report, that they should filter for HCPs that are on their TCLs or within their territory or area of responsibility prior to reviewing the data. Likewise, before reviewing HCP prescriber data, colleagues should make reasonable efforts to filter for HCPs that are on their TCLs or within their territory or area of responsibility to ensure information is utilized only by those with a legitimate business need.

The American Medical Association (AMA) administers a program by which HCPs can opt-out of having their prescriber data released to pharmaceutical companies for use in marketing. Pfizer is required to check the opt-out list quarterly and has 90 days to comply with an HCP's request. Pfizer shall also maintain its own opt-out list internally and check against it. If an HCP has opted-out, Pfizer will respect that preference and will not use his or her prescriber data in connection with promotional activities. If you learn that an HCP on whom you call has asked for his or her prescriber data not to be released, even though you would not have access to the HCP's prescriber data, you should be especially careful to avoid any discussion of prescribing habits in your promotional presentations to the HCP. The AMA program allows HCPs to report specific instances of inappropriate behavior by pharmaceutical sales representatives or companies. Thus, it is important that you familiarize yourself with these rules and conduct your activities accordingly. Using prescriber data inappropriately not only compromises your credibility with the HCP, but it is also a violation of Pfizer policy, may subject you to disciplinary action up to and including termination.

### Handling Consumer Access and Deletion Requests

Certain state privacy laws give broad consumer rights to patients and customers as well as HCPs with regard to their Personal Information and how Pfizer may use it. Consumers as defined under the applicable law may have the right to obtain access to and get a copy of or ask Pfizer to delete the Personal Information that Pfizer holds and processes about them. Such requests may reach Pfizer via phone, email, mail or otherwise and you should immediately forward any such requests to your team attorney and/or the Global Privacy Office to ensure Pfizer can meet the deadline to respond under the law. You may not directly respond to any such request unless instructed to do so. Certain laws allow Consumers to also opt-out from sales of their Personal Information at any time. Such laws define sales broadly to include any selling, providing, **making available** or disclosing personal information in exchange for any consideration or thing of value, i.e. not only sales for money. If you receive any such opt-out request, you must also immediately forward it to your team attorney and/or the Global Privacy Office.



### Providing Your Personal Information When Required By Vendor Credentialing Processes

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

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

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

- Always tell your manager if a hospital or institution (or institution's vendor) wants you to provide your Personal Information to gain site access.
- If the hospital, institution, or vendor has a written credentialing policy, be sure to provide a complete and current copy to the Vendor Credentialing team and your team attorney to review in advance.
- Do not sign any Business Associate Agreement or other legal document without consulting your manager and team attorney.
- Give the hospital or vendor Pfizer's approved template Confidentiality Letter Agreement (available through a link in the Guidelines, accessible on [MyPfieldNet](#)).
- Do not share your Personal Information before the HCP or vendor signs an approved Confidentiality Agreement to protect your information.



- Do not modify Pfizer's approved template Confidentiality Letter Agreement without your team attorney's approval in advance.
- Do not sign a Confidentiality Agreement that is not an unmodified Pfizer template without your team attorney's approval in advance.

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

### ***Corporate Policies on Your Responsibility for Safeguarding Personal Information***

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

- [Corporate Policy 403](#) on the *Acceptable Use of Pfizer Information Systems*;
- [Corporate Policy 404](#) on *Protecting the Privacy of Personal Information*;
- [Corporate Policy 405](#) on *Enterprise Records and Information*;
- [Corporate Policy 411](#) on the *Information Incident Response Policy*; and
- [Corporate Policy 903](#) on *Your Responsibility to Report Information about Safety, Quality or Performance of Pfizer Products*.

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

- Not leaving your Pfizer equipment or Personal Information unattended or in an unsecured location, e.g., an unlocked car;
- Encrypting your computer and using encrypted USB flash drives; (i.e. Never using unencrypted e-mail to transfer Personal Information outside of the Pfizer network;
- 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](mailto:GSOCwatchroom@pfizer.com)) or to the local



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IT Service Desk (the worldwide list of contact telephone numbers is available online at <http://ITSupport.pfizer.com>); and

- Never using unencrypted e-mail to transfer Personal Information outside of the Pfizer network.

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

### For More Information

- For more information on information system policies, see [Corporate Policy 403, Acceptable Use of Pfizer Information Systems](#).
- For more information on protecting the privacy of Personal Information, see [Corporate Policy 404, Protecting the Privacy of Personal Information](#).
- For more information on records management, see [Corporate Policy 405, Records and Information Management](#).
- For more information on handling sensitive information, see [Handling Sensitive Information: Safeguarding Our Information](#).
- For more information on information system policies, see [Corporate Policy 411 the Information Incident Response Policy](#).
- For more information on information system policies, see [Corporate Policy 903, Your Responsibility to Report Information about Safety, Quality or Performance of Pfizer Products](#).
- For copies of the Privacy Pledge and Patient Health Information Confidentiality Agreement, see the “Compliance” tab on [MyPfizerNet](#).
- For access to the Patient Authorization template, see the “Compliance” tab on [MyPfizerNet](#).
- For more information on health screening and hiring vendors, see Orange Guide Chapter 13: Health Screenings.
- Questions may be referred to your manager or Legal.
- You can also call the Privacy Office Helpline at 212-733-0228 (worldwide) or 877-356-6195 (within the U.S.), or you can e-mail the Privacy Office at [Privacy.officer@pfizer.com](mailto:Privacy.officer@pfizer.com).



## **CHAPTER #9 – SPEAKER PROGRAMS FOR HCPS**



Chapter

#9

SPEAKER PROGRAMS FOR HCPs

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## Chapter #9 Speaker Programs for HCPS

### Introduction

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

Speaker programs are closely scrutinized by Pfizer and regulators. In addition, particularly when an HCP is paid to speak for Pfizer, the engagement is subject to scrutiny under anti-kickback and other healthcare laws. The Food and Drug Administration (FDA) considers promotional speakers to be speaking on behalf of Pfizer. Thus, **Pfizer is responsible for the content and conduct of speaker programs**. This includes all information presented by the speaker and any payments related to the program, as well as the venue and other details of each speaker program.

This Chapter sets forth policy for all relevant Pfizer colleagues who organize, host, and/or attend a speaker program. Note that this includes not just Sales Colleagues such as Sales Representatives and District Business Managers but also other Field Commercial Colleagues, such as Key Account Managers. It may also include marketing colleagues to the extent that they organize, host, and/or attend a speaker program. When any Field Commercial Colleague or marketing colleague organizes, hosts, or attends a speaker program, that individual is responsible for ensuring that the conduct and content comply with the rules set forth in this Chapter.

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

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





## Speaker Program Checklist

Lead Time	<p>Speaker programs must be submitted in Centris with the following minimum required lead times:</p> <ul style="list-style-type: none"><li>• <b>14 days:</b> All live and webconference/teleconference sponsor programs.</li><li>• <b>5 days:</b> All out-of-office webconference/teleconference link programs.</li><li>• <b>3 days:</b> All in-office webconference/teleconference link programs.</li></ul>
Pre-program Discussion	<p>You must review the policies (including your duty to make a corrective statement) and the approved slide deck (downloaded from the appropriate system) with the speaker prior to each program.</p>
Projecting Slides	<p>You are responsible for projecting the slides using your Pfizer device with a projector (except at live roundtable/table top programs) to ensure the presentation is the current, unaltered RC-approved version. For a webconference or teleconference program, you are also responsible for ensuring appropriate A/V equipment is used and that the attendees can clearly hear the remote speaker's presentation and see the slides.</p>
Compliance Slide(s)	<p>All speaker programs must start with a review of the mandatory compliance slide(s), which includes statements that Pfizer is sponsoring the presentation and that the speaker is presenting on Pfizer's behalf. Either the speaker or the representative may present the mandatory compliance slide(s).</p>
Slide Decks	<p>Speakers may only present RC-approved slide decks. Speakers must present all required slides in the RC-approved slide deck and must not add any non-RC approved slides or other content.</p>
Corrective Statement	<p>The information provided verbally by the speaker must also be consistent with the RC-approved slides and product labeling and must balance benefits and risks. Pfizer colleagues in attendance should be familiar enough with the deck and package insert to identify inappropriate statements or other issues with the speaker's presentation and must make a corrective statement, as required.</p>
Handouts	<p>Only RC-approved educational information that has been approved for such distribution can be handed out to attendees.</p>



Time Requirements	<p>Set expectations ahead of time to ensure attendees are able to stay for the entire program duration, and if an attendee misses part of the program, the speaker or a Pfizer colleague should make every effort to review any safety/risk slides that were missed as soon as reasonably possible.</p> <ul style="list-style-type: none"><li>• Out-of-office programs: 45 minutes, inclusive of Q&amp;A.</li><li>• In-office programs: A minimum of 30 minutes is required, inclusive of Q&amp;A.</li></ul>
Venue	<p>Must be appropriate and conducive to a scientific or educational presentation.</p>
Insufficient RSVPs	<p>Insufficient appropriate RSVPs 7 calendar days prior to the program (3 calendar days for out-of-office link programs) cannot go forward. Any cancellation must be communicated as soon as possible to the speaker.</p>
Entering RSVPs	<p>When a Pfizer colleague is entering an RSVP on behalf of an attendee, they should do so only when the HCP has clearly indicated their intention to attend the program.</p>
In-office Minimum Attendance Requirements	<ul style="list-style-type: none"><li>• 3 appropriate attendees who are not affiliated with the speaker are required to attend.</li><li>• 2 out of the required 3 minimum attendees must be individuals from the Approved Attendees List.</li></ul>
Out-of-office Minimum Attendance Requirements	<p>At least 3 appropriate individuals from the Approved Attendees List who are not affiliated with the speaker are required to attend.</p>
Restrictions on Attending Same Topic or Product	<p>Individuals are prohibited from attending a program on/for:</p> <ul style="list-style-type: none"><li>• <b>Same topic:</b> More than 2 times during a calendar year.</li><li>• <b>Same product:</b> More than 3 times during a calendar year.</li><li>• <b>Non-product programs:</b> May attend more than 3 non-product programs per year but no more than 2 non-product programs on the same topic.</li></ul>
Active Speaker Attending in Non-speaking Capacity	<p>An active speaker for Pfizer may not attend a speaker program in a non-speaking capacity if the speaker has received training on the topic that will be discussed.</p>



Limits on Speaker Utilization per calendar year	<ul style="list-style-type: none"><li>• <b>On TCL:</b> 3 programs for a speaker on your Territory Credit List ("TCL"), for all products on which they speak.</li><li>• <b>Within District:</b> 6 programs within a district in the aggregate for a speaker on the TCL of any member of that district.</li></ul> <p>Colleagues who do not have a TCL but still host speaker programs (e.g., Vaccines reps, Oncology KAMs) must not utilize a speaker called on by any member of their district more than 6 times in a calendar year in the aggregate. This applies regardless of product or topic but does not apply to link programs.</p>
Food and Beverage Limits	<p>Unless further restricted by state or other laws, food and beverages must be modest by local standards and:</p> <ul style="list-style-type: none"><li>• <b>Out-of-office:</b> must not exceed \$135 per attendee, including tax, tip, and delivery charges.</li><li>• <b>In-office:</b> must not exceed \$40 per attendee, including tax, tip, and delivery charges.</li></ul>
Determining Appropriateness of Attendees	<p>While Centris will assist in your determination of attendees' appropriateness, you must still make a good faith effort to ensure that all attendees:</p> <ul style="list-style-type: none"><li>• Practice in an appropriate specialty that is not excluded for the promoted product;</li><li>• Do not hold active licenses from states that impose restrictions on meals (if you plan to provide one at the program); and</li></ul> <p>Are appropriate based on Pfizer's attendee rules.</p>
Transparency & Disclosure	<p>The Sunshine Act requires Pfizer to report certain payments and other transfers of value to U.S.-licensed physician speakers and attendees (e.g., speaker fees, travel expenses, value of meals). Certain states and federal institutions have additional disclosure obligations, which are described further in Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions.</p>
Tracking Attendees	<p>All Attendees should be tracked, regardless of whether they have opted out of receiving meals or other disclosable value.</p>
Reporting Speaker Program Violations	<p>If a speaker commits a violation of Pfizer policy, you must correct the violation during the program, coach the speaker after the program, and report the violation in the Centris closeout process.</p>



## Your Role in Setting Up a Speaker Program

When you have an HCP speak on Pfizer's behalf, you are engaging in a promotional act. Speakers hired by Pfizer are considered to be speaking on behalf of Pfizer, and Pfizer is responsible for all content presented at the program. In addition, whenever an HCP is paid to speak for Pfizer, the engagement is subject to scrutiny under anti-kickback and other healthcare laws. Accordingly, you must have a legitimate business rationale that a planned speaker program will help address an unmet educational need among intended audience members.

### ***Speaker Nomination***

Speaker nominations must be based upon the speaker's expertise/experience with the product or disease state, credentials, ability to communicate effectively to the targeted audience, and any criteria set by the brand team. Please note that your brand or BU may have certain restrictions regarding who is permitted to submit nominations as well the number of speakers that may be nominated. Sales colleagues may not proactively attempt to gauge an HCP's interest in becoming a speaker or nominate a speaker in order to establish a relationship, gain or improve access to the speaker, reward past prescribing, or induce future prescribing. Speaker nominations are vetted regarding qualifications and tier status, internal and external exclusion lists, and license status.

### ***Timing***

All speaker programs **must** be submitted in Centris within the required minimum lead time. All live and webconference/teleconference sponsor programs must be entered into the Centris system at least fourteen (14) calendar days prior to the proposed program date. Centris will prevent the creation of any new live or webconference/teleconference sponsor program less than fourteen (14) calendar days prior to the scheduled date of the program.

All out-of-office webconference/teleconference *link* programs must be entered into the Centris system at least five (5) calendar days prior to the proposed program date. Centris will prevent the creation of any out-of-office webconference/teleconference link program less than five (5) calendar days prior to the scheduled date of the link program. All in-office webconference/teleconference *link* programs must be entered into the Centris at least three (3) calendar days prior to the proposed program date. Centris will prevent the creation of any in-office webconference/teleconference link programs less than three (3) calendar days prior to the scheduled date of the program.

It is highly recommended that colleagues enter programs into the system with additional lead time (i.e. 28 days prior to the program is the suggested lead time) in case logistical issues arise.

This is a critical requirement for ensuring compliance with policies governing interactions with speakers, including accurately determining when a speaker has reached their annual speaking fee cap.



### ***Choose the Relevant Topic and Select an Appropriate Speaker***




The topic of each speaker program must be RC-approved and included in Centris. After choosing a topic, select a speaker from Centris. Only speakers available in Centris may be utilized. Centris Speakers will appear “active” in Centris and available for selection only when they have completed the relevant brand's Core Product or Topic Training (as applicable) and Pfizer's compliance training and have signed a Pfizer Speaker Agreement. Speaker selection must be solely based on the speaker's expertise, credentials, and ability to communicate effectively to the targeted audience. You cannot engage a speaker in order to establish a relationship, gain or improve access to the speaker, reward past prescribing, or induce future prescribing.

A Sales colleague must not host more than three (3) programs in a calendar year utilizing a speaker on their Territory Credit List (TCL). Sales colleagues within a District must not host programs utilizing a speaker on the TCL of any member of their District more than six (6) times in a calendar year in the aggregate. For example, if a speaker is on a representative's TCL, that representative may host, at most, three (3) programs in a calendar year utilizing that speaker, and the other members of their District may only host an additional three (3) programs utilizing that speaker during the same calendar year for a total of six (6) programs. Colleagues who do not have a TCL but still host speaker programs (e.g., Vaccines territory managers, Oncology KAMs) must not host programs utilizing a speaker called on by any member of their District more than six (6) times in a calendar year in the aggregate. These rules apply regardless of product or topic, but do not apply to link programs.

Violations of these policies, including holding a program not entered in Centris without prior Legal approval or entering a fictitious program date in Centris, could subject you to disciplinary action.

For more information on how to activate a speaker in Centris, consult your manager, IQVIA, or the Meetings & Events (M&E) team.

#### **Speaker Selection**

	Can individuals other than physicians speak at promotional speaker programs?
	Yes. Any person with the requisite expertise and credentials may speak on Pfizer's behalf. It may be appropriate in some cases for nurses, pharmacists, patient ambassadors, or patient advocates to speak on certain topics or to targeted audiences.
	Can a physician who works at the VA be a speaker for Pfizer?



### Speaker Selection



Possibly, but you may not engage a speaker who works for the VA until you know and understand the special rules that apply to speakers who work for the VA. Please see Orange Guide Chapter 4: Federal Employee Interactions and Lobbying for information about these rules.

### Scheduling Issues



An out-of-town speaker has asked a colleague to schedule a speaker program to coincide with the speaker's personal travel schedule, so that Pfizer can reimburse his personal travel expenses. Is this permissible?



No. You cannot conduct a speaker program for the benefit of the speaker. Out-of-town speakers may only be used when there is a legitimate business reason to do so, and your scheduling decisions should only be motivated by the availability of the appropriate audience.

### Managing RSVPs

You are responsible for managing attendance of appropriate attendees, which includes collection and recording of RSVPs as well as processing and confirmation of RSVPs. You have direct oversight of RSVPs and, therefore, you are responsible for managing the headcount as well as ensuring the appropriateness of all attendees.

### Speaker Program Content

All slides presented by a speaker must be those in the RC-approved slide kit available to the speaker in Centris at <https://pfizerengagementportalhcp.force.com/connect>. The speaker is prohibited from creating or inserting their own slides (including introduction, speaker bio, case study, and disease state slides). Speaker slide decks are locked to prevent the addition of slides or changes to approved slides. Speakers must present all required slides in the RC-approved slide deck and must not add any non-RC approved slides or content.

In very limited circumstances, the Review Committee ("RC") may permit a speaker to present slides that are not contained in the approved speaker kit. Colleagues must submit the speaker's proposed slides sufficiently in advance for RC review approval **prior** to the speaker program (the "Exceptions Process"). Please contact the M&E team for details.

Remember, any information provided by a speaker must be:







- Accurate, truthful and not misleading;
- Consistent with product labeling (unless in response to an unsolicited question – see below);
- Supported by substantiated and scientifically-sound data; and
- Appropriately balanced with information on both benefits and risks.

Investigational or unapproved uses of Pfizer products may not be proactively discussed. Off-label information may be provided **only** in response to a specific unsolicited question from an attendee. Before briefly answering an attendee's question, the speaker must state that the information to be discussed is off-label and is based on the speaker's personal experience, knowledge, or opinion. The speaker may not use unapproved slides to support the answer and the response must be concise and narrowly tailored to the question asked. If the attendee asking the question requires additional information or the question cannot be adequately answered briefly, the speaker (or Pfizer colleague) must refer the attendee to the Medical Information department. Pfizer colleagues may not ask questions of the speaker during speaker programs, unless necessary to help ensure approved content is presented appropriately. Colleagues must ensure that any such question is not likely to lead to discussion of any unapproved content.

Speakers may not engage in a consultation during a speaker program and may not review charts or otherwise provide medical advice for individual patients.

#### Use of Pfizer Approved Speaker Slide Kits

	Is a speaker required to use all slides contained in a Pfizer approved slide kit?
	Speakers must present all required slides in the RC-approved slide deck. In particular, a speaker must appropriately emphasize all slides that relate to safety and risk (e.g., warnings, contraindications, adverse events) to ensure fair balance, even if they appear duplicative. If the presentations listed in Centris allow the speaker to select certain slides from the approved deck, he or she must be certain to include all slides identified as mandatory in the final deck and present them at the program. (Note that for speaker slide decks intended for use with consumers, all slides must be presented.)
	What if an attendee is not present for the entire program because he or she arrived late or has to leave the room during a portion of the program?
	You should set expectations with the attendees ahead of time to help ensure they are able to stay for the entire program duration. However, if an attendee does miss a portion of the program, you or the speaker must review any safety or risk slides that the attendees missed. This can be done by the speaker or the Pfizer colleague as soon as reasonably possible after the conclusion of the program.



## Review Policies with Speakers



Before the program, you are responsible for downloading a copy of the speaker's slides from Centris and for holding a discussion with the speaker to review Pfizer's promotional speaker policies and to ensure that he or she understands Pfizer's requirements for the presentation. You should reserve sufficient time when both parties are able to review the deck and applicable Pfizer policies including, but not limited to, your duty to make a corrective statement. A copy of Pfizer's promotional speaker policy is provided to all speakers as part of their contract. Your pre-program discussion with the speaker must include the items outlined in the Speaker Program Checklist located at the beginning of this Chapter, including the following reminders:

- The speaker is speaking on Pfizer's behalf and all proactive statements must be consistent with the label and approved slide deck;
- The speaker must present a current RC-approved slide deck, without any unapproved materials or modifications, and you will be prepared to project the slides from your Pfizer device with a projector (except at live roundtable/table top programs, where handouts may be used if the speaker is on-site);
- The appropriate duration of the program, inclusive of Q&A time is a minimum of 45 minutes for out-of-office programs, or a minimum of 30 minutes for programs with attendees in an in-office setting;
- For webconference/teleconference programs, the location of the sponsor program determines the minimum required length of the link program(s);
- The program must start with a review of the mandatory compliance slide(s), which includes statements that Pfizer is sponsoring the presentation and that the speaker is presenting on Pfizer's behalf;
- If an attendee asks the speaker a specific unsolicited off-label question, the speaker may answer briefly and limited to the specific question asked, after stating that the information to be discussed is unapproved and is based on the speaker's personal experience, knowledge, or opinion;
  - If the attendee asking the question requires additional information or the question cannot be adequately answered briefly, the speaker (or Pfizer colleague) must refer the attendee to the Pfizer Medical Information department; and
- You are obligated to make a clarifying or corrective statement if the speaker presents off-label or other unapproved information that was not in response to a specific unsolicited question.









#### Use of Unapproved On-Label Clinical Reprints

	Can a speaker present data from an unapproved clinical reprint that is substantiated, scientifically sound and seems to be on-label but is not RC-approved?
	No. All information presented proactively must be RC-approved.

#### Roundtables/Table tops and Use of Approved Materials

	When a speaker program involves a small group of attendees in a live “roundtable” format, does the speaker have to use Pfizer approved slides?
	Yes, a speaker must always use only RC-approved slides.
	Can attendees take a copy of the printed materials with them?
	Maybe. You should consult with the team attorney to determine whether there are any restrictions on providing copies of the printed deck or materials to attendees. Certain teams prohibit the distribution of printed copies of the speaker slide decks as handouts. In any case, the relevant product package insert must be made available to attendees at all speaker programs.

#### Arrange Meeting and Speaker Logistics with IQVIA

IQVIA will assist you in setting up programs that are effective and compliant by, among other things, booking and confirming speakers, coordinating speaker travel arrangements, securing a venue, and creating invitations. You can contact the appropriate marketing agency or IQVIA for assistance. Also, note that Field Commercial Colleagues should **not** expense any speaker program expenses using their corporate credit card for reimbursement. All such expenses should be processed through IQVIA.

#### Venue Requirements

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

- Is conducive to the exchange of scientific information. All programs must be held in a private room or in a semi-private room, taking into account the factors below. The purpose of the program is to convey information. The venue's environment should not detract from that purpose.





**Factors to consider:**

- **Noise Level:** Programs should be held in a venue that permits attendees to clearly hear the speaker's presentation without noise distractions.
- **Visibility:** Slides must be clearly visible to all attendees utilizing appropriate A/V equipment. It is generally not appropriate to use an iPhone, iPad, or laptop to present the slides without projecting the slides onto a larger display except at live roundtable/table top programs, where handouts may be used if the speaker is on-site (not remote). Colleagues should arrange to have the appropriate equipment needed brought on-site; you can bring your own, borrow from a colleague, or indicate your AV needs (e.g., screen, projector) during program setup in Centris.
- **Privacy:** The content of the presentation should not be visible to or be overheard by individuals who are not intended attendees of the speaker program.
- Is considered modest by local standards. For an out-of-office program, no more than \$135 per attendee may be spent on food, beverage, tax, tip, and delivery charges and no more than \$40 per attendee may be spent on food, beverage, tax, tip, and delivery charges for an in-office speaker program.
- DOES NOT involve recreation or any other entertainment component. The [PhRMA Code](#) expressly prohibits any kind of entertainment at industry-sponsored programs.



Speaker Program Venue Examples (Dos and Don'ts)	
Permitted	Prohibited
Private room at a restaurant (subject to price restrictions).	Private Box at a theatre performance or sporting event.
Semi-private room in the back of a restaurant separate from main dining room with 3 walls and a curtain for privacy.	Semi-private room with glass walls allowing other patrons to view projected slides and no sound barrier to protect from restaurant noise.
Conference room at a hotel or convention center.	Conference room at a museum or location of a celebrity event.
Program held at a moderately priced local restaurant.	Program held on a dinner boat cruise or a restaurant that offers or is associated with any form of entertainment.



### Speaker CVs

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

### Programs at Private Clubs

	May I hold a speaker program in a private room at a restaurant located within a country club or golf club?
	Generally, no. Holding a program at a country club or golf club, where recreation is often provided, may have the appearance of impropriety and is, therefore, discouraged. Programs should never involve any recreational activities and the cost of using any venue as well as payment for the meal must be billed directly to Pfizer.

### Preparing and Distributing Invitations

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

Only approved invitations available in Centris may be used. You may not alter the approved invitations in any way. Similarly, any communications accompanying the delivery of speaker program invitations should avoid making or implying inappropriate or incomplete promotional claims.

Invitations that have been approved for use should normally be distributed in person or by regular mail with no additional written statements beyond the content of the invitation itself. Colleagues may also deliver approved speaker program invitations via e-mail, but only if the e-mail accompanying the invitation contains the required language as included in the Pfizer Speaker Program Invitation Template.



***Pfizer Speaker Program Invitation Template***

Subject: "Pfizer Speaker Program Invitation – Event Date [XX/XX/XXXX]"

"Dear [insert name],

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

- Per Pfizer policy, this invitation is only intended for the healthcare professional addressed above and should not be forwarded to others.
- Please review important notifications provided at the bottom of the invitation.
- Please note that your institution/employer may have additional restrictions regarding your attendance and/or participation in programs/meals (if offered) and it is your responsibility to be aware of those restrictions.
- If you know of another healthcare professional who might also be interested in attending, please let me know.

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

Sincerely,

[Colleague name]

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

No other information may be included in the e-mail message – such as the name of any Pfizer products, indications, disease states, therapeutic areas or similar matters. Furthermore, the e-mail should not contain the colleague's e-mail signature block. Colleagues who e-mail an invitation also must refrain from changing any document file name, which should reflect only the meeting number. Under no circumstances should a file name include a product name or indication.

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

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





## Determine the Appropriate Audience

You, not the speaker, are responsible for selecting the audience for your speaker program. The audience must consist of attendees who have a legitimate interest in the subject matter and are appropriate in light of the attendees' role in and responsibility for patient care. Additionally, the invitees must not be chosen for the purpose of encouraging referrals for the speaker. It is impermissible for a speaker to promote their own practice in connection with a Pfizer speaker program. (Likewise, speakers may not distribute business cards for the purpose of promoting their practices during programs.)

You must make a good faith effort to ensure that all attendees: (1) practice in an appropriate specialty that is not excluded for the promoted product; (2) do not hold active licenses from states that impose restrictions on providing meals (if you plan to provide one at the program); and (3) are appropriate based on Pfizer's attendee rules. While Centris has controls to help ensure only appropriate attendees are invited to programs, you are ultimately responsible for ensuring that your attendees are appropriate.

### Appropriate Attendees

	Can anyone in the office attend because, arguably, they all have a role in "patient care"?
	No. You need to assess whether the program content is appropriate and, therefore, warrants their attendance, because of their role in and responsibility for patient care. If the program is heavily focused on the clinical data of the product, then you should ask yourself if that is something that the potential attendee needs to know for their job or would benefit their interactions with patients. If they assist patients with insurance reimbursement and that does not require an understanding of the clinical data, then they may not be an appropriate attendee.

Remember that some states may prohibit or limit providing food or beverages to HCPs licensed in those states, including during speaker programs (regardless of where the HCP practices or where the speaker program occurs). For example, HCPs who are currently licensed to practice in **Minnesota** or **Vermont**, as well as employees of Vermont HCPs, may not attend any speaker program (in-office or out-of-office) if food will be provided. If you are unable to determine in Centris whether an HCP is currently licensed in one of these states, consult Veeva CRM or the HCP License List on the [MyPfieldNet Compliance page](#). In addition, some state employees may be prohibited from accepting gifts (which often include meals) from pharmaceutical companies. For more information about state laws that limit the provision of gifts to HCPs, please see Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions.

The audience of a speaker program must include at least three (3) appropriate attendees – as defined below for in-office and out-of-office programs – who are not affiliated with the speaker (i.e., not part of the

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speaker's medical practice, practice group, or institution). If attendees receive compensation as employees from the same business entity-even if they work in different locations-they are considered members of the same practice or institution. The speaker does not count toward the three (3) attendee minimum.

All individuals who attend Pfizer speaker programs are prohibited from attending more than two (2) speaker programs per year on the same *topic* or three (3) speaker programs per year on the same *product*. For example, if an attendee has already attended two (2) programs on the same topic, he or she may only attend one additional program on that same product in a calendar year, and it must be on a different topic. An active speaker for Pfizer may not attend a speaker program in a non-speaking capacity if the speaker has received training on the topic that will be discussed. However, it may be appropriate for active speakers to attend speaker programs on other products or topics for which they have not received speaker training.

#### **Out-of-Office Speaker Programs**

For Pfizer-hosted out-of-office programs, both live and webconference/teleconference, you must have a legitimate expectation that at least three (3) individuals from the Approved Attendees List below who are not affiliated with the speaker will attend, unless an exception has been given by Legal or Compliance for a unique program type. It is your responsibility to determine that the individual has an Approved Attendee designation, utilizing the [HCP Look-Up Tool](#) or Centris functionality. Additionally, you must confirm that: (1) each Approved Attendee has a legitimate interest in the subject matter and is appropriate in light of the attendee's role in and responsibility for patient care; and (2) does not otherwise violate Pfizer's attendee rules.

Approved Attendees List	
Advanced Nurse	AN
Advanced Practice Registered Nurse	APRN
Certified Nurse Anesthetist	CNA
Clinical Nurse Specialist/Certified Nurse Specialist	CNS
Chiropractor	CRP
Doctor of Dental Surgery	DDS
Doctor of Osteopathy	DO
Doctor of Podiatric Medicine	DPM
Lab Director ( <b>Xalkori only</b> )	---
Licensed Practical Nurse	LPN
Medical Doctor	MD
Naturopathic Physician	ND



Approved Attendees List	
Nurse-Midwife	NM
Nurse Practitioner	NP
Doctor of Optometry	OD
Physician Assistant	PA
Pharmacist	PHARM
Doctor of Pharmacy	PHARMD
Pharmacy Intern/Pharmacist Intern	PHI
Pharmacist	PHR
Pharmacy Technician	PHT
Psychologist	PSY
Quality Director ( <b>Xalkori only</b> )	---
Registered Nurse	RN
Registered Pharmacist	RPH
Respiratory Therapist	RT
Social Worker/Master of Social Work	SW
Tobacco Treatment Specialist ( <b>Chantix only</b> )	TTS

Once you have a legitimate expectation that at least three (3) Approved Attendees who meet criteria (1) and (2) above will attend a program, and their RSVPs have been recorded in the system, you may permit attendance by additional attendees, including students studying for degrees on the Approved Attendees List, who have a legitimate interest in the subject matter and are appropriate in light of their role in and responsibility for patient care. Please manage your invitees and attendee rosters carefully to ensure your program is compliant.

The requirement to have three (3) individuals from the Approved Attendees List **does not** apply to programs listed in Centris as Non-Product Programs (e.g., Art of Active Listening, Evolution of Patient Navigation, Older Adult Sensitivity Training), which are typically above-brand, non-disease state programs. However, such out-of-office Non-Product Programs must have at least three (3) attendees who would be considered appropriate based on the following: (1) have a legitimate interest in the subject matter of the program; and (2) are not affiliated with the speaker's medical practice, practice group, or institution.



### ***In-Office Speaker Programs***

For in-office speaker programs, two (2) out of the required three (3) minimum attendees must be individuals who are included on the Approved Attendee List. Additional attendees must have a legitimate basis to attend. This means that such individuals may only be invited, and permitted to consume a meal provided for attendees, if the Pfizer colleague determines, on a case-by-case basis, that the program content is appropriate and relevant in light of each additional attendee's role in and responsibility for patient care.

### ***Webconference / Teleconference Speaker Programs***

Webconference and teleconference programs use technology that allows attendees to participate in speaker programs from remote locations ("link sites") when physical attendance at the speaker's location ("sponsor site") is not possible. For webconference or teleconference programs conducted in-office, individuals from the Approved Attendee List, other medical professionals, and other appropriate office staff attending the program from link sites (as well as any attending at the sponsor site) are counted toward the aggregate number of attendees required by Pfizer's minimum attendance policy. For in-office programs, this requires three (3) attendees, at least two (2) of which have credentials on the Approved Attendee List, and the program's minimum anticipated attendance must be met at least seven (7) calendar days prior to the program as discussed in more detail below. For an in-office webconference or teleconference program, you can have as few as a single attendee at an individual site as long as the minimum attendance requirements are met across all sites. However, for any sponsor or link program site located at an out-of-office venue (e.g., a restaurant), there must be a legitimate expectation that at least three (3) individuals from the Approved Attendees List will attend at that out-of-office site. Once you have a legitimate expectation that at least three (3) Approved Attendees will attend a webconference or teleconference program at an out-of-office venue, you may permit attendance at that site by additional attendees that have a legitimate interest in the subject matter and are appropriate in light of their role in and responsibility for patient care. This site attendance requirement applies to both sponsor and link out-of-office venues.



The Pfizer colleague must ensure that A/V will be appropriate for each webconference or teleconference program site and that the attendees can clearly hear the speaker's presentation and see the slides (e.g., it is generally not appropriate to use an iPhone, iPad, or laptop to present the slides or audio content without projecting the slides onto a larger display).

An appropriately trained colleague must monitor the webconference or teleconference program to ensure compliance with all of the policies set forth in this Chapter.









#### Providing In-Office Meals to Office Staff

	When conducting an in-office speaker program at a medical office, is it ok to provide a meal to office staff in addition to individuals on the Approved Attendees List and other appropriate attendees at the program?
	Yes, it is generally permissible to provide office staff with a meal so long as they are appropriate attendees for the speaker program, meaning they have a legitimate interest in the subject matter and are appropriate in light of their role in and responsibility for patient care. If they are not appropriate attendees for the speaker program or are unable to attend the program to receive the information presented, they should not consume the meal provided for speaker program attendees or be included in the attendee roster.

#### Specialty Exclusions



	May I invite HCPs to a speaker program if they belong to a specialty that is excluded for the product being discussed?
	No. If you are unsure whether a prospective attendee is subject to an applicable exclusion, consult the HCP profiles in Veeva CRM to verify their status before extending an invitation. Remember, if you cannot detail an HCP on a particular product, you are not permitted to invite the HCP to a speaker program on that product.

#### Speaker Suggesting or Inviting Attendees

	May a program speaker or invitee personally invite other prospective attendees? May a speaker suggest attendees?
	<p>A speaker or invitee may suggest other attendees to you in advance of the program, but it is your responsibility both to determine that each of the prospective attendees is appropriate and then to extend the official invitation. RSVPs for the program should not be collected by the speaker or other attendees.</p> <p>You cannot conduct a speaker program for the benefit of the speaker, and therefore, it would be improper to invite attendees at the request of a speaker without a justifiable business rationale for including them. Your sole purpose in holding the speaker program must be to educate attendees about Pfizer products (or other topics in an approved presentation). Therefore, it would be improper to invite attendees at the request of a speaker without an appropriate business rationale for including them.</p>



### Speakers to One Medical Office or Practice

	May a Pfizer colleague invite a speaker to speak in-office to attendees at a single medical office or practice?
	Yes, if overall at least three (3) appropriate attendees who are <b>not affiliated with the speaker</b> are expected to attend and two (2) out of those three (3) minimum attendees are individuals who are included on the Approved Attendee List set forth above. Please note that Pfizer cannot pay members of the same business organization to educate each other.



### Employee Led Speaker Programs

For Employee Led Speaker Programs, the speaker is a certified Pfizer colleague who is not paid an honorarium. As a result, different attendance rules apply. For both in-office and out-of-office Employee Led Speaker Programs, there must be a legitimate expectation that there will be at least three (3) attendees present who have a legitimate interest in the subject matter and are appropriate in light of their role in and responsibility for patient care. For more information regarding Employee Led Consumer Programs, see Chapter 16: Consumer and Employee Interactions.

### Spouses or Domestic Partners as Guests





Guests of attendees, including their spouses or domestic partners, are not permitted to attend Pfizer promotional speaker programs unless they independently qualify as appropriate attendees. For out-of-office programs, this means the spouse/domestic partner must either be on the Approved Attendees List, or once you have met the minimum requirement of three (3) attendees from the Approved Attendees List, the spouse/domestic partner may attend if they have a legitimate interest in the subject matter and are appropriate in light of their role in and responsibility for patient care. For in-office programs, there must also be a legitimate reason for a spouse/domestic partner to attend and the colleague must determine, on a case-by-case basis, that the spouse/domestic partner has a legitimate interest in the subject matter and is appropriate in light of the individual's role in and responsibility for patient care.

### How to Handle Uninvited Guests

	What should I do if someone who was not invited to the program shows up?
	Appropriate attendees may attend programs, even if they are not directly invited, if there is room for them at the program. However, you must determine whether the attendees are appropriate based on Pfizer's in-office and out-of-office attendee policies. You must also ensure that the attendees are not part of an excluded specialty or currently licensed in a restricted state. You must accurately record the attendees'



#### How to Handle Uninvited Guests

	details in Centris. If an attendee is deemed not to be appropriate, based on notifications in Centris or the attendee's responses to screening questions, you must respectfully ask him or her to leave the program.
	What should I do if a receptionist at an office I call on indicates that he or she will be attending a speaker program to which he or she was not invited?
	Because a receptionist's responsibilities are generally administrative, he or she would not be an appropriate attendee. It is your responsibility to inform him or her that he or she should not attend the program. You must ensure that all speaker program attendees are appropriate, given their role in and responsibilities for patient care and their legitimate interest in the program content.
	What should I do if an attendee brings a spouse/domestic partner who is not otherwise an appropriate attendee to a speaker program? Is it OK for the guest to stay if the attendee agrees to pay for their meal?
	No. You must remind the attendee that Pfizer guidelines and the PhRMA Code prohibit guests, spouses, or domestic partners from attending Pfizer speaker programs. This is clearly stated on the approved speaker program invitation. If the guest does not independently qualify as an appropriate attendee, you must respectfully ask that they leave the program.

#### RSVPs and Cancellation of Programs

For a live program to move forward, there must be sufficient RSVPs to meet the minimum attendance requirements entered into the system at least seven (7) calendar days prior to the program date. For example, if a colleague is holding an out-of-office program, there must be RSVPs from at least three (3) individuals from the Approved Attendee List seven (7) calendar days prior to the program for it to move forward. If there are insufficient RSVPs to meet the minimum attendance requirements seven (7) calendar days prior to a program, the responsible Pfizer colleague will be contacted by IQVIA to initiate a cancellation procedure. It will be that colleague's responsibility to notify the speaker as soon as practicable to avoid triggering an obligation to pay the speaker for the cancelled program.

For a webconference/teleconference link program held at an out-of-office venue, there must be RSVPs from at least three (3) individuals from the Approved Attendee list for the link location at least three (3) calendar days prior to the program for the program to move forward. If there are insufficient RSVPs three (3) calendar days prior to the program, IQVIA will contact the responsible colleague to initiate a cancellation procedure for that link program location.





In-person speaker programs with only one (1) attendee may not take place. Therefore, you must cancel programs in the below situations:

- You have sufficient RSVPs for your in-person speaker program but subsequently received unexpected cancellations within seven (7) days of the program and only one (1) appropriate attendee will be present for the program; or
- You arrive at the venue for your in-person speaker program and only one (1) appropriate attendee is present.

When a Pfizer colleague is entering RSVPs on behalf of any attendees, they should *only* enter such RSVPs when the HCP has clearly indicated their intention to attend the program. In other words, colleagues **should not** enter RSVPs when it is unclear whether an HCP will attend, when the HCP has only expressed interest but not confirmed attendance, or when the colleague only believes that the HCP *might* attend.

#### Attendee Cancellations

	For an upcoming out-of-office program, I have three (3) RSVPs from appropriate Approved Attendees (and have a legitimate expectation that they will all attend). Two (2) other appropriate attendees have also RSVP'd that they will attend. On the day of the program, one of the individuals who is an Approved Attendee informs me that she will be unable to make it. Do I have to cancel the program? If I don't cancel, are the other appropriate attendees still permitted to attend although I don't have three (3) attendees with Approved Attendee designations?
	You are not required to cancel the program. If you have three (3) RSVPs from appropriate Approved Attendees recorded in the system, and you had a legitimate expectation that you would have three (3) such individuals attend but had a cancellation close to the program date (for out-of-office, within seven (7) calendar days), you may hold the speaker program. In addition, the other appropriate attendees may attend even though you may only have two (2) Approved Attendees in attendance. However, if there are no appropriate attendees, a speaker program must be cancelled.

As a general matter, you should manage your invitations to ensure that, even with potential cancellations, you will have at least three (3) appropriate Approved Attendees at your speaker program. Speaker programs are monitored for compliance with Pfizer policies. Non-compliance with this policy or any other Pfizer policy may result in discipline. You should explain the circumstances around a potential policy deviation when you close out the program in Centris.



## U.S. HCP Payment Disclosure Policy

Pfizer must comply with the reporting and disclosure requirements of the Sunshine Act and other requirements, including the laws of certain states. Included in scope for reporting are any payments or transfers of value that are made directly or indirectly to a covered recipient including U.S. physicians, certain other HCPs, and teaching hospitals.

If an HCP does not want to have items reported, he or she must not accept or receive meals, speaker fees, or other value from Pfizer. Pfizer maintains a record of HCPs who have “opted out” of receiving disclosable items from Pfizer, which you can view on the [MyPfieldNet Compliance page](#) or [Global Policy Xchange on GCO On Demand \(OpSource\)](#). Colleagues should review the list prior to choosing a speaker, inviting attendees, and conducting a speaker program. If an attendee has opted out, but nevertheless consumes a meal, the value of the meal will be reported. Attendees may not pay for their own meals.

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

## Your Role During a Speaker Program

### ***Electronic Sign-Ins at Speaker Programs***

Centris will allow Pfizer sales colleagues who are added to a program in Centris as hosts or collaborators to capture attendee sign-ins on their tablet devices. The use of electronic sign-ins is required, barring a technical issue. If you are unable to utilize the electronic sign-in feature, you are required to maintain a written sign-in sheet and to upload that sign-in sheet into Centris at closeout per your training.

### ***Screening Walk-In Attendees***

Appropriate attendees may attend programs, even if they are not directly invited, if there is room for them at the program. Colleagues are expected to attempt to match all walk-in attendees to existing customer profiles in Centris in order to ascertain whether each is an appropriate attendee based on Pfizer’s in-office and out-of-office attendee policies, including brand-specific specialty exclusions, state license restrictions, etc. If there is no match, colleagues must ask appropriate screening questions to help verify that the attendee is not an excluded specialty or licensed in a state with restrictions.

If a walk-in is an inappropriate attendee, you must respectfully ask him or her to leave. Please be courteous and explain the reason that they cannot attend the program. For example, if an HCP brings their spouse, you can explain that the PhRMA code does not allow spouses to attend programs unless they independently qualify as an appropriate attendee.



If you permit an inappropriate attendee to attend the program, the individual's attendance must still be documented in Centris.

### ***Monitor for Consistency with Labeling***

The information presented during a speaker program must be consistent with the FDA-approved labeling for Pfizer's products and present a fair balance of the benefits and risks( i.e., it should not be inconsistent with the approved presentation deck).



**During the program, you must be prepared to project the RC-approved slide deck from your Pfizer device on a projector, and you must monitor the presentation to ensure that the speaker's discussion is consistent with the slides and the product's labeling.** For all webconference or teleconference speaker programs, a Pfizer colleague not the speaker-must control the webconference and teleconference, including the flow of the slides, to ensure that the speaker appropriately covers all slides, and to ensure that they have the ability to make corrective statements, if necessary. Monitoring the content of the program is the primary responsibility of Pfizer colleagues in attendance at speaker programs. Monitoring content takes precedence over other activities, such as dealing with food service issues.

You must ensure that the speaker presents the safety information in the presentation, consistent with product labeling and including any warnings, contraindications, adverse events, and other safety information in order to provide a fair and balanced presentation. Further, if any attendee arrives after this information has been presented or leaves prior to it being presented, the speaker or Pfizer colleague should make every effort to review that content with such attendee as soon as reasonably possible after the conclusion of the program.

Pfizer colleagues may not ask questions of the speaker during speaker programs, unless necessary to help ensure approved content is presented appropriately. Colleagues must ensure that any such question is not likely to lead to discussion of any unapproved content.

Different rules may apply to speaker programs with consumer audiences. For more information regarding presentations to consumers, see Chapter 16: Consumer, Patient, and Employee Interactions.

### **Off-Label Information**

	What should I do if a speaker presents off-label information during their presentation that was not in response to a specific unsolicited question?
	<p>You must:</p> <ul style="list-style-type: none"><li>• Promptly and courteously clarify to the audience that the off-label information provided is not within product labeling and is not a part of the approved Pfizer presentation. This should be done as soon as possible after the speaker has</li></ul>



#### Off-Label Information

presented the off-label information, even if the speaker proactively informs the audience that the information is off-label.

- Remind the speaker after the presentation that Pfizer's guidelines require that off-label information be provided only in response to a specific, unsolicited question.
- When you close out the program in Centris, indicate, as prompted in the system, that a violation was committed by the speaker. Once submitted, you will be contacted for additional information. Speakers who proactively speak off-label may be subject to further action, up to and including deactivation.
- Keep in mind that the mandatory compliance slide(s) at the beginning of each speaker program notifies attendees that a Pfizer colleague must make a corrective statement if the speaker presents information that is inconsistent with an FDA-approved label or Pfizer policy.

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

#### Handouts and Giveaways

Copies of the approved package insert for each Pfizer product being discussed must be made available at each presentation. Only RC-approved educational materials that are approved for such distribution may be provided to attendees. If permitted by the RC, you may disseminate paper copies of Centris presentation slides at a program. Colleagues should consult with their brand teams to determine whether they are permitted to provide copies of the printed deck or materials to attendees. You may not distribute electronic copies of Centris presentation slides without first consulting your team attorney. You, not the speaker, are responsible for copying and disseminating any approved materials to attendees. Copies of slides created by the speaker cannot be handed out (even if they have been RC-approved through the Speaker Slide Exceptions Process).

#### Gifts to Attendees of Speaker Programs



Can I purchase token gifts for attendees at my speaker program? Can I purchase a token thank you gift to give to the speaker?



No. Attendees may only be given RC-approved educational promotional items that have been approved for distribution, comply with Pfizer guidelines and the PhRMA Code, and are permissible under state law. Further, you are not permitted to provide speakers with any additional items of value for speaking on Pfizer's behalf.





## Payment and Reimbursement

### Speaker Fees

You are not responsible for negotiating the amount of a speaker's speaking fee. Fees are determined based on pre-set criteria.

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



#### Speaker Fees

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

### Closeouts

After a program, Pfizer colleagues must enter program information in Centris to close out the program, including flagging any policy violations that may have occurred. If there is not an appropriate check box for a violation, please select "Other Reportable Incident" and you will be contacted for further details.


#### Cancellation and Payment Issues

	What should I do if I hold a program with fewer than three (3) attendees due to last minute cancellations, but the unexpected no-shows cause me to spend more than the applicable meal cap on the meal (including food, beverage, tax, tip, and any delivery charges)?
	You must always accurately record expenditures on meals, even if they exceed the applicable meal cap. You will be asked to document the circumstances around the potential policy deviation after you close out the program in Centris. You can reduce your risk of violating this important policy by selecting inexpensive menu items and for out-of-office programs, or by selecting venues that do not require large minimum guarantees.







### Cancellation and Payment Issues

	In the event that Pfizer has to cancel a speaker program, does Pfizer still pay the speaker?
	If Pfizer cancels a speaker program within five (5) business days of the scheduled engagement, and the speaker requests payment, Pfizer is contractually obligated to pay the speaker their speaking fee, with very limited exceptions. However, you must attempt to reschedule a cancelled program within 90 days of such cancellation and the speaker will be obligated to conduct the program for no additional speaking fee. Please note that the program may occur more than 90 days after the date of cancellation as long as the program is <b>rescheduled</b> on the same topic within 90 days. You must make every reasonable effort to reschedule the cancelled speaker program within this timeframe. If a program is cancelled more than five (5) business days in advance or if the speaker requests the cancellation, Pfizer is not required to pay the speaker's fee.

### Attending the Speaker Program

	Do I have to be present during a speaker program that I host?
	You always must be present with the speaker during the entire speaker program to ensure that Pfizer guidelines are followed throughout, as this is the host's most important role at a speaker program. You must also monitor any program conducted remotely by webconference or teleconference. If you cannot attend, you may ask your manager or other appropriately trained colleague to attend on your behalf. However, you must notify IQVIA and receive approval if there is a change in the program host listed in Centris. If no appropriate colleagues are available to attend, the program must be cancelled.

### Speaker Training

Speaker training is an essential activity because the FDA holds companies accountable for the presentations of their speakers. Speaker training sessions should be held in venues and locations (typically limited to the speaker's country of practice unless there are security or logistical concerns) that are appropriate and conducive to informational communication and training about medical information. Specifically, resorts are not appropriate venues.



## Speaker Programs at Third Party Meetings

Third party meetings held by groups such as local medical associations, residents at institutions, or local disease advocacy organizations may provide you with an opportunity to promote Pfizer products to individuals who are gathering together for another purpose. Holding a promotional program in this circumstance must be based on a legitimate business purpose to present information about Pfizer products and cannot be based on a desire to support or otherwise fund an independent meeting.

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

- You must submit programs in Centris prior to the program date with the minimum required lead time described above, as with other speaker programs.
- You must have a legitimate promotional speaker program in connection with the meeting.
- **All** Pfizer policies and processes regarding speaker programs must be adhered to; for example, programs at third party meetings must meet the duration and content requirements of other speaker programs. Further, if the customer permits spouses or guests to attend its meeting or there will be excluded specialties in attendance, holding a Pfizer speaker program in connection with the meeting would not be appropriate.
- You must make it clear to the customer or organization that Pfizer is not a “sponsor” of its business meeting. Explain that Pfizer is engaging in a separate promotional activity with attendees of the meeting. Identify to the audience a clear start and end to the Pfizer promotional program to avoid the misperception that Pfizer is supporting any part of the meeting itself.
- If you provide a meal, it must be offered only as part of the Pfizer program, and must be incidental to and not otherwise the focus of the program. It would not be permissible to provide the meal more than 30 minutes in advance of the Pfizer program, nor after the program is completed.
- Pfizer cannot split the cost of a meal with the host of a third party meeting. However, you may conduct a Pfizer speaker program during a meal that is provided and paid for entirely by a third party, as long as you make clear that Pfizer is not responsible for providing the meal. Meals provided by third parties will not be reported as part of Pfizer’s payment disclosure policy.
- Before or after the Pfizer program, you should avoid being present during any discussion of a Pfizer product that you anticipate will be inconsistent with that product’s labeling.
- As with other speaker programs, you must capture all attendee information in Centris. Before confirming the program, you should coordinate with the third party to ensure that you will receive all necessary information about the attendees.



If a colleague were to participate in any way in the content of the non-Pfizer meeting, the entire meeting might be considered a promotional event and could then be governed by the same promotional rules that apply to all Pfizer speaker programs and other promotional activities. For information on detailing at third-party meetings, see Orange Guide Ch. 2: Interactions with HCPs.

If an Account Manager intends to host a speaker program at a third party meeting and the topic of the program does not address products or disease states, the Account Manager may work with the host of the third party meeting to publicize the program. Specifically, the Account Manager may ask the host to include the Pfizer program on the agenda for the third party meeting. The Account Manager also may provide the host with an approved invitation for the third party to distribute to attendees.

**In all instances, it must be clear that Pfizer is not the “sponsor” of the third party meeting and that Pfizer is engaging in a separate promotional activity with attendees of the meeting. Also, as noted above, all Pfizer policies and processes regarding speaker programs must otherwise be adhered to, and the Account manager must capture all appropriate attendee information in Centris.**

### Speaker Programs at Third-Party Continuing Education Events

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

- The Pfizer program must be conducted in a room physically separated from the space where Continuing Education (CE) activity is conducted.
- At the start of the program, you must clearly communicate to attendees that it is a separate Pfizer promotional presentation not accredited for Continuing Medical Education (CME) credit.
- Pfizer cannot provide meals or beverages in connection with the Pfizer program. Any meals provided by a CME provider must be made available to all CE event attendees, including those not attending the Pfizer presentation. This policy applies to all programs at CE events, including programs hosted by Account Managers with topics that do not address products or disease states.
- No advice or input may be provided regarding the content of the medical education activity.
- No financial or other support, including payment for event expenses or meals, assistance with setting up logistics, or handling non-Pfizer speaker arrangements, may be provided in connection with the Pfizer program (subject to very narrow exception for logistical expenses discussed below). Financial support for a CE event may only be funded by an independent medical education grant requested



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through Pfizer's Independent Grants for Learning & Change website. For more information, see Orange Guide Chapter 3: Support of External Organizations.





#### Third-Party Meeting Venues

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

#### Meals Provided by Medical Education Organizers During a Pfizer Speaker Program

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

#### Physical Separation of Speaker Programs at Medical Education Events

	The organizers of a medical education event require that Pfizer pay a fee to cover expenses that are directly associated with a promotional speaker program, such as the cost to rent a separate presentation room. Must this fee be paid through a medical education grant from the office of Independent Grants for Learning & Change?
	No. Standard fees required to cover the fair market value of logistical expenses associated only with the Pfizer speaker program may be paid by the appropriate Pfizer Colleagues.
	I've been offered an opportunity to provide a promotional speaker program during a medical education event, but the organizers have told me that no separate room will be available. Can I still hold the program?
	Generally, no. However, if it is possible to physically separate your presentation space within the event room, you may consult with your team attorney or BU compliance about an exception to determine if and how the program may be conducted appropriately under the circumstances.



### For More Information

- For more information about Pfizer's policies and procedures for conducting speaker programs, please refer to Centris or the "Speaker Programs" tab on [Global Policy Xchange on GCO On Demand](#).
- For more information about retaining HCPs for activities other than speaker programs, including preceptorships and colleague training, refer to the "HCP Engagements" tab on [Global Policy Xchange on GCO On Demand](#).
- For more information about Pfizer's policies for conducting compliant speaker programs for consumers, see Orange Guide Chapter 16: Consumer, Patient, and Employee Interactions.
- To determine whether an HCP is licensed in Minnesota or Vermont, consult Veeva CRM or the HCP License List on the [MyPfieldNet Compliance page](#).
- For more information about state laws that limit the provision of gifts (including meals) to HCPs, see Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions.
- For more information about the HCP payment disclosure policy, see Orange Guide Chapter 18: Meals, Educational Items, Greenstone Giveaways, and HCP Payment Disclosure.
- Refer any additional questions to the M&E team, your manager, or your team attorney.



## CHAPTER # 10 STARTERS



Chapter

#10

STARTERS

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## Chapter #10 Starters

### Introduction

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

#### ***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 HCPs eligible to receive starters and only if they are expected to distribute them for free, on-label use by their patients.
- 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 quantities or dosages based on off-label use is not permitted.





### **Key Points to Ensure Compliance**

- Starters may be packaged separately or in kits that may include PhRMA Code compliant educational items. All patient and provider materials packaged with starters must be reviewed and approved by the applicable Review Committee (RC) prior to distribution. Individual starter units cannot be altered in any way either before or after they are delivered to an HCP.
- Only licensed HCPs authorized by their states' laws to receive and prescribe medications may sign a request for starters. Pfizer policy requires Sales Colleagues to witness the signature personally on every starter request.
- Sales Colleagues using Veeva are required to use the electronic Starter Activity Form (eSAF) within Veeva for starter transactions - a paper Starter Activity Form (SAF) may only be used 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 use paper SAFs must be entered into Veeva as soon as possible after the call is made.) - Except for shipment acknowledgements which are handled in STORK.
- 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 RxPathways. 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.

### **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 provided 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 Colleagues 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 states or implies that he or she is using a Pfizer product for an off-label use, providing starters to that HCP for such off-label use may be considered off-label promotion and could 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 minimum amount necessary.

#### On-Label Use Starter Allocation and Distribution

	I am on a product team reviewing starter allocations for a product that HCPs 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 Colleagues will not detail these uses. Is this permissible?
	No. Off-label uses should not be considered when determining starter allocations. When Pfizer distributes starters, it is engaging in product promotion. Providing starters to HCPs in quantities or at dosages that might be deemed to support off-label uses could be considered off-label promotion. Off-label use can also be implied if Pfizer provides starters to a specialist who does not treat the condition for which the product is indicated (e.g., Eliquis to Oncology Specialist, Xtandi to OBGYN Specialists).

#### Starter Packaging



Separate starter packaging, including the sample identification on the label (i.e., "Sample – Not for Sale"), is required by the 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 intentionally or inadvertently sell samples).

Starter "packaging" includes all product containers (e.g., blister cards and bottles), individual unit boxes (e.g., the box containing a single sample bottle) and starter packs. Starter packages must remain intact and, as the labeling on starters is FDA-approved, Pfizer Sales Colleagues may not alter starter labeling or packaging. Applying stickers or writing on starter packaging is not permitted. 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 or on the colleague's own initiative, 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 behind.



### Stickers

	Can a Sales Colleague place Pfizer Review Committee-approved (i.e., RC- approved) product stickers on starters?
	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 could “misbrand” the package, rendering it 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, Sales Colleagues may follow the instructions found in the <a href="#">Starter Operations Compliance</a> Manual and use the accompanying template to create them. Please note, however, that while these adhesive tracking labels can be left with the starters they are not, under any circumstances, to be affixed to the starters by a Pfizer colleague.

### Appropriate Use of Formulary Stickers

	Can a Sales Colleague put “Now on Formulary” or other approved stickers in the sample closet?
	Yes. With the approval of the HCP’s office staff, a Sales Colleague 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 may be done with respect to a particular product’s starter packaging, he or she should consult his or her manager, NA GCO NA HCP/Patient Sample Operations, or the relevant 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 unit boxes in which they were provided (if applicable); and
- DO NOT apply stickers or labels to any starter packaging, including the individual unit boxes, product containers, sample packs, and outer display packaging.



## Inclusion of Materials with Starters

Provided that starter product packaging remains intact, starters may be offered in kits that include PhRMA Code compliant educational items, such as patient journals or other disease state educational booklets. Starter kits may also include co-pay coupons, co-pay cards, savings cards, and other similar offerings to consumers for the specific starter product.

Before such materials may be distributed in a starter kit, they must be reviewed and approved for such use by the applicable brand 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. These additional materials must be submitted to the FDA at the time of first use. As with any promotional materials, Sales Colleagues may not alter these additional materials in any way or add their own promotional materials to them.

### Adding Materials to Starter Packages



Can a Sales Colleague insert RC-approved promotional items such as a packet of co-pay cards or vouchers into a starter package for the relevant product?



No. Promotional materials must be specifically approved by RC for distribution as part of a starter package. If a Sales Colleague independently adds materials to a starter package – even if those materials are themselves RC-approved – it could constitute an impermissible alteration of the starter packaging.

## Distribution of Starters to Approved Recipients

Detailed procedures for starter accountability and compliance are set forth in the [U.S. Starter Compliance Manual](#). Sales Colleagues 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 (e.g., NPs and PAs) and their ability to prescribe and/or receive starters within their state.

In addition, some states have particular limitations on distributing starters for controlled substances like Lyrica. Sales Colleagues should check with their manager, GCO NA HCP/Patient Sample Operations, or their team attorney if they have questions about who can receive particular Pfizer starters in their 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 provide the starters for an off-label use; or
- If the prescriber's license number has not been verified in Veeva.

In the past, other pharmaceutical companies and individuals have been charged under the Federal False Claims Act and the Anti-Kickback Statute 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 Colleagues must personally witness the signature on all starter requests.

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, GCO NA HCP/Patient Sample Operations, or relevant team attorney.



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

Pfizer GCO NA HCP/Patient Sample Operations handles all PDMA-mandated FDA reporting, as well as compliance with the reporting requirements set forth in Section 6004 of the federal Affordable Care Act (with support from the Pfizer Transparency Team). It is critical that Sales Colleagues adhere to all policies, procedures, recordkeeping, and system requirements pertaining to starter distribution to ensure compliance with all applicable tracking and reporting laws.





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

#### On-label Use of Starter

	If a starter package containing a particular dosage of a product is not used on-label by a particular specialty because that specialty would never see the appropriate type of patient, but there is another starter dosage that would typically be used on-label by the same specialty, is there any limitation on what Sales Colleagues can distribute to that specialty?
	Yes. Sales Colleagues may only distribute starter packages which are consistent with the on-label use of the product for each particular specialty. Thus, if a Pfizer product has different approved dosages for individual indications, Sales Colleagues may only distribute those starter dosages that are indicated for the treatment of conditions that the prescribers they call on are likely to see among their patient population.

#### Distribution of Starters to Physicians for Personal Use

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

#### Hospitals, VA, and DoD Institutions

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

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 paper dual-signature **"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 GCO NA HCP/Patient Sample Operations by logging on to [PROMOSprime](#) and choosing that item under the order category



"Starter Ops Forms." As further described in this Chapter, for Sales Colleagues using Veeva, 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, 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 Federal Employee Interactions and Lobbying Chapter in this Guide.

**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, Sales Colleagues should contact GCO NA HCP/Patient Sample Operations or their team 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-Sponsored Research (ISR)** grant. (For more information on scientific research, see the Pfizer-Sponsored and Non-Sponsored Clinical Research Including Investigator-Sponsored Research Studies (ISRs) Chapter in this Guide.) HCPs seeking to assist their patients in mitigating their medication costs should be referred to Pfizer RxPathways. (For more information, see the Patient Assistance Programs Chapter in this Guide.)

Requests for medication from charities or from healthcare providers for charitable missions should be directed to the Global Health & Patient Access team.

## 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.



### ***Starter Storage Requirements***

Starters must be stored securely and under thermostatically-maintained, temperature-controlled conditions in accordance with the product's labeling to maintain the starters' integrity, stability, and efficacy. Starters must be stored away from hazardous materials and any other substances that could cause contamination or otherwise degrade them.

Starters may be transported in an automobile trunk during the business day but should never be left there overnight. For this reason, only the number of starters that are expected to be distributed on a particular day should be carried in a Sales Colleague's trunk, with any remaining quantities removed and returned to storage at the end of the day.

If starters are stored in a commercial warehouse unit, the lease contract for that space should contain language confirming that it is artificially temperature-controlled and be in Pfizer's name with access made available to both the Sales Colleague and his/her manager during normal hours of operation. Starters should be stored off the floor on shelves or pallets. In addition, Sales Colleagues should confirm that the facilities in which they lease space either use an onsite generator to maintain their unit's ambient temperature in the event of a power outage or will call them if such an outage lasts 24 hours or longer. Sales Colleagues whose storage facilities sustain an unmitigated power outage lasting more than 24 hours should suspend sampling and contact Starter Compliance via e-mail ([StarterCompliance@pfizer.com](mailto:StarterCompliance@pfizer.com)) for further instructions.

### ***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 Compliance Manual](#), including:

- Guidelines for acknowledging the receipt of starter shipments immediately upon acceptance;
- Documentation of the starters delivered to licensed HCPs;
- Procedures for transferring starters between Sales Colleagues; and
- Entry of starter transactions into Veeva at the time of their occurrence.

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





### **Completion of eSAFs and SAFs**

Sales Colleagues using Veeva must use their approved device (i.e., tablet or iPad) 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 Colleague is delivering starters at an institution that requires starters to be left with its pharmacy and not with the individual HCPs 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 GCO NA HCP/Patient Sample Operations in very limited circumstances while the Veeva system is inoperable due to significant hardware or software malfunctions for an extended period of time, until such time as the malfunction is resolved. (Sales Colleagues should ensure that their approved devices (i.e., tablets or iPads) are charged; drained batteries do not qualify as a device malfunction.) Written requests may only be submitted by Sales Colleagues by e-mailing a description of the issue, including information provided as part of the CSC Help Center assigned ticket, to [StarterCompliance@pfizer.com](mailto:StarterCompliance@pfizer.com).

If a paper SAF is used as permitted above, Sales Colleagues must enter the relevant information into Veeva as soon as possible after completing the paper SAF transaction.





The Veeva and paper SAF starter call records are designed to document requests for starters and confirm receipt of provided starters. The Veeva (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 Veeva 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 Sales Colleague's approved device (i.e., tablet or iPad) 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.)

In the limited instances described in the Starter Compliance Manual, paper SAFs may be used to document your starter transactions subject to the same requirements for documenting starter transactions electronically (e.g., Sales Colleague must witness signature of HCP), with the exception of the preceding rule concerning the capture of recipients' signatures electronically using Veeva.



### Witnessing Signatures for Starters

	When a Sales Colleague delivers starters to a HCP's office, can the receptionist take the approved device (i.e., tablet or iPad) to the HCP for signature?
	No. The Sales Colleague's device should never be given to anyone to take away and should always remain in the Sales Colleague's immediate proximity. Pfizer policy requires that the Sales Colleague always personally witness the HCP signing the starter request. (In the limited circumstances where a paper SAF is permitted, a receptionist may take the SAF to the HCP for signature as long as the Sales Colleague can clearly see the HCP signing the form.)
	Is it permissible to accept a request for starters from an HCP at a location other than the one to which the starters will be sent?
	No. Sales Colleagues are required to confirm that the locations to which starters are shipped are medical offices where patients are treated, and it is Pfizer's policy that this verification be performed in person. When accepting requests for starters for controlled substances, such as Lyrica, it is essential that Sales Colleagues also confirm that the HCP is registered with the DEA at the office where he/she is called on and to which those items will be

### 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 Veeva, timely call reporting, routine synchronization with the Veeva server, and the correction of any errors or discrepancies found in the course of recording starter information.

Sales Colleagues should regularly review their weekly **Veeva 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 GCO NA HCP/Patient Sample Operations for further guidance.

In addition, all **starter losses and thefts** should be reported to GCO NA HCP/Patient Sample 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 returned promptly to Pfizer's authorized destruction facility. Sales Colleagues should rotate their starters upon





receiving each delivery, placing those closest to their date of expiration in front to ensure that they distribute them first.

You can still deliver "soon-to-expire" starters to an HCP, but once actually expired, they must be returned to Pfizer's authorized destruction facility.

HCPs seeking to return expired or damaged starters should be directed to call Pfizer's Starter Customer Service Team (1-800-533-4535) to schedule an appointment for the pickup of those items.

#### Paying for Bins in Starter Closets

	Can a Sales Colleague pay for bins or space in starter closets in HCPs' offices?
	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 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. Vouchers, like Starters, are intended to allow appropriate patients to utilize a product for a limited time for the purpose of allowing the prescribing HCP to evaluate efficacy and safety.

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.

Brand teams may offer both Starters and vouchers. Sales representatives may distribute both starters and vouchers to the same HCP office in accordance with the above principles. Prior to distributing the resources to a given HCP, however, sales representatives should carefully consider the needs of a particular HCP or office. For example, it may be appropriate to leave vouchers at a health system with restrictions on drug sampling. It may also be appropriate to leave starters with an HCP who desires to start treatment immediately without waiting for the patient to redeem a voucher. Sales representatives should clearly indicate the appropriate use of these resources to HCPs, including that: (1) vouchers are not intended to address financial hardship and insurance delays; and (2) an individual patient should receive either a voucher or starter, but not both. The intent is to prevent a patient from receiving both Starters and vouchers



to extend beyond a reasonable trial period (i.e. stacking) and for HCPs to direct patients to the appropriate resources to address financial hardship and insurance delays.

Additional requirements for Pfizer teams implementing voucher programs may be found in Chapter 19 of the White Guide.

Improper use of vouchers can implicate the state and federal false claims acts and anti-kickback laws and 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 are intended to allow appropriate patients to utilize a product for a limited time for the purpose of allowing the prescribing HCP to evaluate efficacy and safety. Do not position vouchers to HCPs for the purpose of addressing long term issues such as patient access or financial need.
- Voucher disbursements must be recorded completely and accurately in Veeva to ensure compliance with all applicable federal and state reporting requirements;
- 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 GCO NA HCP/Patient Sample Operations, the relevant Sales Manager, or team attorney.
- For Pfizer's policies for complying with the PDMA, see the [Starter Compliance Manual](#).



## Orange Guide - Chapter 10: Starters

- Sales Colleagues who need to order "In House Pharmacy" Starter Activity Forms can obtain them by calling Standard Register at 1-800-313-8263.
- For more information on the use of product in scientific investigations, see the Pfizer- Sponsored and Non-Sponsored Clinical Research Including Investigator-Sponsored Research Studies (ISRs) Chapter.
- For more information on distributing starters in government institutions, see Orange Guide: Chapter 4 - Federal Employee Interactions and Lobbying.



**CHAPTER #11 – THE PFIZER  
PATIENT ASSISTANCE PROGRAM,  
INSTITUTIONAL PATIENT  
ASSISTANCE PROGRAM,  
DONATIONS TO ICPAPS, AND  
PATIENT SUPPORT PROGRAMS**



**Chapter**

**#11**

**THE PFIZER PATIENT ASSISTANCE  
PROGRAM, INSTITUTIONAL PATIENT  
ASSISTANCE PROGRAM, DONATIONS TO  
ICPAPS, AND PATIENT SUPPORT  
PROGRAMS**

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## Chapter #11 The Pfizer Patient Assistance Program, Institutional Patient Assistance Program, Donations To ICPAPS, and Patient Support Programs

### Introduction

Pfizer believes that all patients should have access to the medicines prescribed by their Healthcare Providers ("HCPs"). For decades, Pfizer has partnered with HCPs, community health centers, free clinics, and pharmacies to help patients access the medicines they need through a number of programs for eligible patients.

This Chapter describes key Pfizer policies regarding Pfizer's charitable activities to support patients' access to their prescribed medications, including Pfizer's internal free drug Patient Assistance Program ("PAP"), its Institutional Patient Assistance Program ("IPAP"), and Pfizer's donations to Independent Charity Patient Assistance Programs ("ICPAPs"). This Chapter also briefly describes the activities of Pfizer's Patient Support Programs, specifically, Pfizer's product-Specific or therapeutic-area specific Patient Support Hubs ("Hubs"), which provide patients with a single point of access to obtain limited and tailored assistance in conjunction with a Pfizer therapy prescribed by the patient's HCP (including access and reimbursement support for a prescribed Pfizer Product), and Pfizer RxPathways, through which patients may access the Pfizer PAP, which provides free Pfizer Products to eligible patients who have been prescribed such Products. Pfizer also offers certain Savings and Free Trial Programs (e.g., co-pay cards, discount cash pay cards, vouchers, free trial programs). See White Guide Chapter 19 for information regarding these programs.

#### ***Pfizer Patient Assistance Program and Institutional Patient Assistance Program***

As part of its commitment to improving patient access to medicines, Pfizer established a charitable internal free drug program that provides commercially-available Pfizer drug products ("Products") free of charge to financially-eligible uninsured and underinsured patients. This program is referred to as the Pfizer PAP. Pfizer operates both the PAP and IPAP on behalf of the Pfizer Patient Assistance Foundation ("PPAF"), a non-profit 501(c)(3) private operating foundation. Pfizer also operates the IPAP, through which Pfizer provides select Products to financially-eligible, uninsured patients through over 300 federally-qualified community health centers, disproportionate share hospitals, free clinics, and state pharmacy programs.<sup>1</sup> Through this initiative, Pfizer donates applicable Products to participating institutions that in turn provide the medicines for free to eligible patients treated at the facilities, based on eligibility requirements determined by Pfizer. Information regarding Pfizer's policies related to the PAP and IPAP is provided in

<sup>1</sup> Product availability varies by institution.



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this Chapter. Information regarding the PAP and IPAP processes and procedures is available in the Pfizer Patient Assistance Program & Institutional Patient Assistance Program Standard Operating Procedure (“PAP/IPAP SOP”).

### ***Donations to Independent Charity Patient Assistance Programs***

Pfizer also may make charitable donations to ICPAPs, which are independent, U.S. 501(c)(3) non-profit organizations that operate patient assistance programs to help financially needy patients, including federal healthcare beneficiaries (e.g., Medicare patients), access their medicines by assisting such patients with their out-of-pocket copay obligations. ICPAPs may establish funds that provide financial assistance with copay obligations associated with treatment for specific disease states, which may include copay obligations for branded and generic drugs or other treatments associated with the disease state. ICPAPs operate independently from Pfizer and award assistance to patients based on their independently-developed eligibility criteria. Information regarding Pfizer's policies related to donations to, and interactions with, ICPAPs as it relates to Pfizer Colleagues is described in this Chapter and in more detail in [Corporate Policy and Procedure #803: Contributions to Independent Charity Patient Assistance](#).

### ***Patient Support Hubs and Pfizer RxPathways***

Patients may access the Pfizer PAP, information regarding other financial assistance options (including ICPAPs), and a variety of patient support programs by contacting either Pfizer RxPathways or a Hub. Information regarding Pfizer's policies related to Hubs and Pfizer RxPathways is described in this Chapter. Additional information regarding Hub processes and procedures is available in the Pfizer Standard Operating Procedure For Patient And Reimbursement Support Hubs (“Hubs SOP”).

## **Core Compliance Principles**

The Pfizer PAP, IPAP, donations to ICPAPs, and other patient support programs<sup>2</sup> play an important role in assisting patients with accessing medically necessary products that are prescribed by their HCPs. However, several federal and state laws and other regulatory guidance are implicated in connection with the operation of these programs, including, for example, federal and state anti-kickback statutes, the federal Beneficiary Inducement Statute, the federal False Claims Act, government price reporting obligations, federal and state privacy laws, and U.S. Department of Health and Human Services' Office of Inspector General (“OIG”) guidance. It is Pfizer's policy to establish and implement these programs and activities consistent with all applicable laws, regulations, and guidance issued by the OIG.

These programs and activities are intended to support appropriate patient access to independently-prescribed Pfizer medicines (or to other prescribed medicines in the case of ICPAP donations) and are not

<sup>2</sup> These programs include co-pay cards, discount cash pay cards, vouchers, free trial programs, and the Pfizer Savings Program.



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intended to: (i) induce a patient to select a Product; (ii) induce an HCP to prescribe, or reward an HCP for prescribing, Products; or (iii) reduce economic or administrative burdens for an HCP (or related practice or office staff). Pfizer Colleagues are not permitted to promote Pfizer's patient support programs as a reason to prescribe a Product.

Pfizer offers its programs in a non-discriminatory fashion to all eligible patients who are prescribed an applicable Pfizer medicine and the availability of these offerings is unrelated to the volume or value of business generated by any HCP or healthcare facility. To ensure that Pfizer meets these obligations, the Pfizer Commercial Solutions Platform ("CSP") Legal Team reviews and provides guidance regarding the programs and activities covered in this Chapter, including PAP, IPAP, donations to ICPAPs, and RxPathways/Hub activities in the United States, Puerto Rico and the U.S. Virgin Islands. In addition, [CSP Legal](#) must review and approve the inclusion and deletion of Products to the Pfizer PAP and IPAP. The ICPAP Review Committee must approve all donations to ICPAPs.

Consult [CSP Legal](#) for additional information on Pfizer's PAP, IPAP, interactions with ICPAPs, and CSP Legal on the design and implementation of other patient support programs.

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

***Key Points to Ensure Compliance***

Pfizer Colleagues must follow the requirements described in this Chapter when:

- (i) engaging in activities related to the Pfizer PAP or IPAP;
  - (ii) interacting with ICPAPs, to the extent appropriate; or
  - (iii) Engaging in patient support programs, as well as when discussing these programs and resources with HCP customers.
- Pfizer PAP/IPAP:
    - On behalf of PPAF, Global Health & Patient Access and other authorized Pfizer Colleagues operate the Pfizer PAP and IPAP consistent with their charitable purpose.

Free Product is provided without the intent to induce, reward, or influence a patient's use of a Product; to induce, reward, or influence an HCP's prescribing decisions; and/or to endorse or recommend the purchase of a Product.



### **Key Points to Ensure Compliance**

- Free Product is provided only after prescribers have made an independent clinical decision that the Product is medically appropriate for the individual patient.
- Free Product is awarded based on reasonable, uniform, and consistent measures of financial need and without regard to the HCPs or suppliers used by the patient or the insurance plan (if any) in which the patient is enrolled.
- Free Product is provided outside of any insurance benefit.
- [ICPAPs \(See also Corporate Policy and Procedure #803\):](#)
  - Global Health & Patient Access (with ICPAP Review Committee oversight) is solely responsible for ICPAP copay donations and related activities and, with limited exceptions, Global Health & Patient Access must not share information related to ICPAP donations with other Pfizer Colleagues.
  - Colleagues outside of Global Health & Patient Access must not:
    - Discuss business interests or funding decisions related to donations to ICPAPs for co-pay assistance with Global Health & Patient Access for the purpose of influencing donations; or
    - Seek to influence, or be involved in, any communications between Global Health & Patient Access and the ICPAPs related to donations for co-pay assistance.
  - Except for certain Colleagues engaged in reimbursement support and with Legal approval, Pfizer Colleagues must **not** discuss with HCPs or patients:
    - Specific ICPAPs;
    - The availability of funding in relevant disease states; or
    - That ICPAPs can "overcome co-pay barriers."
- Patient Support Programs Offered through Hubs/Pfizer Rx Pathways:
  - Pfizer's patient support programs are intended to support patient access to independently-prescribed Products.
  - Pfizer Colleagues are not permitted to promote Pfizer's patient support programs as a reason to use or prescribe a Pfizer medicine.



#### **Key Points to Ensure Compliance**

- Because Pfizer's patient support programs are operated to assist patients with accessing prescribed Products, Pfizer Colleagues must not state or suggest that these programs provide substantial independent value to any HCP or reduce or eliminate economic or administrative burdens for an HCP (or related practice or office staff). These programs can only provide limited support to HCPs.
- Patients and HCPs may visit the Pfizer RxPathways website (PfizerRxPathways.com) and/or the relevant Hub websites to learn more about patient assistance and patient support programs offered by Pfizer.
- If you have questions about any of the guidance provided in this chapter, please contact a [CSP Legal attorney](#).

#### **Pfizer Patient Assistance Program and Institutional Patient Assistance Program**

The Pfizer PAP and IPAP are operated by the Pfizer Patient Assistance Foundation ("PPAF"), which is a non-profit 501(c)(3) private operating foundation. PPAF is funded through cash and in-kind (i.e., Product) donations from Pfizer. Pfizer also donates services, facilities, equipment, supplies, and Colleagues' time to the extent necessary for PPAF to conduct its charitable activities related to the Pfizer PAP and IPAP. PPAF operates consistent with its certificate of incorporation and bylaws. Pfizer Colleagues elected to PPAF's Board of Directors and Pfizer's Global Health & Patient Access team, some of whom serve as officers of PPAF, have primary responsibility for managing the Pfizer PAP and IPAP operations on behalf PPAF, with support from certain other functions (e.g., Legal, Compliance, Global Procurement, Finance, Pfizer Global Supply).

Pfizer's Global Health & Patient Access team, on behalf of PPAF, is responsible for the day-to-day operations of the Pfizer PAP and IPAP, including establishing patient and institution eligibility criteria and determining Product inclusion and exclusion criteria.

All Pfizer Colleagues that conduct business related to the Pfizer PAP and IPAP work on behalf of PPAF. As such, they must fulfill the independent charitable objectives of PPAF.



### ***The Pfizer Patient Assistance Program (i.e., Free Drug Program)***

**Overview:** The Pfizer PAP provides eligible uninsured and underinsured patients who meet program-specific financial need criteria and other eligibility requirements with Products prescribed by their HCPs for free. Eligible uninsured patients are enrolled in the program for 12 months. Eligible underinsured patients, who include both commercially and government insured patients, are enrolled through the end of the calendar year. Patients can re-apply as often as needed once their enrollment period expires. The free Product is delivered to enrolled patients via doctors' offices, home delivery, or retail pharmacies – depending on the Product.

To learn more about the Pfizer PAP and whether they may be eligible for free Product, patients or their advocates may contact Pfizer RxPathways or a Hub, if a Hub is available for the Product prescribed.

**Medicines Covered:** At present, over 60 Pfizer Products are available for free through the Pfizer PAP. A full list of Products available through the Pfizer PAP is available on the [PfizerRxPathways.com](https://PfizerRxPathways.com) website.

In general, the majority of Pfizer medicines are available through the Pfizer PAP, EXCEPT the following:

- Medicines that are typically administered in the hospital inpatient setting only (the Pfizer PAP is for outpatients only);
- Medicines that are classified as opioids; and
- Medicines that have lost their patent exclusivity and have affordable multi-sourced generics available (with affordable defined as \$30 or less for a 30-day supply).

**Eligibility Requirements:** In order to qualify for free Product from the Pfizer PAP, patients and their HCPs must meet the following eligibility requirements:



- Patients must have a valid prescription for the Product for which they are seeking assistance.
- Patients must have no prescription coverage (uninsured) or not enough coverage (underinsured) to pay for the Product.
- Patients must complete an application form that asks for basic patient information (e.g., name, address, phone number, e-mail address, annual gross household income, household size, and insurance status (e.g., uninsured, commercial insurance, government insurance)). The patient's HCP also must complete a section of the PAP application form that asks for basic information about the HCP, including name, address, and DEA number. *Note: The information requested in the PAP application form may include Personal Information or Sensitive Personal Information and must not be used or disclosed unless certain conditions are met.* For more information on Personal Information and Pfizer's policies for protecting patient privacy, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.



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- Patients must demonstrate financial need by meeting specific household income requirements, which vary by Product, but start at 400% of the Federal Poverty Level, adjusted for family size. Patients must provide proof of income, such as a W2 form, a paystub, or prior year's tax return with their PAP application form.
- Patients must live in the United States, U.S. Virgin Islands, or Puerto Rico.
- Patients must be treated by a healthcare provider licensed in the United States, U.S. Virgin Islands, or Puerto Rico.
- Patients prescribed certain Products may be required to seek alternate forms of coverage or financial assistance, such as Pfizer co-pay cards (for commercially insured patients only), Medicaid, Medicare Part D Low Income Subsidies, or ICPAP support, before they can be enrolled in the Pfizer PAP.

### Referring Patients to the Pfizer PAP

	You are a Sales representative and an HCP tells you that he has Product X patients who are uninsured. He asks you whether Pfizer can provide these patients with free product. Product X is included in the Pfizer PAP. Should you refer him to the Pfizer RxPathways website and tell him to have his patients apply to the Pfizer PAP?
	Yes, you may inform the HCP that he can refer patients to the Pfizer <a href="#">RxPathways website</a> or its toll-free number (1-844-989-PATH) for information about the Pfizer PAP and other available assistance programs. You may also inform the HCP that he can refer the patient to a Hub, if available for the Product. Field sales representatives must not imply or guarantee that Pfizer will provide any specific assistance to patients. Field sales colleagues also must not answer patient-specific questions regarding the Pfizer PAP and should direct HCPs with such questions to the applicable PAP vendor or other resource (e.g., applicable Pfizer website) for additional information.

### Medicare Part D Patients and the Pfizer Patient Assistance Program

As described above, patients with prescription drug coverage through commercial plans or government healthcare programs, like Medicare Part D, can apply to receive Products for free through the Pfizer PAP if such patients are having difficulty paying for their medicines. The Pfizer PAP provides free drug to eligible patients enrolled in government healthcare programs, including Medicare Part D, as described below.

According to guidance issued by the OIG, manufacturers may not subsidize the co-pay or other out-of-pocket expenses of Medicare Part D beneficiaries. Such subsidies, according to OIG, are likely to implicate the federal anti-kickback statute. This is why Pfizer often prohibits federal health care program beneficiaries from using copay coupons/cards and Pfizer copay card/coupon rules always prohibit their use for any products reimbursed by federal healthcare programs (See White Guide Chapter 19, Savings and Free Trial Programs, for more information about copay cards and other Pfizer savings programs). In contrast, OIG





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has stated that manufacturers may provide free medications to Medicare Part D beneficiaries so long as manufacturers provide such free medications entirely outside the patients' Part D benefits. This means that the Part D beneficiary may receive free medicine through a PAP and will not file any claim for payment with the Part D plan associated with such medicine. The free drug provided to such patients also must not count toward the beneficiary's true out-of-pocket costs ("TrOOP") or overall Part D spending.

In order to help ensure compliance with all applicable legal requirements, the Pfizer PAP must meet the requirements listed under the Compliance Core Principles – Pfizer PAP and IPAP on page 5 of this chapter.

### Pfizer Patient Assistance Program and Medicare Part D

	A patient with Medicare Part D prescription coverage is having difficulty paying for her Pfizer primary care medicine. Can she apply for assistance through the Pfizer PAP?
	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 to receive free drug from the Pfizer PAP. Patients should call Pfizer RxPathways or the relevant Hub to learn more. If eligible, a patient will receive her Product for free through the end of the calendar year. Pfizer's PAP vendor will instruct the patient that she must not file any claims for payment with her Part D plan or count the free Product that she receives from the PAP towards her TrOOP or overall Part D spending. In addition, Pfizer's PAP vendor will instruct the patient that she must provide notification to her Part D plan that the Product is being provided outside of her benefit.

### Institutional Patient Assistance Program

**Overview of Program:** The IPAP provides select Products to eligible, financially needy, uninsured patients through over 300 federally-qualified community health centers, disproportionate share hospitals, free clinics, and state pharmacy programs.<sup>3</sup> Through this initiative, Pfizer donates the participating Products to participating institutions that in turn provide the Products for free to eligible patients treated at the facilities, based on eligibility requirements determined by Pfizer.

#### Medicines Covered:

At present, many Pfizer medicines are available for free through the IPAP. For a complete list of Products available, visit [PfizerRxPathways.com](https://PfizerRxPathways.com).

<sup>3</sup> Product availability varies by institution and eligibility.

<sup>v</sup> Terms and Conditions apply.





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### ***Eligibility Requirements***

To qualify to receive Product for free through the IPAP, patients must:

- Receive their care at an institution that participates in the program;
- Have no prescription coverage (unlike the Pfizer PAP, which helps both uninsured and underinsured, the IPAP is for uninsured patients only); and
- Have a household income of at or below 400% of the Federal Poverty Level, adjusted for family size.

The institutions that participate in the IPAP are responsible for ensuring that patients meet the program eligibility guidelines. Pfizer audits participating institutions on a regular basis to ensure compliance with program rules.

### ***Compliance Core Principles – Pfizer PAP and IPAP***

In order to help ensure compliance with all applicable legal requirements, all Pfizer Colleagues must adhere to the following core principles:

- Free Product will be awarded based on reasonable, uniform, and consistent measures of financial need and without regard to the providers, practitioners, or suppliers used by the patient or the insurance plan (if any) in which the patient is enrolled.
- Free Product will be provided outside of any insurance benefit.
- Free Product will be provided only after prescribers have made an independent clinical decision that the Product is medically appropriate for the individual patient.
- Free Product must be provided without the intent to induce, reward, or influence a patient's use of any Product, to induce, reward, or influence an HCP's prescribing decisions, and/or to endorse or recommend the purchase of a Product.
- Pfizer will operate the Pfizer PAP and IPAP consistent with their charitable purposes and without undue influence from Pfizer Commercial Colleagues.

### ***PAP/IPAP Guidance for Pfizer Field Commercial Colleagues***

The Global Health & Patient Access team is responsible for administering the Pfizer PAP and IPAP on behalf of PPAF. Pfizer Field Commercial Colleagues must not be involved in the development, operation or management of the Pfizer PAP and IPAP.



### ***Interactions and Communications with Pfizer PAP/IPAP Vendors***

Other than Pfizer Colleagues authorized to act on behalf or in service of PPAF, and Field Reimbursement Managers (“FRMs”) in limited circumstances, Pfizer Field Commercial Colleagues must not communicate with the vendors that administer the Pfizer PAP and IPAP for any PAP-related reason.

- This prohibition does not prevent Field Commercial Colleagues from communicating with Hub vendors who also administer the Pfizer PAP regarding other patient support programs or activities, as appropriate.
- FRMs may contact a PAP vendor to inquire about the status of a PAP application or PAP Product order, and act as a liaison between an HCP and a PAP vendor regarding PAP application questions. However, FRMs must not fill out or submit PAP applications.
- Pfizer Field Commercial Colleagues shall refer all questions or concerns regarding vendors’ operation of the Pfizer PAP and IPAP to Global Health & Patient Access.

### ***External Communications Regarding Pfizer Foundation PAP/IPAP***

Communications by Pfizer Colleagues, contractors, or third-party vendors with patients and/or HCPs regarding the Pfizer PAP and IPAP must be factual and non-promotional. All communications must be truthful, non-misleading, and consistent with Pfizer policies and procedures and applicable laws and regulations. For information on the approval process for PAP/IPAP marketing materials see White Guide Chapter 4, Marketing Programs.

Pfizer Field Commercial Colleagues must follow the guidance summarized below when engaging HCPs in proactive or reactive discussions regarding the Pfizer PAP and IPAP:

- The Pfizer PAP and IPAP must not be used as a tool to promote Products, to differentiate Products from competitor products, or to influence HCP prescribing habits.
- Although the Pfizer PAP and IPAP are available to all eligible patients irrespective of their diagnosis, Field Commercial Colleagues must not promote the availability of the Pfizer PAP and IPAP for any off-label Product uses.
- Field Commercial Colleagues must not describe the Pfizer PAP and IPAP as a way to fill gaps in Product coverage (e.g., Medicare Part D donut hole).
- Field Commercial Colleagues must not make any statements about the potential outcome of an application or guarantee enrollment in, or provision of free Product through, the Pfizer PAP or IPAP.
- Field Commercial Colleagues must not fill out or submit PAP applications on behalf of patients or HCPs.



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- All marketing materials that reference the Pfizer PAP or IPAP must be approved through all applicable Pfizer materials review processes.

### **Additional Guidance on PAP Data**

- All PAP data reports must be requested from GHPA, i.e. colleagues outside of GHPA may not request data directly from the vendors. GHPA must consult with [CSP Legal](#) prior to distributing any new report type/data to anyone not working on behalf of PPAF.
- Pfizer Colleagues may use these reports for operational purposes only, including but not limited to, financial forecasting and budgeting, evaluating current and projected Product utilization, and compliance monitoring and program auditing. Pfizer Colleagues must not use Pfizer PAP/IPAP data and reports to drive commercial objectives (e.g., to increase product utilization and any related strategy).

For more details see the Pfizer Patient Assistance Programs and Institutional Patient Assistance Program Standard Operating Procedure.

### **Role-Specific Guidance**

In addition to the general guidelines described above, the following guidelines apply to specific Pfizer teams.

#### **Pfizer Field Sales Colleagues**

Field Sales Colleagues may provide limited, factual, high-level information regarding the Pfizer PAP or IPAP to HCPs when describing all applicable Pfizer patient support offerings. Such communications must be consistent with Pfizer-approved materials. Field sales colleagues must not answer patient-specific questions regarding the Pfizer PAP or IPAP and should direct HCPs with such questions to the applicable PAP vendor or other resource (e.g., [Pfizerxpathways.com](https://pfizerxpathways.com)) for additional information. These colleagues must not fill out or submit applications on behalf of patients or contact a PAP vendor for any reason.

#### **Field Reimbursement Managers (FRMs)**

FRMs may discuss the Pfizer PAP or IPAP with HCPs when describing all applicable Pfizer patient support offerings. Such communications must be consistent with Pfizer-approved materials. These discussions must be limited to a factual, non-promotional description of the Pfizer PAP or IPAP, including applicable eligibility criteria and terms and conditions. In addition, FRMs may answer patient-specific questions about the Pfizer PAP or IPAP, direct HCPs to the applicable PAP/IPAP vendor, provide HCPs with copies of a PAP application and/or explain the application, contact a PAP vendor to inquire about the status of a PAP application or PAP Product order, and act as a liaison between the HCP and the PAP vendor regarding

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PAP application questions. However, FRMs must not fill out or submit PAP applications. All communications must be transparent regarding program eligibility criteria, and other key terms and conditions.

**Patient Affairs Liaisons (PALs)**

PALs may discuss the Pfizer PAP or IPAP with patients post-prescribing decision as part of discussions regarding all applicable Pfizer patient support offerings. Such communications must be consistent with Pfizer-approved materials. These discussions must be limited to a factual, non-promotional description of the Pfizer PAP, including applicable eligibility criteria and terms and conditions. PALs also may answer general questions about the Pfizer PAP or IPAP, direct patients to the applicable PAP vendor, and provide patients interested in enrolling with copies of a PAP application and/or explain the application. However, PALs must not fill out or submit applications on behalf of patients or contact a PAP vendor for any reason. All communications must be transparent regarding program eligibility criteria, and other key terms and conditions.

**Field Clinical Educators**

Field Clinical Educations must not discuss the Pfizer PAP or IPAPs with patients or HCPs and should refer all HCP and patient questions regarding the Pfizer PAP or IPAP to the PAP vendor or other applicable resources (e.g., website) for information.

For question, or role-specific PAP/IPAP guidance regarding other Pfizer teams or roles not mentioned in this Chapter, contact your team attorney.

The chart below contains additional tips on what Pfizer Field Commercial Colleagues should and should not say regarding the Pfizer PAP and IPAP:

DO	DON'T
Inform HCPs that Pfizer RxPathways and/or relevant Hubs can connect patients to the many forms of financial assistance that Pfizer offers to eligible patients, including the Pfizer PAP.	Do not promote the Pfizer PAP or IPAP as a tool to influence prescribing habits.
Remind HCPs that Pfizer offers free drug for a large number (over 60) of Products.	Do not guarantee assistance or support under the Pfizer PAP or IPAP.
Explain that the Pfizer PAP may help eligible patients receive their Product for free.	Do not interfere with an HCP's treatment decisions for a patient.
	Do not refer to the Pfizer PAP as a patient discounting program.



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DO	DON'T
Remind HCPs that patients with insurance (such as Medicaid, Medicare Part D, or private/commercial insurance) may qualify to receive free Product if they meet the Pfizer PAP eligibility criteria and comply with program requirements.	Do not describe free drug provided through the Pfizer PAP or IPAP as a way to fill gaps in coverage (e.g., Medicare Part D donut hole).

### Independent Charity Patient Assistance Programs

Pfizer also may make monetary charitable contributions to ICPAPs through its Global Health & Patient Access group. Pfizer believes all individuals deserve access to quality healthcare and all medicines prescribed by their physicians. Charitable contributions to ICPAPs can provide a means to help patients access their medicines by providing significant financial assistance to patients for co-pay, deductible, and/or premium obligations for prescriptions (collectively, “co-pay assistance”). ICPAPs may focus financial assistance on costs associated with treatment for specific disease states, and generally have disease-state funds that provide co-pay assistance for all branded and generic drugs or other treatments associated with the disease state. ICPAPs must operate entirely independently from Pfizer and award patient assistance based on their independently-developed eligibility criteria. Patients who apply for free product through the Pfizer PAP may be required to seek alternate forms of coverage or financial assistance, such as Pfizer co-pay cards (for commercially insured patients only), Medicaid, Medicare Part D Low Income Subsidies, or ICPAP support, before they can be enrolled in the Pfizer PAP.

While federal healthcare program beneficiaries can obtain co-pay assistance through independent, third-party ICPAPs, Pfizer may not directly subsidize the co-pay or other out-of-pocket expenses of Medicare Part D beneficiaries or other federal healthcare program patients. Given this restriction on Pfizer directly subsidizing the out-of-pocket expenses of federal healthcare program beneficiaries, donations to ICPAPs may implicate the federal anti-kickback statute. The OIG, however, has issued guidance permitting ICPAPs to provide co-pay assistance to federal healthcare program beneficiaries using donations from manufacturers if sufficient safeguards exist. It is Pfizer's policy to comply with government guidance and laws in making contributions to ICPAPs to ensure those safeguards are met.

*For additional guidance on interactions with ICPAPs, please see [Corporate Policy and Procedure #803 Contributions to Independent Charity Patient Assistance Programs](#).*



### ***ICPAP Guidance for Pfizer Field Commercial Colleagues***

Pfizer Field Commercial Colleagues must not be involved in any activities related to donations to ICPAPs and must not communicate with Global Health & Patient Access about ICPAPs or funding decisions for the purpose of influencing donations to ICPAPs. Field Commercial Colleagues also must not have any communications with ICPAPs on the topic of copay donations.

[Corporate Policy and Procedure #803](#) places strict limitations on the receipt and sharing of data received from third parties related to ICPAP donations. For example, Field Commercial Colleagues must not obtain ICPAP-related data from any source that is disaggregated or patient-specific, shows how many Pfizer patients are helped by a particular ICPAP or disease state fund, or shows how many patients returned to Pfizer to apply for PAP assistance after applying for ICPAP assistance. Colleagues must never attempt to correlate or calculate the amount or frequency of ICPAP donations with the ICPAP's support of *patients prescribed Pfizer Products*.

Pfizer Field Commercial Colleagues must not discuss with HCPs or patients:

- Specific ICPAPs;
- The availability of funding in relevant disease states from ICPAPs; or
- That ICPAPs can overcome co-pay barriers.

Certain Colleagues engaged in reimbursement support and approved in advance by Legal may provide to HCPs materials approved by the relevant Product Review Committee that discuss generally the range of patient support programs and resources to which Pfizer RxPathways (or the relevant Hub) connects patients (including information about ICPAPs).

***Pfizer policy places strict limitations on Pfizer Field Commercial Colleagues and other Commercial Colleagues' ability to discuss ICPAP donations or the availability of ICPAP assistance with HCPs or patients:***

- **Do not** assist HCPs, customers, or patients in communicating with, or applying to, ICPAPs.
- **Do not** direct HCPs, customers, or patients to particular ICPAPs.
- **Do not** inform HCPs, customers, or patients to which ICPAPs Pfizer donated, to which disease state fund(s), or amount of donations.
- **Do not** try to obtain information from any source regarding whether a patient has successfully obtained assistance from an ICPAP.
- **Do not** communicate with any ICPAP about copay donations. If you receive funding requests or other communications from an ICPAP, refer the requestor to [PfizerICPAPRequest@pfizer.com](mailto:PfizerICPAPRequest@pfizer.com).



If you have any questions regarding any of this guidance, please contact your team attorney or [CSP Legal](#).

### ***ICPAP Guidance for Field Reimbursement Support Colleagues (e.g., FRMs)***

Vendors may provide certain patient-specific or disaggregated information to Pfizer Colleagues engaged in reimbursement support (e.g., Field Reimbursement Managers) in the event such information is critical to the Colleagues' job responsibilities with respect to assisting patients' access to their prescribed Products.

***Other Pfizer Colleagues must not seek to obtain or be provided with such information.***

In addition, there are specific guidelines in relation to ICPAPs that FRMs must follow when carrying out their job responsibilities:

- FRMs are permitted to visit the websites of ICPAPs to determine whether they are funded and open for patients but **must not** communicate with ICPAPs for any copay assistance reason, including to follow-up on any patient's application for support from the ICPAP.
- FRMs may provide an HCP or office with the names, phone numbers, or website information for the **full list of relevant** Independent Charity PAPs that are **open** for patients.
  - FRMs may then follow-up with the HCP's office to inquire about the status of a patient's application to an Independent Charity PAP.
  - FRMs should **not** contact any ICPAP directly to follow-up. FRMs are permitted to visit websites of ICPAPs to determine whether they are funded and open for patients and can share that information with other FRMs.
    - Searches should include all ICPAPs with funds for the relevant disease state at issue.
  - When proactively sharing the full list of relevant ICPAPs that are open for patients, you must also mention the availability of other avenues of assistance, including Pfizer's free drug PAP.
- If an FRM receives an inquiry from an HCP or office regarding Pfizer's support of ICPAPs, the FRM should refer the HCP or office to the Global Health & Patient Access team.
- FRMs may track in the Field Reimbursement SharePoint site whether a co-pay concern has been resolved but **must not** indicate that the concern was resolved because the patient received assistance from an ICPAP or track the name of any specific ICPAP.
- FRMs **must not** share information about whether any specific ICPAP has or has not provided co-pay assistance with other Pfizer Colleagues or with HCPs or offices.

For more details on the guidelines applicable to Oncology FRMs, see Pfizer Oncology Field Reimbursement Manager (FRM) Guidance or contact your team attorney.



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If you are a Reimbursement Support Colleague and have questions regarding your role in connection with ICPAPs or have not yet received the applicable ICPAP training, please consult your manager, the Chief Compliance Counsel for your business, or [CSP Legal](#).

### Pfizer RxPathways® and Patient Support Hubs

Pfizer has established Pfizer RxPathways and Hubs to connect eligible patients to, and in the case of Hubs to provide patients with, a range of resources such as benefits investigation and verification, limited prior authorizations and appeals assistance, drug delivery and administration support, co-pay support, financial assistance, and patient education.

- **Pfizer RxPathways®** is not brand-specific and serves as a single point of access that connects patients, regardless of their insurance status, to available financial assistance and other patient support programs, such as the Pfizer PAP, IPAP, Hubs, co-pay and savings offers, free trial programs, and other resources. Pfizer RxPathways is run by the Pfizer Global Health & Patient Access team.
- **Hubs** provide Product-specific or disease-state specific patient support and offer eligible patients a single point of access for a range of financial assistance and other patient support programs. Hubs are jointly managed by the SAS COE and Global Health & Patient Access teams. The offerings that the Hub provides, or to which the Hub connects patients, are overseen by different teams depending on the offering (e.g., Global Health & Patient Access is responsible for Reimbursement Support and the Pfizer Patient Assistance Program services, while the SAS COE is responsible for the development, review, and implementation of Hub-related fee-for-service arrangements (outside of Reimbursement Support and PAP) that meet the legitimate business needs of Pfizer and the patients who have been prescribed Pfizer medicines).

It is Pfizer's policy to establish and implement Pfizer RxPathways and the Hubs consistent with all applicable laws and regulations. To that end, Pfizer RxPathways and the Hubs provide no more than limited reimbursement support to patients who are prescribed a Pfizer medicine. RxPathways and the Hubs are intended to support patient access to independently-prescribed Pfizer medicines and are not intended to reward or induce an HCP for past, present or future prescribing of Products or to reduce economic or administrative burdens for an HCP (or related practice or office staff).

Pfizer offers its RxPathways and Hub activities in a non-discriminatory fashion to all eligible patients after they are prescribed an applicable Pfizer Product by their HCP. The availability of RxPathways and Hub support is unrelated to the volume or value of business generated by any HCP or healthcare facility. To ensure that Pfizer meets these obligations, the Pfizer CSP Legal Team must review and provide guidance for RxPathways and each Hub operating in the United States. Additionally, Pfizer annually re-evaluates the need for specific Hub activities on a Product-by-Product basis to substantiate the need for their continued offering.





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Pfizer Colleagues must not promote Pfizer's Hub activities as a reason to prescribe a Pfizer medicine. In addition, because the Hubs are operated to assist patients with accessing prescribed medicines and offer no substantial or independent value from the Product, Pfizer Hub programs are not a means to reduce economic or administrative burdens for an HCP and her staff. Pfizer Colleagues should not suggest otherwise.

Pfizer Colleagues must follow the guidance summarized below when engaging their HCP customers in discussions regarding RxPathways or the Hubs:

- Pfizer Colleagues must limit promotion of the availability of RxPathways and Hub activities to RC-approved information about RxPathways and any Hub program.
- Pfizer Colleagues must not promote RxPathways or Hub programs and activities to induce HCPs to prescribe Products or to discourage HCPs from prescribing alternative therapies.
- Pfizer Colleagues (with the exception of Field Reimbursement Managers) should refer all inquiries from their HCP customers regarding the status of a particular patient case to the applicable Field Reimbursement Manager through the appropriate channel or refer the HCP or office staff to RxPathways or the applicable Hub.

### For More Information

- For more information about Pfizer RxPathways, including the Pfizer PAP, IPAP and Savings Program, or Reimbursement Support Services, please contact The RxPathways Team at [PfizerRxPathways@pfizer.com](mailto:PfizerRxPathways@pfizer.com) For more information about Hub activities, please contact the [SAS COE team](#).
- For RC-approved FAQs and Talking Points, visit <http://MyPfieldNet.pfizer.com>.
- If you have additional questions about the information covered in this Chapter, please contact [CSP Legal](#) or your team attorney.



## **CHAPTER #12 – DISCOUNT ARRANGEMENTS AND CONTRACTING**



Chapter

#12

DISCOUNT ARRANGEMENTS AND  
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## Chapter #12 Discount Arrangements and Contracting

### Introduction

Pfizer offers price concessions in order to meet competition and to make its products available to customers and patients. Price concessions can be offered prospectively as invoice discounts as well as retrospectively through rebates. Pfizer may offer price concessions to purchasers and payers, such as Distributors, Specialty Pharmacies, Pharmacy Benefits Managers (PBMs), Integrated Delivery Networks (IDNs), Long Term Care Pharmacy Providers, Group Purchasing Organizations (GPOs), and government programs (hereinafter "Customers"). This Chapter provides guidance concerning Pfizer's price concessions to Customers (hereinafter "Discount Arrangements") and the process of negotiating and entering into Discount Arrangements with Customers, which is referred to as "contracting."

Generally, Discount Arrangements must be approved before being offered to Customers and only certain Field Commercial Colleagues are responsible for offering and contracting for Discount Arrangements. Only Field Commercial Colleagues who have responsibility for and received the appropriate training should offer Discount Arrangements to Customers. Furthermore, only Discount Arrangements that have the necessary approvals should be offered. All colleagues are responsible for complying with Pfizer's policies regarding Discount Arrangements and contracting.

**Non-compliance with these policies by any colleague, even those who are not responsible for contracting, can put the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination of employment.**



### ***Key Points to Ensure Compliance***

- Only offer approved Discount Arrangements to Customers.
- Only colleagues with contracting responsibility should extend approved Discount Arrangements to Customers.
- Approved Discount Arrangements should be set forth in writing, (usually a contract with limited exception) and such writing should include all relevant terms and conditions. There should be no "side deals."
- Do not offer any items of value or payments in exchange for the purchase, prescription or recommendation of Pfizer products.
- Do not discuss grants, service agreements, other items of value, or tools and resources in connection with Discount Arrangements.
- Do not attempt to leverage any non-discount arrangements to induce the purchase, prescription or recommendation of Pfizer products.
- Do not attempt to leverage, link, or reference a commercial rebate agreement in order to secure access to a Medicare Part D rebate agreement, or vice versa.
- Do not discuss Pfizer pricing policies or practices with competitors or Customers.

## **Discount Arrangements**

As explained in Chapter 1, certain “**safe harbors**” permit legitimate activities that might otherwise be seen as violating the Anti-Kickback Statute. The **Discount safe harbor** allows Pfizer to discount the price of a product, provided that the discount is properly reported to the government and complies with other safe harbor requirements. In addition, the **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. For these reasons, Discount Arrangements should be set forth in writing, preferably a contract between Pfizer and the Customer. Pfizer seeks to memorialize each Discount Arrangement in writing, usually a contract, but occasionally in the form of a less comprehensive writing such as an invoice or reconciliation statement to ensure that it meets the applicable safe harbors to the Anti-Kickback Statute.



## Discount Arrangements and Price Reporting

Pfizer's Discount Arrangements with Customers can affect the price that state and federal healthcare programs pay for Pfizer products. Therefore, Pfizer must be sure to include all eligible price concessions made to Customers in the prices it reports to the government. Failure to do this may cause Pfizer to submit a false report to the federal government and create liability under the False Claims Act. For example, to participate in the Medicaid Drug Rebate Program, Pfizer must provide the federal government a rebate equal to the greater of 23.1% of **Average Manufacturer Price (AMP)** or the difference between a manufacturer's **Best Price** and the **AMP** for each unit of product paid for by State Medicaid agencies. Pfizer calculates and reports to the federal government the **Best Price** for each Medicaid covered product. When reporting **Best Price**, Pfizer must 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. Failure by Pfizer to include such price concessions in its calculations could cause it to report a false **Best Price** in violation of the False Claims Act.

Discount Arrangements with Customers may also affect a number of other government programs in which Pfizer participates, including Medicare, 340B Public Health Services Outpatient Drug Discount Program, and its Federal Supply Schedule agreement with the Department of Veterans Affairs.

## Contracting Guidance

To help ensure the accuracy of Pfizer's price reporting and compliance with the Discount Safe Harbor and other applicable laws, only colleagues with contracting responsibility who have received the appropriate training should offer Discount Arrangements to Customers. Colleagues with contracting responsibility should offer only Discount Arrangement that have received the necessary approval. When extending a Discount Arrangement, there should not be any "side deals" or other offers that are not part of approved offer. And all Discount Arrangement terms should be clearly set out in a writing, preferably a contract.

Furthermore, colleagues should not discuss grants, sponsorships, additional service contracts, collaborations, tools and resources, or other items of value in connection with Discount Arrangements, as those items may have to be included in Pfizer's government pricing calculations. Additionally, providing grants, additional service contracts, or other items of value in return for the purchase, prescription or recommendation of Pfizer products may be considered an improper inducement under the Anti-Kickback Statue and is prohibited by Pfizer policy.

Discussions with Customers about Discount Arrangements should be kept separate from discussions about other potential business opportunities, including any pull through activities. This can best be achieved by



holding separate meetings to discuss Discount Arrangements. Where it is not possible or practical to have separate meetings on Discount Arrangements issues, the following guiding principles will help mitigate risk.

***Prior to the meeting:***

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

***During the meeting:***

- Stick to the agenda.
- Firewall discussions into appropriate segments. One possibility is to separate all discussions where Pfizer is purchasing goods or services from the Customer (i.e., where Pfizer is the "customer") from those where Pfizer is providing discounts, goods, or services to the Customer (i.e., where Pfizer is the "seller").
- Coordinate the attendance of individuals who are not part of the contracting process by having individuals step out of or arrive later during a joint meeting so that individuals who should not be privy to contracting discussion are not in attendance.
- Manage the other side's attempts to link discussions of multiple projects by deferring the issue for future conversation or delegating the issue to colleagues not in attendance.
- Approach discussions of non-contracting business opportunities carefully during the negotiation period prior to and around the time of rebate contract expiration.

***After the meeting:***

- Evaluate the contracting offer and other business proposals independently and on their own merits; separate business teams within Pfizer should do the respective evaluations.
- Be mindful of how financial and other notes regarding the contracting offer and other business opportunities may appear in hindsight. For example, the valuations for each business opportunity on the same worksheet may imply that the opportunities are connected and interdependent when the intent was otherwise.
- In some instances, Legal may advise the business unit to have a cooling off period between contract negotiations and other arrangements or other discounting discussions.

In addition, Pfizer's internal documentation should keep Discount Arrangements and other Customer business separate. Internal analyses of Discount Arrangements should be separate and independent from the analysis of other business activities with the relevant Customer.



### “Swapping” Discounts between Commercial and Part D Plans

Many Pharmacy Benefit Managers (PBMs) currently manage both commercial and **Medicare Part D** books of business. These organizations will negotiate discounts from pharmaceutical companies on behalf of the government under Medicare Part D, as well as on behalf of their own commercial business. The government has expressed concern that entities will utilize Medicare Part D leverage to obtain preferential discounts for their commercial books of business.

#### Medicare Part D

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

"Swapping" describes a situation whereby a PBM and pharmaceutical company agree to "swap" access to the organization's Medicare Part D book of business in exchange for greater rebates for the organization's commercial books of business. A PBM might be willing to accept higher costs under Medicare Part D in exchange for lower commercial plan costs because the government subsidizes a portion of its Part D plan costs, while it often remains entirely at risk for its commercial plan costs. Pfizer must never engage in swapping and must avoid situations that could create a perception of swapping.

In order to avoid the appearance of swapping, Commercial and Medicare Part D negotiations should be conducted separately, and preferably at separate meetings. If separate meetings are not possible, follow the meeting guidelines set forth above. Internal and customer facing documentation regarding Commercial and Medicare Part D negotiations should clearly distinguish between the two. This is best achieved by creating separate presentations and offer sheets for Customers and analyzing Commercial and Part D offers in separate internal documents.

#### Meetings on Commercial and Part D Contracts



May I discuss a commercial contract and a Part D contract in the same meeting with a Customer?



Yes. You may do this if the two are not linked or discussed contemporaneously. For example, it is acceptable to discuss the commercial contract during the first half of your meeting, and then indicate to the Customer that you are moving on to the Part D contract discussion for the remainder of your meeting.





## Antitrust and Competition Laws

Antitrust and competition laws protect free enterprise by prohibiting agreements between Pfizer and our competitors to set prices, terms, or conditions of sale. The term “Prices” includes discounts. To ensure full compliance with U.S. antitrust laws, you should never discuss the following topics with any competitor or with multiple Customers at any time:

- Pfizer's pricing policies;
- Pfizer's current or future prices, discounts, rebates, or other terms and conditions of sale generally or as they relate to other Customers;
- Pfizer's current or projected profits or profit margins;
- A Customer's current or projected profit or profit margins;
- Pfizer's current or projected costs;
- Pfizer's business, marketing, and promotional plans;
- Pfizer's bidding policy or its intent to bid or not to bid for particular business;
- Pfizer's plan to do business or not do business with particular Customers; and
- Pfizer's intention to engage or not engage in particular research activities.

Antitrust laws also prohibit discriminatory pricing and promotional practices. More specifically, U.S. antitrust laws prohibit selling goods of like grade and quality to competing purchasers (who are resellers of those goods) at different prices where competition will be damaged. In essence, this requires Pfizer to offer similarly situated Customers the same prices and discounts absent an exception or defense. Pfizer therefore carefully assesses Discount Arrangements prior to them being offered. To ensure compliance, Pfizer colleague should offer only Discount Arrangements that have received the necessary approval.

## Discount Arrangements and Confidentiality

Pfizer colleagues should use caution in discussing Discount Arrangements with anyone other than the eligible Customer. The contracts under which Pfizer extends Discount Arrangements often contain confidentiality provisions that limit both parties' ability to share them with third parties and may even limit Pfizer's ability to share their terms internally within Pfizer. Pfizer colleagues should not share with third parties the terms of a Customer's Discount Arrangement absent review of the governing contract by your legal counsel. This includes instances where you seek to share information with a customer of a Pfizer Customer (for example, a plan under a PBM).



### For More Information

- Questions may be referred to your manager, [CSP Legal](#), Pfizer Essential Health (PEH) Legal, Contracting Development, or Compliance Manager.
- Arrangements under which Pfizer procures item of tangible value (such as data or services (including consulting) are covered in Orange Guide Chapter 15: Service Agreements and Other Non-Discount Customer Arrangements with Accounts.



## **CHAPTER #13 – HEALTH SCREENINGS**



Chapter

#13

HEALTH SCREENINGS

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## Chapter #13 Health Screenings

### Introduction

Colleagues working with Organized Customers or certain specialty markets may wish to support or hold health screenings. These screenings often take place as part of larger health fairs. Pfizer sponsors screenings to benefit the quality of patient health care. Screenings can promote the early detection of diseases and may offer patients a meaningful opportunity to manage a disease or condition.

This Chapter is relevant to all colleagues who have a budget that supports health screenings and are colleagues who are permitted to offer or implement health screenings sponsored by Pfizer.

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

#### ***Key Points to Ensure Compliance***

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



### Screenings Offered to an Employer for its Employees

Screenings must be funded out of your promotional budget and approved by your Payer and Channel Access (PCA) Regional Director or Sales Director. You must not offer health screenings to employers who are HCPs or payers of healthcare items and services, such as hospitals, clinics, medical practice groups, and Managed Care Customers (MCCs) who seek reimbursement from the federal government, except for employers who may receive a government retiree drug subsidy for retirees. Unless otherwise approved by your team attorney or PCA Legal, the screening must be limited to current employees and their beneficiaries and must expressly exclude retirees who are beneficiaries under the employer's retiree health plan.

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

- The screening must be conducted by an approved third-party vendor that routinely conducts such screenings, and the vendor must sign Pfizer's Screening Services Agreement.
- The screening cannot be organized or designed in any way to generate referrals for any particular Organized Customer.

#### **Privacy Issues**

Consumer health fairs and screenings implicate privacy issues when they involve obtaining Personal Information from individuals, including details that relate to an individual's health status. Pfizer's ability to use any Personal Information that is collected is strictly limited by the terms in the Patient Authorization and Release form.

Personal Information is any information that relates to an identifiable individual or can be used to identify a person, either directly or indirectly (e.g., by combining different sets of indirect identifiers). Examples include a person's name, physical and e-mail addresses, phone numbers, and identification numbers.



For example, a Pfizer representative cannot pass specific data about an individual's health status to an employer at an employee health fair unless the employee has specifically authorized the representative to provide that data to the employer.



Data may be shared with an employer or employer health plan ONLY if: (1) the data is aggregated and de-identified; and (2) all screening participants whose data is being shared have signed the Pfizer Patient Authorization and Release form.

- The Pfizer Patient Authorization and Release form is available on [MyPfizerNet](#) within the “Compliance” tab under the “Forms” tab. For more information on the topics of patient authorization and de-identification of data, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.

#### Providing Health Screening Data to a Customer

	An Organized Customer wants Pfizer to conduct a disease screening for employees of an employer to whom the Organized Customer provides pharmacy benefits. The Organized Customer also wants Pfizer to provide them with the aggregated, de-identified data from the screening. Can I organize the screening and provide the data?
	Maybe. The only reason you can conduct a disease screening is to improve patient care. You cannot subsidize the operating expenses of the Organized Customer or the employer by conducting a screening that they would do on their own. If there is an independent valid reason for Pfizer to fund the screening, Pfizer can organize it. Aggregated, de-identified data from the screening can only be provided to the Organized Customer if each screened employee signs Pfizer's Patient Authorization and Release and the release specifically provides that the data can be provided to both the employer and the MCC administering the drug benefit. MCCs are not appropriate entities to whom Pfizer should offer screenings. In the scenario above, the MCC should not appear as a co-sponsor of the event unless the MCC independently provides funding or services.

#### Screenings Offered to the Public at Large

##### ***If organized by a Hospital, Non-Profit Organization, Managed Care Organization, or Other Third Party:***

- Pfizer's office of Global Medical Grants (“GMG”) can support a screening organized by a third party through an unrestricted educational grant, provided that the event meets Pfizer's requirements for unrestricted educational grants. You must NEVER promise that a grant will be provided for a health screening or for any other reason. The requestor must apply directly to GMG for funding and will receive notice from GMG regarding whether the request has been approved.
- The requesting organization is solely responsible for logistics and content of the event.
- The screening event must be advertised and open to the community at large (e.g., advertised in the newspaper or on TV or radio).





- The screening must not be organized or designed in any way to generate referrals for any particular Organized Customer.
- Pfizer exhibits and displays are not permitted at any event funded by a GMG grant.

***If organized by Pfizer:***

- The screening may be funded out of your promotional budget and must be approved by your PCA Regional Director or Sales Director.
- These types of screenings are promotional in that they "promote" Pfizer generally (Pfizer is the "product"). Colleagues can promote Pfizer products at these screenings with an exhibit and display as long as the exhibit and display booth is physically separate and apart from the screening area and adheres to other Pfizer policies and procedures governing advertising and promotion. No financial ROI analysis can be performed, tying a product's sales or market share to this event.
- The screening must be conducted by a third-party vendor that is not a HCP or payer and that routinely conducts such screenings. The vendor must sign Pfizer's Screening Services Agreement, which can be downloaded from MyPfizerNet under the [Compliance tab](#).
- The screening cannot be organized or designed in any way to generate referrals for any particular customer.
- The screening must be advertised and open to the community at large, and any materials advertising or promoting the event must be approved by the relevant Review Committee ("RC-approved"). If you are unsure which Review Committee is appropriate, consult your team attorney.

**On Site Health Screenings "Open to the Community"**

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





**REMEMBER:**

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

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

### Other Key Points for Health Screenings

#### ***Field Commercial Colleague Participation***

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

#### ***Important Points to Remember***

- Do not use a screening to drive or attempt to generate patient referrals to any HCP.
- Contract with an approved third-party vendor that routinely conducts such screenings to perform the disease screening customer program.
- Data may be shared with an employer or employer health plan if: (1) the data is aggregated, and all personal identifiers have been removed (as set forth in Orange Guide Chapter 8: Privacy: Protecting Personal Information); and (2) all participants whose data is being shared have signed the Pfizer Patient Authorization and Release form.
- Use only approved documents and obtain necessary documentation:
  - Pfizer Vendor Agreement;
  - Pfizer Patient Privacy Release; and
  - An invoice from the vendor for the services.



#### Health Screenings and Exhibit Booths at Health Fairs



Pfizer is participating in a local health fair where we will be organizing and conducting lipid screenings. Can Pfizer also have a separate promotional exhibit and display booth where we hand out approved consumer materials on Pfizer products?



Yes. So long as the exhibit booths are separate and not joined with the screening, you can provide RC-approved consumer materials at a health fair where Pfizer is also conducting a health screening. For example, the exhibit booths and health screenings can be at the venue as long as the two events are held in separate rooms or there is a partition. It should never be the case or appear to be the case that Pfizer is conducting the screening in order to encourage people to ask their doctor about Pfizer products.

#### For More Information

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



## **CHAPTER #14 – ORGANIZED CUSTOMER AND PAYER TOOLS AND RESOURCES**



**Chapter**

**#14**

**ORGANIZED CUSTOMER AND PAYER  
TOOLS AND RESOURCES**

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## Chapter #14 Organized Customer and Payer Tools and Resources

### Introduction

Organized Customer and Payer Tools and Resources (hereinafter, “OCP Resources”) are provided by Pfizer to educate customers, benefit patients, and improve patient outcomes. In general, the purpose of the OCP Resources is to promote wellness, disease prevention, patient awareness, and improve health care. OCP Resources can be generally categorized as:

- Product related; or
- Unbranded.

### Colleagues Governed by this Chapter

**This Chapter applies to Account-facing colleagues who are authorized to offer or provide OCP Resources to Accounts, including, but not limited to, Account Management Colleagues, Marketing Colleagues and Medical Outcomes Specialists (MOS). Please note that MOS are governed by the Green Guide and Marketing Colleagues are governed by the White Guide, but their uses of RC-approved OCP Resources and interactions with customers in connections with these resources must comply with guidance provided in this Chapter.**

In general, OCP Resources are not intended for use by Sales Colleagues. The specific details of these OCP resources should **not be shared** with sales colleagues unless approved by Review Committee for that purpose. Additionally, Sales Colleagues should **not be trained** on any resources that are not approved for their use with customers.

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

### Appropriate Recipients

OCP Resources can be used with Organized Customers who meet certain capability criteria as part of Pfizer's mission to enhance healthcare. Such customers may include, but are not limited to, Health Plans, Health Systems, Medical Groups, Integrated Delivery Networks, Long Term Care Facilities, VA/DoD, HMOs, certain hospitals, employers, Specialty Pharmacies, and Pharmacy Benefit Managers (PBMs). Generally, OCP Resources are not intended for use with individual HCPs or prescribers.



OCP Resources should be broadly offered to eligible Organized Customers because offering them only to select customers could be perceived as providing items of value in order to increase prescribing or improve formulary status with those specific customers which may implicate the anti-kickback laws or other healthcare laws. Nevertheless, you may consider the availability of internal Pfizer resources as well as prioritize Organized Customers for which the resources will most positively impact patients care.

Field Commercial Colleagues should consult Orange Guide Chapter 5: Interactions with Health Systems and Medical Groups and Orange Guide Chapter 18: Meals, Educational Items, Greenstone Giveaways, and HCP Payment Disclosure for more information on our disclosure obligations under the Sunshine Act for additional guidance before offering or providing OCP Resources to customers.

The decision to provide an OCP Resource must be based on the Organized Customer's ability to use the resource appropriately. Pfizer's reason to offer or provide OCP Resources must **never** be to:

- Solely establish Pfizer's relationship with an Organized Customer;
- Solely improve Pfizer's relationship with an Organized Customer or HCP;
- Gain or improve access for our Sales Colleagues;
- Reward past prescribing or induce future prescribing;
- Influence an upcoming formulary decision; or
- Offer an implied discount on the price of our products.

#### ***Key Points to Ensure Compliance***

- Any OCP Resources provided to Organized Customers must be RC-approved. Do not design your own or modify OCP Resources.
- OCP Resources must not be provided with any contingencies or conditions. Do not condition the offer or provision of OCP Resources on increased prescribing or improved formulary status.
- OCP Resources are designed to help improve patient care and support appropriate use of our products. The decision to provide OCP Resources must be based on Pfizer's goals of improving health outcomes, patient awareness, wellness, disease prevention, and health care.



#### ***Key Points to Ensure Compliance***

- OCP Resources may help to improve patient care/outcomes, quality performance, and achieve quality objectives upon which reimbursement is dependent. You may never claim, in a direct or implied way, that an OCP Resource can help an Organized Customer achieve quality standards or allow an Organized Customer to obtain financial incentives or otherwise satisfy a requirement imposed by a third party.
- OCP Resources may not underwrite operational or other services for which the Organized Customer would otherwise have to engage or pay on its own.
- OCP Resources and the manner in which they are used should clearly disclose the role Pfizer played in their creation and dissemination.

#### **Product-Related Resources**

Product support-related resources are branded resources intended to educate Organized Customers on our brands, promote the appropriate use of our products, and support patient care and treatment of specific patient populations.

Product-Related Resource must be approved by the relevant brand Review Committee (RC) and, must be consistent with product labeling. You may only provide RC-approved Product-Related OCP resources to Organized Customers, and you may not modify them in any way. In addition, you cannot design your own or customize OCP resources without explicit RC approval to do so.

Product-Related Resources aim to promote our products through education on their appropriate use or demonstration of their benefits. Branded resources that are designed to demonstrate the value of Pfizer products, such as a Budget Impact Model or a Payer Value Proposition (PVP), are outside the scope of this Chapter.

Product-Related OCP resources must never be provided with any contingencies or conditions such as increased prescribing or formulary placement or improvement. Product-Related OCP resources and the manner in which they are implemented with Organized Customers and patients should clearly disclose Pfizer's role in their creation and dissemination. Product-Related OCP resources may be developed by the relevant brand team or regional customer marketing for use by account-facing colleagues with certain Organized Customers, such as IDNs, Health Plans, and/or Government customers, and are meant to be implemented or used at the system or organization level. While individual HCPs are not typically the target



customers for these types of resources, the resources may be used based on the customer's approach, with appropriate RC approval.

The information obtained from an Organized Customer engagement can be provided back to the same Organized Customer to demonstrate the efficacy of the intervention. However, you cannot provide data derived from a Product-Related Resource obtained from one Organized Customer to a different Organized Customer. Commercial Colleagues must work with Field Medical Colleagues on any projects measuring the outcomes or other associated clinical aspects of an intervention.

For more information about currently available tools and resources, review the resources and the associated utilization guidance at [PROMOSprime](#).

### Unbranded Resources

Unbranded Customer Resources support Pfizer's overall mission of improving patient care. Unbranded OCP resources promote an understanding of healthcare market drivers, key trends, and other issues of importance to Organized Customers and Pfizer. With a focus on areas such as adherence, population health, quality, value-based models, and the total cost of care, these tools and resources are intended to enhance account team relevance, foster effective Organized Customer engagement, and improve patient care.

OCP Resources may also be platforms of tools and resources that support the identification, screening, diagnosis, management, or appropriate treatment of specific patient populations aligned to a therapeutic area.

Unbranded Customer Resources are typically developed by the brand team, payer brand marketing, customer marketing, or regional customer marketing and must be approved by a Pfizer Review Committee. Other Unbranded Customer Resources used exclusively by Medical colleagues to through an alternate approval process (i.e. the appropriate Medical Review committee). Unbranded Customer resources may not underwrite operational or other services in which the Organized Customer would otherwise have to engage or for which the Organized Customer would be obligated to pay on its own.

Some unbranded resources are categorized as Skills-Based Learning (SBL) resources. These unbranded resources support improved health outcomes, patient awareness, customer awareness and focus on enhancing healthcare delivery acumen. They may be provided to all health care stakeholders, including both Accounts and individual HCPs.

SBL resources require tracking and disclosure under transparency and disclosure laws such as the Sunshine Act. The Sunshine Act requires Pfizer to report payments or transfers-of-value to U.S.-licensed physicians or teaching hospitals. The payments or transfers-of-value that we report may be direct (e.g., a U.S.-licensed physician receives something from Pfizer) or indirect (e.g., a U.S.-licensed physician receives

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something from an organization that was provided by Pfizer). We may have to report the payment or transfer-of-value even if Pfizer did not influence or direct who should receive the payment or transfer-of-value specifically.

Unbranded OCP resources must never be provided with any contingencies or conditions such as increased prescribing or formulary placement or improvement.



Unless otherwise approved by RC, Unbranded OCP Resources should not be discussed in conjunction with branded materials, as such execution may inadvertently “brand” the OCP materials as a branded resource.

For more information about currently available tools and resources, review the resources and the associated utilization guidance at [PROMOSprime](#).

#### Discussing Pfizer Products or Branded Resources while meeting with Customers

	If I am meeting with an Organized Customer to discuss Unbranded Customer Resources, am I permitted to discuss Pfizer products or branded OCP Resources during that meeting?
	It depends on the RC guidance. Yes, if approved by RC with respect to the specific unbranded resource, you are permitted to discuss Pfizer products during the meeting only if your discussions about Pfizer products are clearly separate from your discussions about the Unbranded Customer Program. In doing so, you must ensure that the Organized Customer understands that the program is not related to the promotion of Pfizer products, and that Pfizer does not expect or intend that the Organized Customer use our products as a condition of providing the program. The program must be provided with no strings attached.

#### The Value of OCP Resources in Meeting Objectives

	Can I conduct a financial ROI analysis on implementation of an OCP Resource?
	It depends on the OCP Resource and what you are measuring. You must not conduct a product-specific ROI analysis on an unbranded Program as you are not permitted to calculate and cannot use Unbranded OCP Resources to achieve a gain in market share. Similarly, you are never permitted to conduct an ROI analysis on the deployment of SBL resources. For other Unbranded OCP Resources that are focused on a specific therapeutic area, you may measure market growth for the specific therapeutic area, and after implementation, an ROI analysis may be appropriate so long as it only measures the impact to a Pfizer product as a part of the overall market growth.



### ***Transfer of Value, Sunshine Act, and Fair Market Value***

Please be aware that some tools and resources may require tracking and disclosure under the Sunshine Act. The Sunshine Act requires us to report payments or transfers-of-value to U.S.-licensed physicians or teaching hospitals. The payments or transfers-of-value that we report may be direct (e.g., a U.S.-licensed physician receives something from Pfizer) or indirect (e.g., a U.S.-licensed physician receives something from an organization that was provided by Pfizer). We may have to report the payment or transfer-of-value even if Pfizer did not influence or direct who should receive the payment or transfer-of-value.

#### **For More Information**

- Consult the [PROMOSprime](#) for information and guidance on use for individual Resources.
- Field Commercial Colleagues should consult Orange Guide Chapter 5: Interactions with Health Systems and Medical Groups before offering or providing OCP Resources to customers.
- Field Commercial Colleagues should consult Orange Guide Chapter 18: Meals, Educational Items, Greenstone Giveaways, and HCP Payment Disclosure for more information on our disclosure obligations under the Sunshine Act.
- Questions may be referred to your manager, appropriate Marketing teams and/or the [Commercial Solutions Platform \(CSP\) Legal Team](#).



## **CHAPTER #14 – SERVICE AGREEMENTS AND OTHER NON- DISCOUNT ARRANGEMENTS WITH ACCOUNTS**



**Chapter**

**#15**

**SERVICE AGREEMENTS AND  
OTHER NON-DISCOUNT  
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## Chapter #15 Service Agreements and Other Non-Discount Arrangements with Accounts

### Introduction

Pfizer enters into a variety of contractual arrangements with its customers. As discussed in Orange Guide Chapter 12, Pfizer provides discounts to certain Organized Customers or Accounts, often in the form of rebates. In addition, Pfizer enters into non-discount arrangements with customers to procure goods or services on behalf of Pfizer. Purchasing data from a pharmacy for purposes of calculating incentive compensation for Pfizer sales colleagues is an example of a non-discount arrangement. This Chapter discusses those non-discount arrangements between Pfizer and its organized customers, or Accounts, including managed care organizations, retail pharmacies, group purchasing organizations, and integrated delivery networks (IDNs). Arrangements with specialty pharmacy (including IDN specialty pharmacies) will be discussed in Orange Guide Chapter 20. Where relevant, the chapter divides non-discount arrangements into those where Pfizer is purchasing some item of value (a "Purchase Agreement") and those where Pfizer is procuring a service (a "Service Agreement").

### Anti-Kickback Analysis

The Anti-Kickback Statute prohibits payments intended to induce someone to purchase, prescribe, endorse, or recommend a product that is reimbursed under federal or state healthcare programs. Under Pfizer policy, all customers are treated as if they are subject to the Anti-Kickback Statute, even though they may not participate in a federal healthcare program. Recognizing that the federal Anti-Kickback Statute, if read literally, could restrict many otherwise legitimate marketing activities and even some non-promotional activities, 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.

#### Personal Services Safe Harbor

This safe harbor protects legitimate service arrangements recorded in a written agreement, of at least one year in duration, where the compensation is determined in advance and on a fair market value basis. Where appropriate, Pfizer endeavors to make Service Agreements meet the Personal Services safe-harbor.



The Anti-Kickback Statute and its safe harbors are critical to consider when entering into non-discount arrangements with any customer, and particularly Accounts who are eligible to receive discounts on Pfizer products under a separate discount arrangement.

When Pfizer is making a payment, directly or indirectly, to an Account that may purchase, prescribe, endorse, or recommend Pfizer products, every non-discount arrangement between Pfizer and that Account must undergo an anti-kickback analysis. This will help ensure that the proposed non-discount arrangement has a legitimate business purpose and that Pfizer is procuring a needed good or service at Fair Market Value (FMV). Arrangements to influence the purchase, prescribing or recommendation of a Pfizer product, or to improve the price or discount at which a customer can purchase Pfizer's products, are not permitted to be considered when a Service Agreement with an Account is being undertaken and may subject Pfizer to liability.

#### **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 any person or entity in a position to purchase, prescribe, endorse, or recommend our products fair market value for the good or service Pfizer receives in return.

To ensure compliance, when entering into non-discount arrangements with Accounts, remember the following principles:

- Ensure the non-discount arrangement serves a legitimate business purpose for Pfizer. Only purchase those goods or services for which Pfizer has a bona fide need. Paying for unneeded goods, services or data can increase the risk that the arrangement is viewed as an illegal kickback.
- Always ensure you are paying FMV for the goods, services, or data. Paying above or below FMV increases the risk that the arrangement may be viewed as a kickback. The company has developed a tool (an excel-based worksheet) to assist commercial and medical colleagues in determining FMV for certain activities that Pfizer may provide to a customer as part of a collaboration. Individuals preparing to engage in a collaboration should contact a Commercial Solutions Platform (CSP) attorney for assistance with the [FMV Calculator Tool](#). If the services you are trying to procure are not in the tool, contact a [CSP attorney](#).
- When procuring Services or data from an integrated delivery network or group purchasing organization related to a Pfizer product, contact your [CSP attorney](#) for assistance.



- Do not leverage Pfizer's ability to purchase goods or services from an Account to influence the purchase, prescribing or recommendation of Pfizer products. For example, do not condition the purchase of data from an Account on formulary access for a Pfizer product.
- To avoid pricing concerns, do not combine discount arrangements with other types of transactions. Do not discuss discount arrangements under which a customer may be eligible for a discount on Pfizer products in conjunction with non-discount arrangements under which Pfizer seeks to procure an item of value or service from the Account.
- Memorialize non-discount arrangements between Pfizer and its Accounts in a written contract. Remember, because contracts can be oral or written, you can unintentionally bind Pfizer. Do not make oral promises to customers.
- Work with the [CSP Attorney](#) who will assist with contract development as well as to mitigate compliance risks.

### Purchase Agreements

The term "Purchase Agreement" refers to a non-discount arrangement between Pfizer and an Account where Pfizer is procuring an item of tangible value to Pfizer. As with any non-discount arrangement, Purchase Agreements must serve a legitimate business purpose where Pfizer is purchasing at fair market value an item for which it has a bona fide need, and the arrangement must be memorialized in a written agreement reviewed by appropriate [CSP Attorney](#). Frequently, Pfizer seeks to purchase data to which an Account has access by virtue of its providing services to its patients, members, or affiliated physicians. Purchase of data from an Account and Pfizer's subsequent use of the data may implicate federal and state privacy laws. Work with the [CSP Attorney](#) to ensure the Purchase Agreement contains the necessary protections for Pfizer and Pfizer's proposed use of the data is consistent with our contractual obligations and applicable privacy laws.

All Purchase Agreements with Accounts must be reviewed and approved by a [CSP Attorney](#).

### Service Agreements

The term "Service Agreement" refers to a non-discount arrangement between Pfizer and an Account where the Account is hired to perform services for Pfizer. Customers are in the unique position of having access to patients taking Pfizer products, to members to whom they provide health benefits, and to providers who are affiliated with the Account. For this reason, Pfizer may from time to time want to retain the Account to engage with such individuals or to disseminate certain information on Pfizer's behalf. As with any non-discount arrangement, Service Agreements must serve a legitimate business purpose where Pfizer is purchasing at fair market value a service for which it has a bona fide need, and the arrangement must be memorialized in a written agreement reviewed by the appropriate [CSP Attorney](#). Common types of Service

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## Orange Guide – Chapter 15: Service Agreements and Other Non-Discount Arrangements with Accounts

Agreements include those for dissemination of Patient Educational materials, Medication Compliance, and "Now on Formulary") Programs.. One example of a service agreement could include engaging an IDN to provide clinical and technical input into the development and testing of prototype Pfizer resources such as a Health IT tool, a specific type of resource intended for use with HCPs, health systems, etc.

All Service Agreements with Accounts must be reviewed and approved by a [CSP Attorney](#) in conjunction with the relevant product attorney and may require review and approval by Intake Committee per guidance from legal.

Privacy laws may limit the scope of permissible activities Accounts may engage in when interacting with patients on Pfizer's behalf. For example, HIPAA and some state privacy laws restrict certain sales and marketing related activities in which our Accounts are paid or otherwise provided remuneration, directly or indirectly, by Pfizer in exchange for communicating with targeted patients or clinicians. Under these laws, certain communication programs require prior written patient authorization. In limited circumstances, Pfizer and its Accounts may implement programs without securing patient authorizations; however, in such cases Pfizer and its Accounts must ensure that the arrangements comply with the terms of the limited exceptions to the patient authorization requirement under the HIPAA marketing rules. State privacy laws may also be implicated by certain marketing arrangements. For more information about HIPAA and state privacy laws, see Orange Guide Chapter 8: Privacy: Protecting Personal Information. Please consult a [CSP Attorney](#) if you have questions on the permitted scope of Accounts' interactions or communications involving patients or clinicians.

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

### ***Key Points to Ensure Compliance***

- Do not discuss Purchase Agreements, Service Agreements, or other arrangements in connection with rebate negotiations.
- Neither Purchase Agreements nor Service Agreements may reference, verbally or in writing, existing discount arrangements.
- Do not enter into Purchase Agreements or Service Agreements for the purpose of inducing the placement or maintenance of Pfizer products on a formulary.





#### ***Key Points to Ensure Compliance***

- Only enter into Purchase Agreements and Service Agreements that support a bona fide Pfizer business need.
- All Purchase Agreements, Service Agreements, and other arrangements must be approved by the CSP Legal team.
- CSP Legal approval is required when deviating from the Pfizer approved template for either a Purchase or Services Arrangement.
- Consult the CSP Legal team, who will consult with the Pfizer Global Privacy Office as needed, to ensure each arrangement complies with federal and state privacy laws.

#### **Patient Education Programs**

Patient Education Programs allow Pfizer to provide RC-approved health information to an Account's patients or members, subject to certain payment and authorization requirements under HIPAA. Unless authorizations are obtained from the patients or members, Pfizer may only provide unbranded health information to the Account's patients or members.

If Pfizer seeks to compensate an Account for sending branded health information:

- The Account must secure individual authorizations from its patients or members before making the communication and must disclose any compensation provided by Pfizer to the Account;
- Any compensation provided to the Account must be equal to the Fair Market Value (FMV) cost of developing and conducting the services to be provided (e.g., mailing any program materials or welcome kits, as applicable);
- Only RC-approved Patient Education materials may be used, and the materials must disclose Pfizer's sponsorship.

**Any proposed changes to approved materials must be reviewed and approved by the appropriate Pfizer Review Committee before the materials can be disseminated.**



## Medication Compliance Programs

Medication compliance programs most commonly referred to as "refill reminder" or "adherence" programs, are outreach programs that provide patients with information about the product they are taking, remind them of the importance of staying on therapy as prescribed, and remind patients to refill their prescriptions. These programs may be implemented without seeking patient authorizations if Pfizer and the Account comply with the requirements of the HIPAA "refill reminder exception."

The type of compensation permitted under the refill reminder exception depends on whether compensation is provided directly by Pfizer to either the Account or its business associate for the associated communications.

- If Pfizer pays an Account directly, Pfizer may only reimburse the Account for the cost of labor, supplies, and postage related to performing the program.
- If Pfizer pays an Account's business associate, Pfizer may compensate the business associate up to the fair market value of the services provided.

Please note that the following activities are **not** permitted under the refill reminder exception:

- Communications regarding new formulations of a currently-prescribed drug or biologic;
- Communications about a drug that may be used in conjunction with a currently prescribed drug or biologic; and
- Communications encouraging an individual to switch from a currently prescribed drug or biologic.

For arrangements that do not comply with requirements of the refill reminder exception, the Account would need to collect patient authorizations before disseminating the communications.

**All materials provided as part of a medication compliance program must be reviewed and approved by the appropriate Pfizer Review Committee.**

## Co-Promote Programs

From time to time, Pfizer may enter into Service Agreements with managed care customers ("MCC") that maintain a formulary where Pfizer products are listed. These Service Agreements provide for the distribution of non-routine formulary information about Pfizer products to the MCC's members. Typically, these contracts compensate an MCC for providing information to its members explaining that a Pfizer product has recently been added to the MCC's formulary or reminding them of the availability of Pfizer products on formulary. Similar to the Medication Compliance Programs above, these formulary announcements are permitted without patient authorization only if the announcements are targeted to the



MCC's members who are currently prescribed the same drug or biologic and remuneration to the MCC only covers the cost of labor, supplies, and postage. If Pfizer pays the MCC's business associate for the services provided, fair market value compensation to the business associate may be provided. For broader targeting of formulary announcements, or for arrangements involving greater compensation, the MCC would need to collect patient authorizations before disseminating the formulary information.

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

- Monthly patient newsletters;
- The annual mailing of the new formulary guide; and
- Announcements of routine formulary changes (e.g., announcements of all changes to formulary since last update that the MCC could do in the normal course of business).

All Co-Promote programs must be vetted by a [CSP Attorney](#) to ensure compliance with relevant laws including privacy laws. The privacy analysis may hinge on factors such as the nature of the communication, the manner in which the Pfizer product is identified or implied, the audience to whom the communication would be targeted, the information used to target the message, and the nature of the remuneration or expenses covered by Pfizer. The [CSP Attorney](#) will consult with the Pfizer Global Privacy Office as needed to ensure compliance.

## Collaborations

A Collaboration is an arrangement between two or more parties who jointly work together toward a common public health goal. Periodically, Pfizer engages its Accounts in Collaborations on various health initiatives of mutual interest and value to both companies that have potential benefits to the health community at large. Unlike a Service Agreement, which is more of a vendor-type relationship, a Collaboration Arrangement documents a transaction of a more significant nature that involves contributions provided by each party. All Collaborations should be supported by an internal Pfizer business rationale and memorialized in a written contract. Collaborations entered into with Accounts by Account Managers and/or Field Medical colleagues are subject to review and approval by a [CSP Attorney](#) and the Intake Committee, as further described in Chapter 5. See Orange Guide Chapter 5: Interactions with Health Systems and Medical Groups for more information on Collaborations. Collaborations with not-for-profit entities are addressed in Pfizer's Standard Operating Procedure (SOP) [Funding Requests for Not-for-Profit Organizations](#). When entering into Collaborations, follow the rules and principles above that apply to non-discount arrangements with Accounts.



## Orange Guide – Chapter 15: Service Agreements and Other Non-Discount Arrangements with Accounts

Additionally, for any engagements with Specialty Pharmacy for specialty types of Service Agreements, please see Orange Guide Chapter 20.

### For More Information

- For more information about HIPAA, see Orange Guide - Chapter 8: Privacy: Protecting Personal Information.
- For Questions regarding FMV/FMV calculator tool, please refer to your [CSP Legal team](#) and/or aligned contact within PCA Customer Marketing, Regional Customer Marketing or Brand Marketing.
- General Questions regarding this chapter should be referred to your manager and/or the [CSP Legal Team](#).



## **CHAPTER #16 – CONSUMER, PATIENT, AND EMPLOYEE INTERACTIONS**



**Chapter**

**#16**

**CONSUMER, PATIENT, AND EMPLOYEE  
INTERACTIONS**

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## Chapter #16 Consumer, Patient, and Employee Interactions

### Introduction

All colleagues must provide truthful, accurate, and balanced product information to healthcare professionals (HCPs). It is equally important that you understand the rules that govern your interactions with consumers (including patients, potential patients, caregivers, and all other non-HCPs), as they are distinct from the rules that apply to your interactions with HCPs. Employees of patient associations or customer organizations, regardless as to whether they hold a professional healthcare degree, shall also be considered consumers and must be treated according to the guidelines in this Chapter.

Pfizer interacts with consumers at various types of events including speaker programs, health fairs, public health screenings, and disease management programs. A variety of laws and industry standards specifically govern your promotional interactions with consumers. These differ in some ways from the laws and standards governing your promotional interactions and activities with HCPs. Similar to interactions with HCPs, however, interactions with consumers can involve promotional risks, including the following:

- The U.S. Department of Health and Human Services Office of Inspector General (OIG) has warned that offering incentives, such as remuneration or free services, to consumers may implicate the federal anti-kickback laws.
- Some state attorney generals have interpreted state consumer protection laws to encompass off-label promotion.
- The Food and Drug Administration (FDA) has established stringent requirements regarding direct-to-consumer (DTC) communications.

Furthermore, the Pharmaceutical Research and Manufacturers of America (PhRMA) has issued guidance related to DTC advertising called *Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines* and PhRMA Principles of Interactions with Patient Organizations. This document provides guidance on ways to ensure that DTC communications provide accurate, accessible, and useful information to patients and consumers. Pfizer has committed to follow this guidance and has adopted its own *Guidance for the Implementation of the Updated PhRMA DTC Principles*.

Pfizer's goal when communicating with consumers is to provide useful and understandable information about conditions and treatment options that will help patients partner with their healthcare providers to make more informed decisions about their treatment.



As with HCPs, your discussions with consumers must comply with all FDA regulations, and all information provided to consumers must:

- Be consistent with product labeling;
- Be truthful and not misleading;
- Be supported by substantial evidence; and
- Appropriately balance the benefits of the product with its risks.

Colleagues are permitted to provide to consumers Review Committee-approved (RC-approved) disease state and product information approved for consumers in the following circumstances:

- Reactively, at consumer events such as community health fairs, health screenings, state fairs, and disease management events where Pfizer has the opportunity to set up a display or exhibit (If asked to participate at a patient association event where there is no display or exhibit opportunity, please consult your team attorney); and
- At speaker programs or presentations organized by Pfizer specifically for consumers, using RC-approved consumer slide decks and contracted HCP speakers or our trained Patient Affairs Liaisons (PAL).

**Non-compliance with the policies in this guide puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination of employment.**

#### ***Key Points to Ensure Compliance***

- When you interact with consumers:
  - Use only RC-approved materials intended for consumers and limit your discussion to the information contained in these materials;
  - Provide fair and balanced information;
  - Do not provide off-label information;
  - Do not provide advice to consumers about their condition or treatment. Refer consumers to their HCP to discuss treatment options;
  - Do not provide advice to consumers about access and affordability. Refer consumers to approved material, the applicable Product Hub or RX Pathways; and
  - Do not discuss competitor products, except to the extent that they have been included in RC-approved consumer materials.





### ***Key Points to Ensure Compliance***

- Pfizer is responsible for speaker conduct and all content presented at Pfizer speaker programs for consumers (whether branded or unbranded). The program and speaker must follow all applicable Centris requirements.
- Meals at consumer programs may not exceed \$50 per person (food, beverages, tax, and tip included).
- Always disclose that you are a Pfizer employee or representative when interacting with consumers. Wear your Pfizer name tag at all times.
- Non-HCP employees of customer organizations may also be considered consumers. Pfizer interactions with customer employees who are not HCPs (such as at a health fair) must follow the principles applicable to consumer interactions.

## **Patient Affairs Liaison (PAL) Activities at Consumer Events**

### ***Exhibits and Displays***

Pfizer is committed to providing information to consumers about their health and Pfizer treatment options. PAL are sometimes provided with opportunities to interact directly with consumers by working at Pfizer exhibits or displays at consumer events such as health fairs, patient advocacy events, and health screenings. The goal of these interactions should be to foster more informed conversations between patients and their HCPs about the patients' health and treatment options.

Always disclose that you are a Pfizer employee or representative when interacting with patients. Wear your Pfizer name tag at all times.

### ***Exhibit Fees, Food, and Booth Staff***

It is permissible to pay fair market value (FMV) for exhibit and display space at a consumer event. Pfizer may provide a very modest snack (e.g., fruit, granola bars, non-alcoholic beverages, or pastries) to those consumers who visit our exhibit. You are permitted to provide a snack only to those consumers with whom you interact, and any snack you provide to consumers should be consistent with the level of interaction you are having with them. It would not be appropriate for you to cover the costs of food items for all event attendees since you are permitted to provide food only to those consumers with whom you interact, and which are within the defined limits set forth in this chapter.



People who are not Pfizer employees, including HCPs, should not work or host at the Pfizer booth. Remember that field-based medical colleagues such as Field Medical Directors (FMD) generally have only very limited interactions with consumers, consistent with the [Green Guide](#) (e.g., interacting with representatives of patient advocacy groups).

### ***Venue***

The consumer event where you are displaying must be located at a neutral venue that is open to the public. (Note that a doctor's office is not considered open to the public). Pfizer-sponsored health screenings cannot be used to direct consumers to particular Pfizer products or to get people to ask their doctors about Pfizer products. Therefore, if Pfizer is also sponsoring a health screening at a consumer event, the exhibit booth and the health screening location must be physically separated, such as by a partition or by being in separate locations. If colleagues are exhibiting at an independent, third party sponsored educational event or conference, Pfizer promotional displays must also be separate from the educational presentation areas.

### ***Materials***

You may only use materials that have been RC-approved for use with consumers, and you must follow any accompanying instructions on use of the materials. For example, if only unbranded consumer materials have been RC-approved, you may not discuss or provide product information to consumers at the event.

### ***Exhibits at Health Screenings***

Colleagues may interact with consumers at exhibit booths located at health fairs, patient advocacy events, or health screenings. Screenings promote the early detection of diseases and offer patients a meaningful opportunity to treat a disease or condition. Colleagues who are present during any patient interactions must clearly identify themselves as Pfizer employees. Wear a Pfizer name tag at all times.

Only Payer Channel Access (PCA) group colleagues are permitted to fund health screenings. Please see Orange Guide Chapter 13: Health Screenings for further information.

### **Follow Pfizer's policies on the reporting of adverse events and other reportable safety information.**

If a consumer shares information about an adverse event, you must report it within 24 hours by phone (800-438-1985) to the Safety group. Refer to the section "Adverse Events and Other Reportable Safety Information" below for an explanation of other reportable safety information.

### ***Items of Value***

Pfizer may provide items of nominal value to consumers at exhibits, displays or public events that are approved by the relevant RC. Examples of such items include mugs, water bottles, and stress balls, that may be provided to consumers that visit a Pfizer exhibit or display, or at a public event where Pfizer sponsors a table. However, items of value may never be provided to solicit business or in a manner that



might suggest that the recipient is being bribed or improperly influenced. The OIG has defined items of “nominal value” provided to consumers as having a retail value of no more than \$15 per item or \$75 in the aggregate per recipient, on an annual basis.

### Educational Presentations to Consumer Audiences

#### ***Pfizer Contracted Speaker as Presenter***

A speaker program for consumer audiences, just like a speaker program for HCPs, is a promotional activity controlled by Pfizer at which contracted HCPs, PAL, approved internal medical speakers or contracted certified nurse educators present an RC-approved slide deck intended for consumers. Colleagues are not permitted to conduct a consumer program unless the relevant RC expressly allows it. As with speaker programs for HCPs, Pfizer is responsible for the conduct and the content of its promotional speaker programs to consumers and, therefore, colleagues must adhere strictly to Pfizer policies regarding consumer presentations and Centris procedures. An HCP speaker must not use the Pfizer program as an opportunity to promote his or her medical services or practice or to recruit new patients.

#### **Content**



Before you hold a speaker program for consumers, review with the speaker these important policies regarding the content of your planned program:

- Speakers must use only RC-approved consumer slide decks, and these slide decks must be used in their entirety. Slides cannot be deleted or created and inserted by the speaker under any circumstance.
- If the speaker is presenting an unbranded consumer slide deck, the speaker cannot discuss information about Pfizer products unless responding to an unsolicited question about the on-label use of a Pfizer product.
- The speaker must remain on-label when providing information about Pfizer products, even if the speaker receives a question from the audience about an off-label use of the product. Consumers are not trained medical professionals; therefore, the dialogue between an HCP speaker and consumers is not considered scientific exchange. The speaker should explain that the product is not indicated for the use described, and the speaker should refer the consumers to their healthcare providers for further information. If the speaker does not appropriately respond to the question, the Pfizer colleague is obligated to make a corrective statement and refer the consumers to their healthcare providers.
- The speaker cannot provide specific medical advice to a consumer attendee, even when the individual requests it. The speaker must refer the consumer to his or her healthcare provider.
- No discussion of competitor products is permitted at branded or unbranded talks unless specifically contained in the RC-approved consumer materials or slide deck.



- As with speaker programs for HCPs, speaker programs for consumer audiences must be a minimum of 45 minutes, inclusive of Q&A, for venue programs, and a minimum of 30 minutes for in-office programs.

#### Providing Copies of Materials

	Can I hand out copies of the consumer slide deck to consumers in attendance at my consumer program?
	No, you may not hand out copies of the consumer slide deck unless you have received clear guidance from the appropriate RC that this is permissible. However, you may hand out RC-approved consumer materials.

#### Attendees

The guidelines you must follow related to consumer attendees are somewhat different than those that apply for HCPs in attendance at speaker programs. In addition to the guidelines below, be sure to follow any specific guidelines provided by the brand team.

- **You must make a good faith effort to broadly advertise a consumer speaker program** you are holding, such that it will likely result in an audience of at least 3 patient-consumers. The three required attendees may not be composed of a mix of patients, caregivers, and family members. You must have three patient-consumer RSVPs in order to move forward with a consumer program. It is not permissible to hire a speaker to address a group of his/her own patients, or patients of a health system or practice for which he or she works.



**A roster must be completed in Centris for every consumer program held. The rosters must *not* include the *names* of any consumer attendees.** Only the total *number* of consumer attendees may be listed in the Consumer Attendance field. For consumer programs, if the HCP is a patient or a family member of a patient or if the HCP does not have a specialty in the disease state and is attending the program as a consumer or care-giver for a patient consumer, then you do not have to capture their name in the Consumer Attendance field. If the HCP has a specialty in the disease state and would be someone a rep would potentially call on or would be able to attend one of our HCP speaker programs due to their specialty in that disease state, then you must record their names in the Consumer Attendance field for disclosure purposes.

- As with speaker programs held for HCPs, the representative and speaker must confirm electronically in Centris that the program was held and that speaking services were provided. For rare disease consumer programs only, PAL have the responsibility to enter, monitor and close out the program in Centris.





- If you are distributing invitations for a mixed audience (consumers and HCPs), only consumer-directed invitations should be used (available from your Meeting Planner).

#### Presentations to a Mixed HCP and Consumer Audience

	If I organize a speaker program where both HCPs and consumers may be present, does the speaker have to use a Pfizer slide kit approved for a consumer audience?
	Yes. Pfizer must comply with existing FDA requirements and the PhRMA Code on DTC Advertising Principles when interacting with consumers. Therefore, where both consumers and HCPs attend a program, the speaker must use an RC-approved consumer slide kit to ensure Pfizer product information, particularly safety information, is presented in a way that consumers can understand. In addition, HCPs attending the presentation are subject to Pfizer's HCP Payment Disclosure policy (See Chapter 18: Meals, Educational Items, Greenstone Giveaways, and HCP Payment Disclosure).

#### Speaker Non-Compliance

	What do I do if a speaker does not conduct a program in compliance with Pfizer's policies?
	You must promptly and courteously provide clarification to the audience on any inaccurate or inappropriate information. This should be done immediately after the information has been presented and prior to any Q&A. In addition, if a speaker does not conduct a consumer program in compliance with Pfizer's policies, you must coach the speaker on the appropriate conduct and report the violation during the Centris closeout. Once you have done this, your manager will receive an e-mail notification regarding the violation.

#### Meals

Providing a modest meal at an educational speaker program is permissible. However, the cost of food, beverage, tax, and tip may *not exceed \$50 per attendee*. Entertainment or recreation may not be provided, and you should make a good faith effort to avoid using venues that provide entertainment (e.g., hotels, with casinos, golf courses and resorts).

Where there is a mixed HCP and consumer audience, the meal limit remains at \$40 per attendee, for both HCP and consumer attendees. Irrespective of recipient, meals may never be provided: (1) to solicit



business; (2) in a manner that might suggest that the recipient was being bribed or improperly influenced; or (3) to steer consumers to a particular HCP or pharmacy.

### Adverse Events and Other Reportable Safety Information

Follow Pfizer's policies on the reporting of adverse events and other reportable safety information. Reportable safety information includes information about the safety, performance, and quality of Pfizer products. Please see Chapter 2 of the OG, for Types of Reportable Safety Information. **Please refer to [Corporate Policy 903: Your Responsibility to Report Information about the Safety, Quality, and Performance of Pfizer Products](#) for a complete list of reportable information.**

If you become aware of reportable safety information, you must report it to the appropriate Pfizer contact within 24 hours. For product complaints only, please send an e-mail to: [PCGCentral@pfizer.com](mailto:PCGCentral@pfizer.com). For all other reportable safety information, submit the report by phone at **800-438-1985**, e-mail to: [USA.AEReporting@pfizer.com](mailto:USA.AEReporting@pfizer.com), or through Veeva CRM from your iPad. All reports of safety information should be forwarded regardless of the seriousness of the event, whether or not there is a causal relationship with the Pfizer product and whether or not the event is mentioned in the product label/instructions. Please provide as much information as possible in your report, including the consumer's name and contact information, if available, along with details of the event and patient's details (e.g., age, gender). However, do not delay submission of your report even if you have only limited information available.

For further information about your reporting responsibilities, please refer to [Corporate Policy 903](#) or the [Pharmacovigilance and Cosmetics Reporting Site](#).

### Employees as Consumers

Employers are increasingly involved in their employees' access and education to their healthcare including medication. As a result, Pfizer may have an interest in calling on employers to present information about Pfizer products relevant to the employer in making these decisions.

Employers often request that Pfizer interact directly with their employees in the interest of providing health education. These employees should be considered consumers, and it is important that Pfizer treat them as such. Accordingly, must ensure that it applies the same principles set forth in this Chapter to its interactions with those employees. As a reminder, all engagements with employees as consumers must be within the scope of your role.

### Providing Materials for Non-Pfizer Consumer Events

There are also situations in which colleagues may provide RC-approved consumer materials to third parties such as HCPs or patient groups for use in their patient education efforts. Colleagues can provide RC-



approved consumer materials for use at patient education programs that are organized and conducted by third parties. However, slide decks may not be shared unless the relevant RC has specifically authorized dissemination of the slide deck in this manner. You cannot offer any speaker payment or other financial support for these non-Pfizer patient education programs, including, but not limited to, providing food or equipment for these programs.

### Consumer Privacy

Pfizer recognizes the importance of safeguarding the confidentiality of Personal Information, including Sensitive Personal Information (SPI). SPI includes health-related information that, on its own or in combination with certain identifiers, such as name, birth date, or social security number, can be used to identify a specific individual. As a colleague, you must not collect or use SPI about consumers when you are interacting with them. In the event you encounter SPI in the course of interacting with a consumer, do not disclose or use such information for any purpose or in any manner that would compromise the confidentiality of such SPI. For a detailed discussion of privacy issues and the appropriate handling of Personal Information, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.

### Other Consumer Interactions

Consumer interactions that are not specifically described in the Orange Guide are not appropriate for you to engage in without specific guidance. Before engaging in any consumer interaction other than those outlined, please confer with your manager or team attorney.

### For More Information

- For more information on handling suspected adverse events, see [Corporate Policy 903, Your Responsibility to Report Information about Safety, Quality or Performance of Pfizer Products](#).
- For more information on speaker programs and additional speaker program resources, please refer the “Help” section in Centris.
- Questions may be referred to your manager or team attorney.



## **CHAPTER #17 – STATE LAWS: HCP AND STATE EMPLOYEE RESTRICTIONS**





**Chapter**

**#17**

**STATE LAWS: HCP AND  
STATE EMPLOYEE RESTRICTIONS**

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## Chapter #17 State Laws: HCP and State Employee Restrictions

### Introduction

States are increasingly enacting laws and regulations that impact our business and restrict our activities, including your interactions with HCPs and state employees. Many of these state laws are more restrictive than federal law and the generally applicable 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 states where they work because certain state laws may 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 but particularly those who may interact with HCPs with an active license in the states discussed in this Chapter and with state employees. This includes Account Managers who interact with various customer employees. Depending on the state, the law may apply to interactions with Account employees even when they are not practicing physicians, by virtue of their continuing to be licensed in the state or their responsibilities in the Account. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination of employment.**

**If a HCP is licensed in multiple states, the most restrictive state's rules will apply.**

If you have any questions about state healthcare compliance laws and HCP-related restrictions:

- Consult the State Law and Policies section on the [MyFieldNet Compliance page](#) or the State Healthcare Law Compliance section on [Global Policy Xchange on GCO On Demand](#);
- Send questions to [StateHealthcareLawCompliance@pfizer.com](mailto:StateHealthcareLawCompliance@pfizer.com); or
- Consult your team attorney.

If you have any questions about state employee gift restrictions:

- Consult with the appropriate Government Relations Director (GRD); or
- Consult your team attorney.



### Summary of Key State / City HCP-Related Healthcare Compliance Laws

State	Important Provisions of the State Law	Key Points to Ensure Compliance
<b>California</b>	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 California HCP.
<b>Chicago</b>	Individuals who market or promote prescription drugs to HCPs in Chicago must obtain a license. Individuals who promote prescription drugs in Chicago for fewer than 15 days per calendar year are exempt from the licensing requirement.  Licensed pharmaceutical representatives who market or promote pharmaceuticals listed on the CDPH website would need to provide a disclosure report.	Colleagues responsible for Chicago and who promote Pfizer products in Chicago for 15 days or more per calendar year must obtain a license. Licenses will be required starting July 1, 2017. Licenses must be renewed every year and continuing education requirements must be satisfied. Licensees will also be required to record certain information about their interactions with HCPs.
<b>Connecticut</b>	The Connecticut Compliance Program Law requires companies to adopt a marketing code of conduct – the PhRMA Code is acceptable.  Starting in 2016, companies must begin tracking payments or other transfers of value provided to Advanced Practice Registered Nurses ('APRN') authorized to practice independently (i.e., not in collaboration with a physician) for reporting.	Follow all Pfizer policies and procedures and the PhRMA Code.  Accurately and completely record all expenditures to all HCPs, including APRNs.



State	Important Provisions of the State Law	Key Points to Ensure Compliance
<b>District of Columbia</b>	<p>Individuals engaged in the practice of “pharmaceutical detailing” must secure a license to detail in person in D.C.</p> <p>Individuals who practice “pharmaceutical detailing” in D.C. less than 30 days per calendar year are exempt from this requirement. The D.C. Board of Pharmacy believes that the exemption may be claimed only by individuals detailing in D.C. “once a year for a short duration of time of less than 30 consecutive days.”</p> <p>Companies must report certain marketing costs.</p> <p>Members of the D.C. Medication Advisory Committee must not receive gifts, including meals or remuneration for speaking or consulting.</p>	<p>Colleagues whose territory or geographic responsibilities include D.C. must obtain a detailer license from the D.C. Board of Pharmacy, renew it every even numbered year, and attend Continuing Education courses.</p> <p>For Sales Colleagues providing meals in Washington, D.C., where the total cost per person exceeds \$25, all individuals partaking in the meal must be listed individually.</p> <p>Do not provide any gift or meal to any member of the Medication Advisory Committee, no matter how nominal the value.</p>
<b>Massachusetts</b>	<p>Adopt a marketing code of conduct consistent with Massachusetts regulations.</p> <p>Companies may not provide meals (including snacks or other refreshments) to MA-licensed HCPs <b>except</b> in the office or hospital setting when accompanied by an informational presentation <b>or</b> if provided in connection with a speaker program or symposia (limited exception for MA HCPs under bona fide service contracts with Pfizer, in connection with job interview, or at exhibit booths at large-scale conferences.).</p>	<p>In-office or in-hospital meals are permissible during educational presentations.</p> <p>Out-of-office “snacks” (as defined in Orange Guide Chapter 18) are prohibited.</p> <p>Pfizer may also provide modest meals at out-of-office speaker programs as well as at symposia taking place at a convention or congress setting.</p> <p>Pfizer may provide modest meals to MA-licensed HCPs in connection with bona service contracts or in connection with a job interview for prospective employment.</p>



State	Important Provisions of the State Law	Key Points to Ensure Compliance
	<p>Pfizer must give HCPs the opportunity to withhold prescriber data.</p> <p>Pfizer must annually report certain HCP expenditures to Massachusetts.</p>	<p>Refreshments or snacks at conference exhibit booths are permissible. If you are unsure whether an HCP has a MA license, check the <a href="#">HCP Lookup Tool</a>. You can also check Veeva CRM, which flags most (but not all) MA HCPs.</p> <p><b>You must make a good faith effort to determine whether an HCP is licensed in Massachusetts.</b></p>
Michigan	<p>Michigan state healthcare regulations require pharmaceutical manufacturers to link mid-level practitioners to supervising physician when requesting starters.</p>	<p>All starter requests recorded for Michigan Advanced Practice Registered Nurses (NP, CNS, CRNA, CNM, AN) and Physician Assistants (PAs) must include the supervising physician's name in the transaction's call notes in Veeva.</p> <p>When starters for controlled substances are included, the supervising physician's name and his or her DEA registration number must also be added to the transaction's call notes.</p>
Minnesota	<p>Gifts to practitioners are prohibited.</p> <p>Pfizer policy prohibits HCP meals to MN practitioners, including nominal meals and snacks. There is limited exception for: (i) for MN HCPs under bona fide service contracts with Pfizer; (ii) refreshments or other snacks at a convention/congress exhibit booth.</p> <p>Pfizer policy prohibits providing text books, journal subscriptions, online subscription services (e.g., Epocrates),</p>	<p>Do not invite MN practitioners to any speaker programs that provide meals (even if the program is outside of MN).</p> <p>Unless an exception applies, do not provide MN practitioners meals or snacks.</p> <p>Do not provide MN practitioners text books, journal subscriptions, online subscription services (e.g., Epocrates, including trial memberships), or anatomical models.</p>



State	Important Provisions of the State Law	Key Points to Ensure Compliance
	<p>and anatomical models, to MN practitioners.</p> <p>Pfizer policy also prohibits engaging MN practitioners as paid consultants, except for the following type of projects:</p> <ul style="list-style-type: none"><li>• Reasonable honoraria and expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting</li><li>• Substantial professional or consulting services of a practitioner in connection with a genuine research project</li><li>• Speaking and speaker training Pfizer must report permissible non-gift expenditures that exceed \$100/year.</li></ul>	<p>Do not engage MN HCPs as commercial consultants.</p> <p>Accurately and completely record all practitioner expenditures.</p> <p>If you are unsure of whether an HCP has a MN license, you can check the <a href="#">HCP Lookup Tool</a>. Also, Veeva CRM flags most (but not all) HCPs with MN licenses.</p> <p>You must make a good faith effort to determine whether an HCP is licensed in Minnesota.</p>
Nevada	<p>Nevada Marketing Code of Conduct requires companies to adopt a marketing code of conduct – the PhRMA Code is acceptable.</p> <p>Manufacturers must provide to the Nevada Department of Health and Human Services (DHHS) a list of pharmaceutical sales representatives who market prescription drugs on behalf of the manufacturer to licensed, certified, or registered health care providers, pharmacies and pharmacy employees, and operators or employees of medical facilities in the state at least once a year.</p>	<p>Follow all Pfizer policies and procedures and the PhRMA Code.</p> <p>Accurately and completely record all expenditures, as well as samples to NV HCPs.</p>





State	Important Provisions of the State Law	Key Points to Ensure Compliance
	Manufacturers must annually report to Nevada DHHS information about transfers of value and samples provided to Nevada covered recipients by registered pharmaceutical sales representatives.	
<b>New Jersey</b>	<p>Meals to a New Jersey prescriber must not exceed \$15 for breakfast or lunch promotional meetings and \$30 for dinner promotional meetings. These limits do not apply to Speaker Programs or Symposia as these programs are considered Educational Events exempt from the restrictions under the New Jersey rule. The restriction applies to Prescribers that practice in New Jersey or have New Jersey patients, regardless of the prescriber's practice site. There are limited exceptions for meals provided to New Jersey prescribers who are under a bona fide services contract with Pfizer or who are interviewing for a job at Pfizer.</p> <p>A New Jersey prescriber shall not accept more than \$10,000 in the aggregate from all pharmaceutical manufacturers in a calendar year for certain Bona Fide Services. Bona Fide Services impacted by the cap include: (1) promotional activities (does not include Speaker Programs); (2) participation on advisory boards; and (3) consulting arrangements. Payments for research activities and/or remuneration for travel, lodging, and other personal expenses</p>	<p>Do not provide NJ prescribers with meals over \$15.</p> <p>You must make a good faith effort to determine whether a prescriber is licensed in New Jersey.</p> <p>If you are unsure of whether a prescriber has a NJ license, you can check the <a href="#">HCP Lookup Tool</a>. Also, Veeva CRM flags most (but not all) prescribers with NJ licenses.</p>



State	Important Provisions of the State Law	Key Points to Ensure Compliance
	associated with the impacted Bona Fide Services are not subject to the \$10,000 annual aggregate cap.	
<b>Vermont</b>	<p>Vermont prohibits all HCP meals, including in-office meals and meals of nominal value (there is a limited exception for: (i) bona fide service contracts; (ii) refreshments or other snacks at a convention/congress exhibit booth; (iii) in connection with a job interview for prospective employment.</p> <p>Vermont also prohibits paid market research surveys involving VT-licensed HCPs. The restriction applies whether the survey is conducted directly by Pfizer or through an independent third party survey research organization.</p> <p>Pfizer must report certain HCP expenditures, as well as samples, coupons, and vouchers, to Vermont.</p> <p>Price Disclosure Forms must be provided to HCPs when detailing and posted on Pfizer's website.</p>	<p>Do not invite VT HCPs to any speaker programs that provide meals or snacks (even if the program is conducted outside of VT).</p> <p>Do not provide VT HCPs with meals or snacks (except in connection with a bona fide service contract, job interview or snacks at a convention exhibit booth).</p> <p>Do not engage VT HCPs as part of any paid marketing research surveys.</p> <p>Accurately and completely record all HCP expenditures, as well as samples, coupons, and vouchers provided to VT-licensed HCPs.</p> <p>Provide VT Price Disclosure Forms to HCPs as appropriate (available on <a href="#">MyPfizerNet</a>).</p> <p>If you are unsure of whether an HCP has a VT license, you can check the <a href="#">HCP Lookup Tool</a>. Also, Veeva CRM flags most (but not all) VT HCPs.</p> <p>You must make a good faith effort to determine whether an HCP is licensed in Vermont.</p>

### 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 \$65 from a company (as a whole, not by employee) <b>per year</b> .	Accurately and completely record all expenditures on state employees. Monitor spending per state employee and coordinate with your colleagues to ensure Pfizer is not spending beyond the \$65 annual limit.
Louisiana	State employees are prohibited from performing certain compensated services for pharmaceutical companies. State employees have a \$62 cap on food, drinks, and refreshments provided <b>during a single event</b> .	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 \$62 during the event.
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 (which the state interprets as no more than \$15) 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.
- Always remember that several state laws may apply regardless of where an interaction occurs.
- 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, MN, and NJ licenses. These restrictions apply to all Pfizer colleagues.



### ***Key Points to Ensure Compliance***

- 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.
- 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 Federal Employee Interactions and Lobbying Chapter in this Guide.
- 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 team attorney or to [StateHealthcareLawCompliance@pfizer.com](mailto: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 California Law.

### ***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. (Like text books, anatomical models etc.)

#### **The value of the following items are not included when calculating the annual aggregate limit:**

- Starters;
- Fair market value payments for services, such as speaking and consulting payments;
- RC-approved promotional literature such as clinical reprints and slim jims;
- Independent educational grants (financial support for continuing education forums);
- Financial support for educational scholarships; and
- Pfizer RC-approved marketing material.

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 team attorney with responsibility for California.

## **City of Chicago**

### ***The Law: Pharmaceutical Representative Licensing Ordinance***

The Chicago Pharmaceutical Representative Licensing Ordinance requires individuals who market or promote prescription drugs to HCPs, while both are physically within the City of Chicago, to obtain a license. Individuals who promote prescription drugs in Chicago for fewer than 15 days per calendar year are exempt from the licensing requirement. Licenses will be required beginning July 1, 2017.

E.g. If an Inside Sales Representative (ISR) is calling on a Chicago HCP via telephone while the ISR is physically in Chicago, then he/she should apply for a license (assuming he/she is doing this for 15 days or



more a year). If the ISR is never physically in Chicago while making the telephone calls, then the ordinance does not apply.

### ***How the Law Impacts Pfizer Colleague Activities***

Colleagues who promote Pfizer products in Chicago for 15 days or more per calendar year must obtain a license. It is the colleague's responsibility to renew the license annually and to remain in compliance with continuing education requirements. License applications will require the following:

- The applicant's full name, residence address, and residence telephone number;
- The applicant's business address and business telephone number;
- A description of the type of work in which the applicant will engage;
- Affirmation that the applicant completed the required professional education course; and
- \$750 licensing fee.

The initial professional education course and application are available on the Chicago Department of Public Health ("CDPH") [website](#).

Licensees will be required to abide by a code of ethics.

Pharmaceutical sales representatives who market or promote a drug listed on the CDPH [webpage](#) during the month that the representative is licensed must track their interactions with health care professionals regarding those drugs for potential disclosure, including:

- A list of health care professionals within Chicago contacted;
- The dates the health care professionals were contacted;
- The location and duration of contact;
- The pharmaceuticals promoted;
- Whether product samples were provided to the health care professional and the quantity provided;
- Whether promotional materials (e.g. brochures, demo models) were provided to the health care professional and the value of those materials; and
- The value of meals provided to the health care professional.

As of July 2017, the disclosure list includes only the category of **Schedule II medications**. Sales representatives who obtain licenses as of October 15, 2017 and do not promote or market a Schedule II drug will not have to track any interactions for the next year until license renewal, at which point they



must again see what drugs or drug categories are listed on the website. The Pfizer Transparency team will submit any required disclosures on behalf of the sales representative.

Chicago can impose significant penalties on Pfizer colleagues for failure to comply with this law, which may include fines of no less than \$1,000 and no more than \$3,000 per violation. If you have any questions concerning the Chicago Pharmaceutical Representative Licensing Ordinance, please contact the Sales and Marketing Attorney with responsibility for Chicago.

## 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 \$65 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 \$65 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 \$65 in items and meals from **Pfizer as a company** during any calendar year. (The \$65 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.

The following items are exceptions to the annual \$65 limit for Colorado state employees:

- Unsolicited 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;
- Unsolicited 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.

#### **Colorado Pricing Disclosure Requirements**

Colorado passed a Price Transparency law, effective August 2, 2019, requiring manufacturers to provide Colorado Licensed Prescribers, the Wholesale Acquisition Cost (WAC) price of their products, and at least 3 generic products in the same Therapeutic Class for any marketed product. Therapeutic Class is defined as “a group of similar drugs that have the same or similar mechanisms of action and are used to treat a specific condition”.

As a result of this new law, we are putting the WAC price for each product and any generic information on our website for it to be available publicly. The information can be found at [www.pfizer.com/coprescribers](http://www.pfizer.com/coprescribers).

Sales Representatives in Colorado are required to do the following:

- Show Colorado Prescribers the landing page of the website at first contact and at every detail; and
- Advise Colorado Prescribers that this is the landing page where they can get the most up to date information on WAC prices and any generic information relating to our products.

If you have any questions, please contact the team attorney with responsibility for Colorado.

#### **Connecticut**

##### ***The Law: Connecticut Compliance Program Law & APRN Disclosure 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 up to \$5,000.

Connecticut law also requires manufacturers to disclose payments and transfers of value provided to Connecticut-licensed Advanced Practice Registered Nurses (APRNs) who practice not in collaboration with a physician (i.e., independently). Definition of Advanced Practice Registered Nurse below for purposes of the Connecticut disclosure law is defined as:

- An APRN who practices “not in collaboration with a physician” (i.e., an APRN who practices independently); and
- Who appears in the Connecticut Department of Public Health annual APRN list, available at <https://portal.ct.gov/DPH>.

#### ***How the Law Impacts Pfizer Colleague Activities***

All colleagues who engage in activities with Connecticut APRNs should be aware that their expenditures on APRNs will be reported and ensure that transfers of value, including their reporting of attendees at speaker programs, is accurate and complete.

### **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:

- Food, gifts and other expenses of \$25 or less;
- Compensation for bona fide clinical trial activities;
- Scholarships and expenses for attending educational, scientific, or policy conferences if attendee is selected by the sponsoring organization; and
- Payments to D.C.-licensed HCPs for participating in blinded market research, if: a) the research is conducted by an "independent survey research organization;" b) the pharmaceutical client does not know the identity of the practitioners participating in the research; and c) the payments are determined and made by the survey research organization.

#### ***Definition of Healthcare Professional***

The D.C. definition of a Healthcare Professional (HCP) is broad. 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. As a result, T&E submissions for meals over \$25 per person to D.C. HCPs, must list all recipients partaking in the meal individually. D.C. can impose significant penalties on Pfizer for failure to comply with this law.

#### ***The Law: Pharmaceutical Detailer Licensing Law***

The Pharmaceutical Detailer Licensing Law 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. However, the law exempts individuals who engage in "pharmaceutical detailing" less than 30 days per calendar year from the requirement to obtain licensure.

The D.C. Board of Pharmacy interprets the exemption as only applying to individuals detailing in D.C. "once a year for a short duration of time of less than 30 consecutive days."



### ***Gifts to D.C. Medication Advisory Committee Prohibited***

D.C. law also prohibits offering a gift or remuneration of any kind to a member of the D.C. Medication Advisory Committee (DCMAC). Colleagues must not give anything of value to any DCMAC member (even if the item is RC-approved or would be acceptable for non-DCMAC members), including:

- 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 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](#) (Question 27).

### ***How the Law Impacts Pfizer Colleague Activities***

Colleagues whose territory or geographic responsibilities include D.C. and who detail HCPs in D.C. must complete and submit a license application to the D.C. Board of Pharmacy. These colleagues must have a valid pharmaceutical detailer license before calling on an HCP in D.C. 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.

Impacted colleagues will need to renew their license each even numbered year prior to the end of February. Colleagues should plan to submit their application by December 31st of the preceding year to allow adequate time for review and processing of your application prior to the deadline. As part of the license renewal application, you will need to attest that you have completed a minimum of 15 hours of continuing education during the two year period preceding the date the license expires. You must register for a "SafeRx Pharmaceutical Detail Licensing CE Program" through P2L. Once registered, you will receive a list of CMR training courses that are approved for CE under the SafeRx Pharmaceutical Detail Licensing Program. It can take up to two months to complete each course offered, and Pfizer will pay directly for home study courses taken with the CMR SafeRx Pharmaceutical Detail Licensing CE Program. If you have completed a CMR Certification or CMR Flex course post receipt of your pharmaceutical detailer's license, you should contact CMR at (800)328-2615 or [program@cmrinstitute.org](mailto:program@cmrinstitute.org) to determine if you already received renewal credit.



The District of Columbia can impose significant penalties on Pfizer colleagues for failure to comply with this law, which may include a fine of up to \$10,000 as well as penalties and sanctions. If you have any questions concerning the D.C. Prescription Drug Marketing Costs Disclosure Law or SafeRx please contact the Sales and Marketing Attorney with responsibility for the District of Columbia.

The Pharmaceutical Detailer Licensing Law requires licensure for any colleague **or speaker** who communicates with a licensed HCP located in DC, for the purpose of promoting a pharmaceutical product. Colleagues whose territory or geographic responsibilities include DC and who detail HCPs in DC must complete and submit a license application to the DC Board of Pharmacy.

The Pharmaceutical Detailer Licensing Law requires that any Speaker we engage to speak in DC obtain a Pharmaceutical Detailer License if they plan to speak **more than once** in DC, in a calendar year.

## 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 \$62 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, amongst others, 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.

*Public employee* is anyone, whether compensated or not, who is:

- An administrative officer or official of a governmental entity who is not filling an elective office;



- Appointed by any elected official when acting in an official capacity and the appointment is to a post or position the appointee is to serve either as a member or employee of the government or a governmental agency;
- Engaged in the performance of a governmental function; or
- Under the supervision or authority of an elected official or another employee of the governmental entity.

### ***How the Law Impacts Pfizer Colleague Activities***

Louisiana public servants cannot be engaged as promotional speakers for Pfizer.

The Louisiana Board of Ethics has stated, however, that a public employee can serve as a consultant (e.g., at a marketing advisory board) as long as the consultant services are related to his or her academic discipline or area of expertise and prior approval has been granted. For example, at LSU, the LSU chief administrative officer would need to approve such a consultancy. Further, if a public servant is involved in research with Pfizer, he or she can in most circumstances receive reimbursement for travel expenses for a Pfizer-sponsored clinical trial. Lastly, the Code of Governmental Ethics and Board of Ethics' rulings do not prohibit a public servant from speaking at a conference where Pfizer has provided an independent educational grant since Pfizer does not control the selection of the speaker or the content of the presentation, and the expenses at such an event would be paid by the conference organizer directly.

#### **Helpful Point**

If you are not sure whether a potential speaker is a Louisiana public servant, you must confirm their status prior to engaging the person as a speaker. If the person receives regular compensation directly from one of the institutions above, they are probably a “public servant” and would be prohibited from receiving compensation from Pfizer for speaking.

The cap on meal expenditures at any program in Louisiana where Pfizer is providing a meal and where there is at least one public servant present is \$62.

This Louisiana 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 team 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 restricts Pfizer's ability to provide meals and other items of value to HCPs licensed in Massachusetts (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. (Remember, Pfizer policy has a \$40 restriction on in office meals for breakfast and lunch which you need to comply with. Office staff are not required to be listed by name since our threshold is \$40 per meal.) 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 an annual audit and 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, as well as employees and agents of such persons (e.g., nurses, office staff, etc.). Examples of Massachusetts HCPs include:

- Physicians;
- Physician Assistants;
- Certified nurse midwife;
- Psychiatric nurse mental health specialists;
- Nurse Practitioners; and
- Employees and agents of such persons (e.g., nurses, office staff, etc.).



Massachusetts HCPs do **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 and individuals *are* considered Covered Recipients for MA disclosure, as described below.

### ***How the Law Impacts Pfizer Colleague Activities***

**All colleagues** (regardless of division, business unit, or role) who engage in activities with Massachusetts-licensed 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 Lookup Tool](#). Sales Colleagues can also access this information on Veeva CRM.

### ***Meals***

The Massachusetts Marketing Code of Conduct is more restrictive than the PhRMA Code with respect to the provision of meals to HCPs. Subject to the other requirements of Pfizer's policies, meals may be provided to MA HCPs in certain limited situations that are specifically identified in the following guidance.

- In-office or in-hospital meals are permissible during educational presentations.
- Out-of-office meals and "snacks" (as defined in Orange Guide Chapter 18) are prohibited.
- Pfizer may also provide modest meals at out-of-office speaker programs and at symposia taking place at a convention or congress setting.
- Refreshments or snacks at convention or congress exhibit booths are permissible.
- There is a limited exception for meals provided as compensation to Massachusetts HCPs who are consulting pursuant to a bona fide contract or meals provided at an investigator meeting whereby such costs are covered within the clinical study agreement or meals provided in connection with a job interview.
- FMDs or MOSs may not provide out of office meals to MA HCPs as the interactions they have do not meet the definition of "scientific exchange" in MA.

As a general matter meals are prohibited in all other situations that are not specifically identified in the guidance above.



Please see the Disclosure section below for T&E requirements for meals provided to Massachusetts HCPs and Covered Persons.

**Helpful Point**

Colleagues may provide modest meals to Massachusetts-licensed HCPs at Pfizer Speaker Programs or as part of an informational presentation in an HCP's office or a hospital setting.

There are also exceptions for meals provided as compensation under valid consulting or other contractual agreements, meals provided in connection with a job interview, and refreshments provided in a convention/congress exhibit 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 the [HCP Lookup Tool](#) or Veeva CRM. The meal and gift restrictions apply even when a Massachusetts-licensed HCP is located in another state.

**Other Prohibited Items of Value and Activities**

Generally, educational items may be provided to Massachusetts-licensed HCPs as long as they are RC-approved and consistent with the PhRMA Code.

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 process and standards associated with Independent Grants for Learning and Change (IGLC)) 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.





### **Disclosure**

Pfizer must track and report annually all expenditures made to Massachusetts Covered Recipients for sales and marketing activities that are \$50 or greater (**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 subject to the meal restrictions set forth above (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. Expenditures that do not need to be disclosed include those associated with rebates and discounts, genuine research, clinical trials, demonstration units, and starters. Disclosed data will be made publicly available on the state’s website.

Co-pay cards, coupons and free trial vouchers may be provided to MA residents or to providers or pharmacies for distribution to MA residents, subject to the following:

- Distribution of these offerings is prohibited for drugs that have an AB-rated generic equivalent (e.g., Lipitor).
- Colleagues must accurately record and track in Veeva CRM the distribution of these items to any HCPs.
- Coupon offers for all schedule II opioids, including Embeda, are prohibited.
- Marketing and other HQ teams developing these programs must abide with the other parameters outlined in the [Massachusetts Update on Loosened Co-pay, Coupon and Free Trial Voucher restrictions, dated August 8, 2012](#).

### **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.

## **Michigan**

### **Starters Policy for Mid-Level Practitioners**

Michigan state healthcare regulations require pharmaceutical manufacturers to link mid-level practitioners to supervising physician when requesting starters.

- All starter requests recorded for Michigan Advanced Practice Registered Nurses (NP, CNS, CRNA, CNM, AN) and Physician Assistants (PAs) must include the supervising physician’s name in the transaction’s call notes in Veeva.



- When starters for controlled substances are included, the supervising physician's name and his or her DEA registration number must also be added to the transaction's call notes in Veeva. Minnesota.

### ***The Law: Gift Restriction Law***

Minnesota prohibits Pfizer from offering or giving any gift of value to a Minnesota healthcare practitioner, as defined below in this section. The definition of "gift" includes any thing 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 (i.e. starters) ;
- 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 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 your team 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 in these circumstances. 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. Additionally, nominal snacks provided at educational/scientific conventions/congress exhibit booths are allowable and not considered banned gifts. 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**

Pfizer policy prohibits engaging Minnesota-licensed practitioners as consultants except with respect to the following types of projects:

- Reasonable honoraria and payment of the reasonable expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting. This does not include internal Pfizer meeting where the audience are Pfizer Colleagues; and
- Compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project.

Engaging Minnesota practitioners as consultants for any other purposes is prohibited without prior Legal approval.

### **Definition of Practitioner**

A "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, dental therapists, optometrists, podiatrists 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 subject to the gift restrictions but are considered covered recipients for state disclosure.



You should treat any Minnesota 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 except as noted herein.

### **How the Law Impacts Pfizer Colleague 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. Refreshments and snacks provided at educational/scientific conventions/congress exhibit booths are also allowed. These types of meals are not considered a “gift” under the state statute.

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 Tool](#). Sales Colleagues can also access this information by looking up the HCP on their Veeva CRM tablet or iPad. Note that Veeva CRM flags most (but not all) MN HCPs.

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 team attorney with responsibility for Minnesota.

#### **Helpful Points**

Colleagues must not offer or give any gift of value to a Minnesota HCP, including certain educational items (e.g. textbooks).

Colleagues must not provide meals or refreshments to Minnesota HCPs, except in the limited instance for certain HCPs under contract with Pfizer or at a congress/convention exhibit booth, as detailed above.

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 the [HCP Lookup Tool](#) for a list of Minnesota HCPs, as noted above.

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).

### ***Pharmaceutical Sales Representatives Registration***

- Pharmaceutical manufacturers are required to provide Nevada DHHS with a list of sales representatives that market prescription drugs to Nevada Covered Recipients (including, but not limited to, Nevada HCPs, pharmacies or employees thereof, and employees of medical facilities). The updated guidance applies to Sales Representatives and District Business Managers ("DBMs") only. Sales Representatives include Inside Sales Representatives (ISRs) and Contracted Inside Sales Representative (CISRs). These are colleagues who detail customers remotely over the phone/web.
- Sales Representatives who reside in Nevada or visit Nevada for 5 days or more annually must be listed on the Nevada Registry prior to conducting business in Nevada.
- ISRs and CISRs must register in NV only if they physically visit NV 5 days or more annually or reside in NV.
- Manufacturers must submit a complete list of all Sales Representatives employed during the previous calendar year annually by January 15. Additionally, manufacturers must provide updates to the Department, as personnel changes occur.



### ***Pharmaceutical Sales Representative Annual Disclosure Report***

On or before March 1 of each year, Pfizer, on behalf of each Sales Representative or District Manager listed on the Nevada Registry, is required to submit a report listing Nevada covered recipients who have been provided a sample or transfer of value greater than \$10 or total transfer of value that exceeds \$100 aggregate for the previous year.

The information provided in the Disclosure Report includes:

- The Sales Representative registry ID;
- The name, credential, NPI, and zip code of the NV covered recipient;
- The date of the interaction;
- The type and amount of transfer of value provided; and
- The product, NDC and quantity of the sample provided.

### **New Jersey**

The Law: The state of New Jersey has placed restrictions on Meals and Consulting Arrangements between New Jersey Prescribers and Pharmaceutical Manufacturers. The law impacts the way Pfizer engages New Jersey Prescribers and restrict Pfizer's ability to provide meals to a New Jersey Prescriber. The law applies to all Pfizer colleagues who interact with New Jersey Prescribers who practice in NJ or who have NJ patients. For practical purposes we will consider New Jersey Prescribers practicing in New Jersey's neighboring states, New York, Pennsylvania and Delaware as potentially having New Jersey patients. This law is more restrictive than the PhRMA Code but does not affect Pfizer's reporting obligations under Open Payments ("Sunshine Act"). Pfizer will continue reporting all meals and other transfers of value required under the Sunshine Act to the Federal Government. All colleagues must ensure that their records on these expenditures are accurate and complete.

### ***How the Law Impacts Pfizer Colleague Activities***

You must make a good faith effort to determine whether an HCP is a Prescriber in New Jersey or has NJ patients. To help you determine whether an HCP is a prescriber in New Jersey, you can check the [HCP Lookup Tool](#). Sales Colleagues can also access this information by looking up the HCP in Veeva CRM.

### ***Definition of a New Jersey Prescriber***

The definition of a New Jersey Prescriber is broad. It includes any New Jersey Prescriber who holds an active New Jersey license and, either practices in New Jersey or has New Jersey patients, regardless of the Prescriber's practice site. New Jersey Prescribers include:



- Physicians;
- Physician assistants;
- Podiatrists;
- Advanced Practice Nurses;
- Dentists; and
- Optometrists.

### **Meals**

Providing meals to New Jersey Prescribers must meet the following conditions:

- Meals provided at promotional meetings may not exceed \$15 for breakfast or lunch and \$30 for dinner.
- The above meal limits apply to in-office, in-hospital and out of office meals but **do not** apply to Speaker Programs and Symposia as these are considered educational events exempt from the restriction.
- The restriction applies to all Pfizer colleagues, not just Field Commercial Colleagues.

There are limited exceptions for meals provided to New Jersey Prescribers that are under a Bona Fide Services contract with Pfizer, if the Prescriber is provided a meal as part of a job recruiting process or if refreshments and snacks are provided at educational/scientific conventions/congress exhibit booths.

### **Consulting Engagements with New Jersey Prescribers**

**New Jersey Prescribers are also subject to the following restrictions with respect to Bona Fide Services they provide:**

- A New Jersey Prescriber shall not accept more than \$10,000 in the aggregate from all pharmaceutical manufacturers in a calendar year, for Bona Fide Services.
- Bona Fide Services include participation on advisory boards and consulting arrangements.
- Being the speaker at a Speaker Program is educational and not considered a promotional activity and thus not subject to the cap. (A Speaker Program is where an approved speaker, typically an external healthcare professional under contract with Pfizer, presents information on products, disease states, or other healthcare topics to a group of appropriate attendees.)
- Payment or remuneration for travel, lodging, and other personal expenses associated with Bona Fide Services are not included in the \$10,000 aggregate cap.

## **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, amongst others, 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. Bear in mind that an HCP with a private practice could also be a New York officer or employee.

#### ***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 food and beverage items of nominal value (e.g., doughnuts, cookies, and non-alcoholic beverages such as soft drinks and coffee) which are not part of a meal. New York interprets “nominal” as a value of \$15 or less.

#### **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 team attorney with responsibility for New York.

#### **Vermont**





### ***The Law: The Prescribed Products Law***

The Vermont Prescribed Products Law significantly restricts Pfizer's ability to provide meals and other items of value to Vermont healthcare providers (HCPs). These laws are more restrictive than the PhRMA Code. They apply to all colleagues and extend to interactions with Vermont HCPs occurring outside of the State of Vermont. Pfizer is required to disclose these expenditures to the State of Vermont.

**In certain circumstances, Pfizer has an obligation to self-report to the State of Vermont if any colleague inadvertently provides 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](mailto: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; and
- Members of the Green Mountain Care Board (whether or not they are licensed HCPs).



### ***How the Law Impacts Pfizer Colleague 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 Tool](#). Sales Colleagues can also access this information by looking up the HCP in their Veeva CRM tablet or iPad. Note that Veeva CRM flags most (but not all) VT HCPs.

### ***Meals***

All meals to Vermont HCPs are prohibited. This prohibition includes the provision of coffee and doughnuts, 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 and those provides in connection with a job interview. 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;
- Authorized expenditures related to clinical trials; and
- Compensation at fair market value for bona fide consulting services, including research and product development meetings.



### **Marketing Research**

The Prescribed Products Gift Ban and Disclosure Law prohibits Pfizer from providing payments to Vermont-licensed HCPs in connection with marketing research surveys (including blinded surveys).

Paid market research surveys involving Vermont-licensed HCPs are banned. The restriction applies whether the survey is conducted directly by Pfizer or through an independent third party survey research organization.

#### **Helpful Points**

Vermont prohibits 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 or in connection with a job interview.

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 [the HCP Lookup Tool](#) for a list of VT HCPs or look up the HCP in the Veeva CRM as noted above.

The meal and gift restrictions apply even when a VT HCP is located in another state.

### **Disclosure of Expenditures to Vermont HCPs**

Most allowable expenditures to Vermont HCPs, or other institutions covered by the law (e.g., Vermont academic institutions, Vermont nonprofit hospital foundations, and professional, educational, and patient organizations representing or serving health care providers or consumers in Vermont), must be disclosed, regardless of the amount.

This includes tracking and disclosing the distribution of samples, coupons, and vouchers. 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 an interview by a manufacturer in connection with a bona fide employment opportunity; and
- 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 HCPs, 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).

Both the long and short Vermont price disclosure forms may be accessed at <http://www.pfizer.com/vtprescribers/>.

The following table identifies which forms are required in connection with typical promotional activities.

Promotional Activity	Action Required
Face-to-face meeting with HCPs (detailing, exhibit booths, professional conferences) in Vermont.	Provide short form to each HCP for each product promoted or detailed.
Mailing to HCPs.	Include short form with mailing for each product promoted.
Telephone calls.	Inform Vermont HCP 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 team attorney with responsibility for Vermont.

#### For More Information

- Refer any questions to the team attorney with responsibility for the relevant state.



**CHAPTER #18 – MEALS,  
EDUCATIONAL ITEMS,  
GREENSTONE GIVEAWAYS, AND  
HCP PAYMENT DISCLOSURE**



**Chapter**

**#18**

**MEALS, EDUCATIONAL ITEMS,  
GREENSTONE GIVEAWAYS, AND  
HCP PAYMENT DISCLOSURE**

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## Chapter #18 Meals, Educational Items, Greenstone Giveaways, and HCP Payment Disclosure

### Introduction

**The Pharmaceutical Research and Manufacturers of America (PhRMA) Code** on Interactions with Healthcare Professionals ([PhRMA Code](#)) 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 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.

As of August 1, 2013, pharmaceutical manufacturers operating in the United States are required to report to the government payments and other transfers of value made to U.S.-licensed physicians and teaching hospitals in accordance with the transparency provisions of the Patient Protection and Affordable Care Act (PPACA), which are commonly referred to as “the Sunshine Act” or “Open Payments” provisions.

These disclosure obligations are reflected in [Pfizer's HCP Payment Disclosure and State Reporting SOP](#), which is broader than the Sunshine Act provisions because certain states have different definitions on HCPs and reporting standards, and individuals other than those covered by the Sunshine Act can influence or cause the administration, prescription, purchase, or recommendation of prescription medicines.

Certain state laws and federal institutions create additional restrictions and disclosure obligations regarding payments and other items provided to U.S. HCPs, as described in the State Laws: HCP and State Employee Restrictions Chapter 17 and the Federal Employee Interactions and Lobbying Chapter 4 in this Guide. HCP payment disclosure is just one of the many ways Pfizer is fulfilling its commitment to increased transparency and public candor.

**This Chapter addresses Pfizer policies regarding the provision of payments, meals, educational items, or anything else of value to U.S. HCPs or certain institutions. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination of employment.**





### ***Key Points to Ensure Compliance***

- Pfizer's Field Force T&E Expense Procedure can be found on [MyPfieldNet](#).
- Except where restricted by law or Pfizer policy, a Pfizer colleague may provide food and beverage to HCPs if the value is modest by local standards. For out-of-office meals, the total cost cannot exceed \$135 per attendee, including tax, tip, and delivery charges. For in-office or in-hospital meals, the total cost, including tax, tip, and delivery charges, may not exceed \$40.
- When an educational or promotional presentation includes a modest meal, the meal must never be 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. Only individual HCPs and office staff members who attend an educational presentation can partake in the meal.
- The PhRMA Code prohibits Sales representatives and their immediate supervisors from hosting out-of-office meals for HCPs, outside of speaker programs. Senior Sales Colleagues (above District Manager level), and Headquarters colleagues (including Marketing, HQ Medical, and senior business leadership) are not subject to this restriction and may host restaurant or other meals following the rules of this Chapter as long as there is a legitimate business reason. Account Managers (see chart below for definition) may provide out-of-office meals to HCPs who do not regularly treat patients, following the rules of this Chapter.
- 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, approved educational items, and other transfers of value provided to HCPs. Pfizer also discloses payments to certain institutions, as well as payments related to clinical research, which are attributed to the principal investigators.
- Certain state laws and federal institutions (e.g., VA/DoD) also limit and/or require the disclosure of payments and items of value provided to HCPs. These laws and restrictions are described in the State Laws: HCP and State Employee Restrictions Chapter and the Federal Employee Interactions and Lobbying Chapter in this Guide. Additional information is also available on Global Policy Xchange on GCO On Demand under the State Healthcare Law Compliance tab and on MyPfieldNet under the Compliance tab.



### ***Key Points to Ensure Compliance***

- Licensed prescribers in Minnesota or licensed HCPs in Vermont, or employees of a Vermont HCP, may not be invited to any speaker program (in-office or out-of-office) if food will be provided. Other reportable HCPs, including physicians, have the option to “opt out” of eating a meal at a speaker program where a meal is provided, in which case the value of the meal will not be reported for them.
- HCPs may permanently “opt out” of being offered meals, snacks, or educational items by contacting [PTI@Pfizer.com](mailto:PTI@Pfizer.com). If a HCP has permanently “opted out” but nonetheless accepts payments, meals, or other disclosable items of value from Pfizer, they will be subject to disclosure. Disclosures pursuant to the Sunshine Act are posted on the Open Payments website maintained by CMS at <http://www.cms.gov/OpenPayments/index.html>.
- Colleagues who interact with HCPs are responsible for verifying their “opt out” status. Sales Colleagues should consult the HCP profiles on Veeva CRM to view an HCP’s “opt out” status. A permanent “opt out” list, accessible to all colleagues, is also available on [Global Policy Xchange on GCO On Demand](#) and [MyPfieldNet](#).
- Colleagues must correctly record in the applicable finance and payment system(s) information necessary to identify institutions and HCPs and the payments or items of value provided to them.
- In-scope payments or other transfers of value provided to U.S.-licensed HCPs and certain U.S. institutions through external parties, such as Contract Research Organizations (CROs) and Contract Sales Organizations (CSOs), are also 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: (1) the meal is modest as judged by local standards, (2) the meal is never the primary focus of the interaction; and (3) the presentation occurs in a venue and manner conducive to informational communication. Recreational and entertainment venues are prohibited. In addition, under Pfizer policy, **out-of-office meals to U.S. HCPs cannot exceed \$135 per attendee (including the cost of food, beverage, tax, tip, and delivery charges) and meals in an in-office or in-**



**hospital setting cannot exceed \$40 (including food, beverage, tax, tip, and delivery charges).** Any pre-dinner food or beverages must be included in the \$135 cap and reported for purposes of the Sunshine Act. No other expenses (e.g., room fees) may be paid to the office or hospital in connection with meals conducted in an in-office or in-hospital setting. Meal costs for meals with HCP attendees may not be split or divided between internal colleagues or with individuals who are employed by co-promote partners.

Providing alcoholic beverages to HCPs in excess or not as part of a meal is prohibited, as it is not conducive to providing scientific or educational information or other business purposes.

The PhRMA Code restrictions on out-of-office meals apply only to sales representatives and their immediate managers. If and when Pfizer colleagues are permitted to provide meals to HCPs varies based on each colleague's role, but always requires a legitimate business reason. The table below provides a high-level summary:

	Host restaurant meals?	Host in-office meals?	Host in-hospital meals?	Host speaker program meals?	Host meals at conventions ?
<b>Sales Representative</b>	No	Yes	Yes	Yes	No
<b>District Manager</b>	No	Yes	Yes	Yes	No
<b>Regional Business Director, Regional President, National Sales Lead</b>	Yes	Yes	Yes	Yes	Yes
<b>Greenstone and Sterile Injectables</b>	Please see Business Meals Provided by Greenstone and Sterile Injectables Colleagues Section				
<b>Account Manager, including AD, DE, KAM, VAM, ADM (only if such colleague does not directly supervise Sales representatives)</b>	Only for non-HCPs or HCPs who do not regularly treat patients or fill prescriptions	Yes	Yes	Yes	Only for non-HCPs or HCPs who do not regularly treat patients or fill prescriptions
<b>HQ Marketing/Medical</b>	Yes	Yes	Yes	Yes	Yes



## Orange Guide - Chapter 18: Meals, Educational Items, Greenstone Giveaways, and HCP Payment Disclosure



For instance, with very limited exceptions, no meals (in-office or out-of-office) may be provided to Vermont HCPs or Minnesota prescribers unless specifically approved by Legal. Further, no out-of-office meals or snacks may be provided to Massachusetts HCPs (subject to a limited exception for meals or snacks provided in connection with speaker programs or at symposia or exhibit booths at a convention or congress). Additionally, for New Jersey prescribers, breakfast or lunch meetings may not exceed \$15 and dinner meetings may not exceed \$30. These limits for New Jersey prescribers do not apply to speaker programs or symposia where food and refreshment may be provided. Refer to the State Laws Chapter for more information on New Jersey restrictions. The VA also prohibits colleagues from providing food items of any type or value to VA staff (including volunteers) at VA facilities, or bringing food into VA facilities for use by non-VA staff, even if a colleague receives approval from on-site staff.

You cannot provide any food or other support in connection with an accredited continuing medical education activity (ACCME, ACPE, or ANCC). Note that "medical education" is not limited to medical education for physicians but also includes education for other HCPs, including pharmacists. Any type of financial support for accredited continuing education, including payment for event expenses or meals, must be funded through an independent professional education grant. Requests for these grants should be sent by the requestor through Pfizer's Global Medical Grants. If certain prerequisites are met, there may be an opportunity for an exhibit or display at an accredited continuing medical education activity. For more information, see Exhibits and Displays below; [Funding Requests for Not-for-Profit Organizations, USFR-SOP-01-02](#); and [Exhibits and Displays SOP 2-01](#).

Before providing any meals or other items of value to HCPs, colleagues should refer to the State Laws: HCP and State Employee Restrictions Chapter and the Federal Employee Interactions and Lobbying Chapter in this Guide. To determine whether an HCP is licensed in Massachusetts, Minnesota, New Jersey or Vermont, Sales Colleagues should consult the physician profiles on Veeva CRM, and other colleagues should search the [HCP Lookup Tool](#). Additional information on state law restrictions and other tools are available under the [Compliance tab on MyPfizerNet](#) and under the [State Healthcare Law Compliance tab](#) on GCO PolicyXchange.



#### Account Manager Out-of-Office Meals with HCPs

	Can a KAM host an out-of-office meal with an HCP who serves as the medical director of a hospital system?
	It depends. Account Managers such as KAMs can provide out-of-office meals to an HCP who is not regularly treating patients. For pharmacists, to be eligible for an out-of-office meal with a colleague who is permitted to host, they must be not regularly filling patient prescriptions. Typically, an HCP or pharmacist who treats patients or fills prescriptions one day per week or less (i.e., no more than 20% of the time) is not "regularly treating patients." As always, there must be a legitimate business reason (related to the HCP's responsibilities outside of treating patients) for meeting over a meal, and the interaction must be conducted in accordance with the provisions of this Chapter, including any other state law or restriction.

#### Meals Provided by Field Sales Colleagues and Their Immediate Managers

Under the PhRMA Code, 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 times a Sales representative or their immediate manager may provide out-of-office meals to HCPs are at Pfizer speaker programs where trained speakers (generally paid external HCPs) present RC-approved information about Pfizer products, disease states, or other healthcare topics, using content controlled by Pfizer. Sales representatives and their immediate managers are prohibited from providing out-of-office meals to HCPs under any other circumstances. Further, it is impermissible to pay for HCP meals at an activity such as independent **continuing medical education (CME)** where the content is not controlled by Pfizer. For more information about speaker programs, see Orange Guide Chapter 9: Speaker Programs for HCPs and White Guide Chapter 4: Marketing Programs.



It is inappropriate for a Pfizer colleague to include an HCP's spouse or other guest in any Pfizer-provided meal, unless the spouse or guest is otherwise an appropriate attendee under Pfizer policies.

It is never appropriate for a Pfizer colleague to offer "take-out" meals or meals to be eaten without the Pfizer colleague present. Meals must be incidental to the provision of informational presentations and discussions. Therefore, only individual HCPs and office staff members who have a role in patient care and engage in an educational discussion with the Pfizer colleague can partake in the meal. For this reason, and to ensure proper reporting for disclosure purposes, Pfizer colleagues should instruct HCPs and their staff not to unwrap or consume meals provided by Pfizer prior to the arrival of a Pfizer colleague.









Meals where you anticipate a large number of attendees (e.g. >15-20 attendees) may require additional pre-planning and discussion with your manager about logistics to ensure there is a meaningful opportunity to engage in educational discussions with **all** HCPs and office staff members who partake in the meal, and to ensure accurate disclosure. Every office operates in a different way, so you should identify the precise circumstances you will encounter and how to best manage the meal. You might consider inviting another Pfizer colleague to assist or conduct a single presentation to provide education to all attendees at the same time, while ensuring that they can see and hear a fair and balanced presentation. You are not permitted to conduct a meal if you cannot ensure there will be a meaningful opportunity to provide information or education to all attendees who partake in the meal.

#### “Meals” Defined


	Does taking an HCP out for a cup of coffee constitute a meal?
	<p>No. Under Pfizer policy, food or beverage items of nominal value (\$10 per attendee or less) – such as coffee, other non-alcoholic beverages, or pastries, are considered a snack and not considered a meal. Pfizer policy permits a Sales representative or their immediate manager to make an occasional educational presentation to an HCP out of the HCP’s office or hospital (such as in a coffee shop near the HCP’s office), along with offering a snack (not a meal), in circumstances where meals are not permitted in an in-office or in-hospital setting, unless further restricted by state law or other laws or policies.</p> <p>Offering a snack (as defined above) out of an HCP’s office or hospital should be reserved for situations in which it is not possible to provide food or beverage in an in-office setting and limited to only one or two HCPs at a time. It should not replace an in-office educational presentation incidental to a meal where permitted.</p> <p>In all cases, the value of any food or beverages provided to a U.S.-licensed physician, regardless of amount, is potentially subject to the requirements of the State Laws Chapter. In addition, these activities may also require public disclosure by Pfizer. Thus, the Pfizer colleague providing the item of value must properly record the expense as described later in this Chapter.</p>



#### Providing a Meal to Office Staff

	If a Pfizer colleague is bringing lunch to a medical office for HCPs to eat during a product discussion, can the colleague also provide lunch to non-HCPs (e.g., office staff) in attendance?
	Yes, the PhRMA Code provides that when conducting in-office (“lunch and learn”) programs for HCPs it is permissible to provide the meal to members of an HCP’s staff who also attend the presentation or otherwise receive educational information unless further restricted by state law or other laws or policies.
	Can a Pfizer colleague provide lunch to HCPs or medical office staff who do not attend the informational presentation or receive educational information?
	No, “take-out” meals are prohibited. Any individual who consumes a meal must receive educational information incidental to their meal. If an HCP or office staff member unexpectedly steps away or excuses themselves without receiving an educational presentation, the hosting colleague should schedule a near-term follow-up to ensure the information is conveyed.
	Can a Pfizer colleague set up a monthly appointment, in an HCP’s office, that includes a meal or snack?
	Maybe. If there is a business rationale to provide educational information, it is appropriate to provide a meal or snack approximately once a month to the same attendees. Under the PhRMA Code, meals may only be provided to HCPs on an occasional basis. Providing a meal or snack more than once a month may be appropriate if there is new information to share or different attendees.

#### Providing “In-Office” Meals to Remotely-Based Customers

	How is “in-office” meal defined for customers who are based remotely? Can a Sales Colleague or their immediate manager host a non-restaurant meal in temporary meeting space rented by customers who do not have a corporate office?
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#### Providing “In-Office” Meals to Remotely-Based Customers



Sales Colleagues and their immediate managers are limited to providing an “in-office” meal under the PhRMA code to ensure the meal is incidental to a substantive interaction and in the setting where the HCP typically conducts professional conversations. Some HCP customers are field-based without a formal corporate office, e.g., retail pharmacy managers (licensed pharmacists who manage a territory of chain pharmacies for large retailers). These customers occasionally rent hotel or other meeting space to conduct business. In such instances, the customer-rented space, excluding all restaurants and restaurant meeting rooms, may be considered “in-office” for purposes of this Chapter, as that is where the customer conducts professional conversations.

If the customer-rented space is at a restaurant or restaurant meeting room, it is not considered “in-office,” and you may not provide a meal at such a location. Sales representatives and their immediate managers may only expense a meal at the customer-rented location incidental to a promotional presentation and in accordance with all requirements of this Chapter; no other expenses such as the meeting space rental may be incurred. As with other “in-office” promotional opportunities, Pfizer colleagues must follow all Pfizer policies for detailing and should leave the customers’ meeting space after the promotional discussion and incidental meal are concluded, in no way involving themselves in the customers’ other business dealings. If colleagues have questions or concerns about promotional opportunities with remotely-based customers, including the provision of meals, they should consult with their team attorney.

#### Providing in-Hospital Meals



What qualifies as an appropriate “in-hospital” meal? Can a Sales representative or their immediate manager host a meal at a hospital food court or a cafeteria within the hospital complex?





An in-hospital meal takes place in offices, conference rooms, or hospital locations that are considered part of the hospital complex. Sales representatives or their immediate managers 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. No other expenses (e.g., room fees) may be paid to the office or hospital in connection with meals conducted in an in-hospital setting.





#### Providing Meals to Pharmacists

	May you provide a meal to a pharmacists or pharmacy technicians?
	Yes, however you may not provide a meal to a pharmacist or pharmacy technician in Vermont. For Massachusetts, Nevada and D.C., pharmacists and pharmacy technicians must be disclosed individually.

#### ***Meals Provided by Senior Sales Colleagues, Headquarters Colleagues, and Account Management Colleagues Permitted to Host Out-Of-Office Meals***

All colleagues are subject to the general rules and restrictions set forth at the beginning of this section. However, the PhRMA Code restriction on out-of-office meals is not applicable to senior Sales Colleagues above District Manager level, Headquarters (HQ) (e.g. Marketing, HQ Medical, senior business leadership) colleagues, or Account Management colleagues for meals with non-HCPs or HCPs who do not regularly treat patients. These colleagues may provide *occasional* modest food or beverage items 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. "Insight Meals" are a type of out-of-office meal with unpaid HCP attendees. All out-of-office meals hosted by senior Sales Colleagues, HQ colleagues, and Account Management colleagues, including those previously identified as Insight Meals, must follow the requirements of this Chapter.

#### **Legitimate Business Reason**

To determine whether the legitimate business reason requirement is satisfied, colleagues hosting such meals should determine whether the proposed interaction is consistent with their role and responsibilities, and whether an interaction over a meal is an appropriate way to achieve their goals and objectives. Some examples of legitimate business purposes might include a discussion regarding local market payer challenges, account dynamics, or understanding how HCPs manage a particular disease state. It would not be a legitimate business purpose to host a meal solely to build a relationship with an HCP or to facilitate the introduction of one HCP to another.

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.



Further, for **all** Sales Colleagues, it is presumed that discussions regarding unapproved indications for Pfizer products, pipeline products, or disease states or therapeutic areas for which Pfizer has no product, are impermissible and thus cannot constitute a legitimate business reason for hosting or attending a meal with an HCP.

### **Meal Planning & Execution**

All out-of-office meals must follow the requirements below:

1. In general, attendance should be limited to no more than 3 HCP attendees at an out-of-office meal to ensure that there is a meaningful opportunity for the hosting colleague to engage with all attendees to meet their objectives. If the hosting colleague believes there is a legitimate justification for including more than 3 HCPs, they should discuss with their manager and align on how the host will ensure there is a meaningful opportunity for them to engage with all attendees.
2. The host must have a legitimate business objective for the interaction and consider having a list of topics and questions or other presentation to facilitate the legitimate business discussion with the attendees for each meal. The host should assess whether the information to be gathered is needed and ensure it is not duplicative of information already available. The materials should be discussed, prior to the meal, with the host's manager, and reviewed as needed, by the team attorney, GPC and/or brand medical depending on their content, and consistent with REG-08. The host's legitimate business objectives should be made available upon request to the host's manager in connection with their review of the colleague's expenses.
3. Any materials and questions to be utilized to facilitate the discussion must be on-label and consistent with overall brand strategy, unless you are a colleague who is permitted by Pfizer policy to engage with HCPs regarding an unapproved product or indication, or disease states or therapeutic areas for which Pfizer has no product. Colleagues should consult their team attorney for any questions regarding whether the topics to be discussed at a proposed meal with an HCP are appropriate.
4. To the extent you are aware that multiple Pfizer colleagues (e.g. RBDs from different geographies or colleagues from both Marketing and Sales) wish to discuss the same topic or use the same materials with different HCPs, the colleagues must all coordinate to ensure that the overall number of events and HCP attendees is appropriate to achieve the business need.
5. Following the meal, consistent with guidance on information sharing between functional roles, the host must share the information gathered with the Brand Team or other Pfizer colleagues, as appropriate, to determine how the information will be utilized to further Pfizer's business. Potential hosts should use these deliverables and insights to assess the need for future meals for the same geography, disease state or product.



***Attendance by Other Colleagues at Meals Hosted by Senior Sales, HQ, and Account Management Colleagues***





When determining who may be in attendance for an out-of-office meal hosted by an appropriate colleague, you must always ensure that the topics of discussion are appropriate for all colleagues in attendance and the ratio of Pfizer colleagues to HCPs is conducive to the business discussion. For example, Senior Sales or HQ colleagues should not discuss a proposed speaker agreement with an HCP in the presence of a sales representative or District Manager. The number of colleagues in attendance for meals hosted by a Senior Sales, HQ, or Account Management colleague must be limited to the minimum necessary to facilitate an appropriate business discussion with all external attendees.

Because sales representatives and District Managers are not permitted to host out-of-office meals under the PhRMA Code, their attendance at out-of-office meals hosted by Senior Sales or HQ colleagues must be carefully considered. The decision to include a sales representative and/or District Manager should be based on their specific expertise relating to the customer, account, or local dynamics and only permitted if necessary, to assist the Senior Sales or HQ colleague in meeting their objectives in an introductory meeting with an HCP. Once an introduction has been made, future attendance by sales representatives and/or a District Manager at a meal with that same HCP would generally be unnecessary. The Senior Sales colleague or HQ colleague must provide a clear justification to their immediate manager for any additional meals with the same HCP and sales representatives and/or District Managers. Sales representatives and District Managers may not attend out-of-office meals for the purpose of conducting promotional activities or discussions that they cannot host on their own (e.g. detailing at a restaurant) or to meet their own objectives of building a relationship with an HCP. The legitimate business reason for the meal must be to meet the objectives of the hosting Senior Sales or HQ colleague, not the objectives of the sales representative or District Manager in attendance.



Any attendance by medical colleagues (HQ or field-based) should be consistent with guidance on joint commercial-medical activities in this guide and the [Green Guide](#). Medical participation is subject to review and approval by the team attorney as well as the GPC (if needed). Sales representatives and medical colleagues may not attend the same out-of-office meal without prior consultation with the team attorney or GPC.



#### Sales Colleagues Attending Non-Speaker Program Restaurant Meals

	An Account Manager plans to provide a restaurant meal to an HCP C-Suite executive who does not regularly treat patients for an appropriate business discussion focused on the delivery of patient care or similar topics related to the HCP's primary role as an administrator or executive. Would it be acceptable for a Sales representative to accompany the Account Manager?
	The circumstances under which this would be appropriate are extremely rare. A Sales representative may only join an Account Manager who is permitted to provide out-of-office business meals if the topics of discussion are appropriate for all colleagues in attendance and in accordance with Pfizer policies on joint interactions. Those policies generally permit Sales representatives to participate in joint meetings with an Account Manager and the customer on an infrequent basis when there is a legitimate business need to do so and the programs or materials to be discussed are RC-approved for joint sales and account management customer interactions. Colleagues should consult their team attorney for any questions regarding appropriate attendees at an out-of-office meal based on the topics for discussion.
	May a Sales representative or District Manager attend a restaurant meal with an HCP if there is no appropriate colleague present, but the parties each agree to pay their own way?
	No, this would not be in the spirit of the PhRMA Code or Pfizer policy.

#### Legitimate Business Reason

	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?
	Yes. This would be considered a legitimate business purpose since it is 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 provide a modest meal incidental to the discussion, unless restricted by state law. For more information, see the State Laws: HCP and State Employee Restrictions Chapter in this Guide.



### Business Meals Provided by Greenstone and Sterile Injectables Colleagues

Greenstone Colleagues and Sterile Injectables Colleagues (Sterile Injectables SHRs, DBMs, and Sales Directors) who do not provide clinical detailing of products may host off-site business meals or snacks for non-HCP customers and HCPs who hold administrative positions and dedicate very little time, if any, to seeing patients or filling prescriptions, generally following the sections on “Meals to HCPs” and “Meals Provided by Senior Sales Colleagues, Headquarters Colleagues, and Account Management Colleagues Permitted to Host Out-Of-Office Meals.” If there is doubt as to whether a particular customer’s role is administrative, please consult with your manager or Legal/Compliance contact. In addition, any local, state, or hospital policies or restrictions must be considered to ensure compliance. Inclusion of a customer’s spouse or other guest in the meal is not appropriate unless the spouse or guest has a legitimate independent business reason to attend.

Off-site meals must be modest by local standards, occasional, and cannot exceed \$135 per attendee — including the cost of food, beverage, tax, and tip. A meal should never be the primary focus in speaking with customers; the central focus must be the business discussion, with the meal being incidental to that primary purpose. In addition, providing excessive or solely alcoholic beverages is prohibited, is considered not conducive to a business discussion, and is presumed recreational.



For all in-office or in-hospital meals provided to non-HCP customers, such meals must be modest and occasional, and may not exceed a total cost of \$40, including tax, tip, and delivery charges. For all in-office or in-hospital meals provided to HCP customers, please follow the guidance found at the beginning of this chapter in the “Meals to HCPs” section.

Before providing any meals or other items of value to customers, colleagues should refer to the State Laws: HCP and State Employee Restrictions Chapter and the Federal Employee Interactions and Lobbying Chapter in this Guide.



	Host restaurant meals?	Host in-office meals?	Host in-hospital meals?	Host speaker programs?	Host meals at conventions?
<b>Greenstone and Sterile Injectables Colleagues with Administrative Customers</b>	Only for non-HCPs or HCPs who do not regularly see patients or fill prescriptions. See guidance found in "Meals to HCPs" and "Meals Provided by Senior Sales Colleagues, Headquarters Colleagues, and Account Management Colleagues Permitted to Host Out-Of-Office Meals" sections above.	Yes. See guidance found in "Meals to HCPs" section above.	Yes. See guidance found in "Meals to HCPs" section above.	Yes	Only for non-HCPs or HCPs who do not regularly see patients or fill prescriptions. See guidance found in "Meals to HCPs" and "Meals Provided by Senior Sales Colleagues, Headquarters Colleagues, and Account Management Colleagues Permitted to Host Out-Of-Office Meals" sections above.

#### In-Office/In-Hospital Meals for Greenstone and Sterile Injectables Customers

	I am meeting with an HCP with a purely administrative role. We are meeting in his office. What can I spend?
	All in-office or in-hospital meals must be modest by local standards and may not exceed a total cost of \$40, including tax, tip, and delivery charges. Keep in mind that additional local, state and hospital restrictions may apply.



#### Educational Items to HCPs

In accordance with the PhRMA Code and Pfizer policy, RC-approved educational items valued at \$100 or less 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.). Educational items that do not directly benefit a patient or are not intended to be used by or with a patient, such as textbooks and reprints, are reportable under the Sunshine Act. If you have a question about whether a specific educational item is approved to be provided to HCPs, consult the relevant product Legal or Regulatory colleague, or submit your question to [StateHealthcareLawCompliance@pfizer.com](mailto:StateHealthcareLawCompliance@pfizer.com).



Further, as with meals, several states and the VA/DoD also impose limitations which are stricter than the PhRMA Code or Pfizer policy on educational items (and other items of value) that may be provided to HCPs. For instance, to ensure compliance with Minnesota state law, Pfizer policy prohibits colleagues from providing certain educational items to prescribers licensed to practice in that state. Before providing educational items to HCPs, colleagues should refer to the State Laws: HCP and State Employee Restrictions Chapter and the Federal Employee Interactions and Lobbying Chapter in this Guide. For further information, and to determine where an HCP is licensed to practice, consult the [HCP Lookup Tool](#) and the other references available on [Global Policy Xchange on GCO On Demand](#) under the "State Healthcare Law Compliance" tab and on MyPfizerNet under the Compliance tab. Sales Colleagues should also consult the State Law Restriction field in Veeva CRM.

#### Out-of-Pocket Gifts for HCPs

	Can I pay for a gift for an HCP out of my own pocket if I do not expense it?
	No. It is not appropriate to purchase personal gifts, or any other items of value for HCPs in the course of doing business, even if you pay out-of-pocket and do not seek reimbursement from Pfizer. The gesture could appear to be an attempt to illegally influence prescribing in violation of anti-kickback laws. This principle applies to any item of value expensed personally, including meals. Remember that <a href="#">The Summary of Pfizer Policies on Business Conduct (the "Blue Book")</a> and <a href="#">Corporate Policy (CP) #203: Conflicts of Interest</a> require you to avoid even the appearance of a conflict of interest.


#### Greenstone Giveaway Items

Items of nominal value, such as pens, may be distributed by Greenstone Colleagues at booths at trade shows and conferences, provided the criteria listed below are met.

- The majority of attendees at the trade show must be non-HCPs or non-practicing HCPs (e.g., GPO meetings, wholesaler trade shows, pharmacy buyer conventions); and
- No other Pfizer brands with clinical detailing messages are represented at the event.

Giveaway items must not, under any circumstances, be distributed in the field (e.g., at hospitals or to practicing pharmacists), nor may these items be made available through the PROMOS online catalog or other sources accessible by all colleagues.

#### Giveaway Items for Greenstone Colleagues

	Can Greenstone Colleagues offer pens at their booth during a trade show?
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#### Giveaway Items for Greenstone Colleagues



Yes. Greenstone Colleague may offer giveaway items of nominal value at a booth or table at meetings and conventions. However, Colleagues must ensure that there are no other Pfizer brands being promoted with clinical detailing messages at the same event (no “detailed” products are displayed), and the majority of the attendees at the meeting or convention are non-HCPs and/or non-practicing HCPs. Prior to arranging to distribute giveaway items at an event, please contact the convention or meeting organizers to confirm that no other Pfizer teams will be attending and exhibiting detailed products.

#### HCP Payment Disclosure Policy

##### Overview

Consistent with its commitment to transparency, in 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 and to U.S. institutions in connection with clinical research, along with the names of the associated principal investigators. Pfizer disclosed on its public website payments and the value of meals, reimbursable travel expenses, and educational items that it provided to U.S.-licensed prescribers and institutions between 2010 and 2014.

Since the Sunshine Act became effective, Pfizer has been disclosing payments in accordance with that law. These disclosures are available on CMS’s Open Payments website at <https://www.cms.gov/OpenPayments/index.html>. The **SUPPORT Act**, which was signed into law, expands the Sunshine reporting requirements effective **January 1, 2021** to include these additional covered recipients:

- Physician Assistants;
- Nurse Practitioners;
- Clinical Nurse Specialists;
- Certified Registered Nurse Anesthetists; and
- Certified Nurse-Midwives.

**Pfizer’s disclosure policy is broader than the requirements of the Sunshine Act and defines “HCP” more broadly than the definition found in the Act. This is so because certain states have different reporting standards, and individuals other than those described in the Sunshine Act can influence or cause the administration, prescription, purchase, or recommendation of prescription medicines.**





The disclosure policy affects any colleague who provides payments, meals, or non-cash items or services of any value to healthcare professionals (including, among others, licensed U.S. prescribers and U.S. clinical investigators) or to U.S. institutions who may employ such healthcare professionals. Colleagues must be familiar with the policy and should proactively discuss our disclosure policies with all U.S. healthcare professionals and institutions to whom they intend to provide disclosable payments or items of value, to ensure they are aware that such payments and other transfers of value may be disclosed.

### ***Items Included in Reporting***

Pfizer's disclosures may include the following types of payments and non-cash items provided directly or indirectly to a broad range of U.S. healthcare professionals and institutions:

- Meals (including snacks/refreshments);
- Business travel expenses;
- Educational Items (e.g., textbooks and reprints);
- Research support (all payments or transfers of value related to R&D, such as clinical site payments, study drug, and equipment that is leased, loaned, or given):
  - Investigator-Sponsored Research (ISR);
  - Non-interventional/Observational Studies;
  - Pre-clinical Research;
  - Phase I-IV Pfizer-Sponsored Clinical Studies;
  - Clinical Research Collaborations (CRCs); and
  - Outcomes Research Studies.
- Consulting Fees and Honoraria;
- Promotional Speaking Fees;
- Publication support (e.g., editorial support provided by an agency);
- Charitable Contributions;
- Grants; and
- Royalty and License Payments.



### Reporting of Indirect Payments or Other Transfers of Value

Under the Sunshine Act, Pfizer must report any indirect payment or transfer of value it requires, instructs, directs, or causes to be provided to a covered recipient. That includes payments where Pfizer knows or expects that a covered recipient would receive any portion of its payment or transfer of value, even if Pfizer does not specify or know the identity of the recipient.

For instance, in-scope payments and transfers of value to U.S.-licensed physicians or teaching hospitals that are processed through third-party entities, such as **Contract Research Organizations (CROs)** or **Contract Sales Organizations (CSOs)**, are disclosable under the Sunshine Act. Also, if Pfizer were to give a medical professional society funds that were earmarked for the purpose of awards or grants to U.S.-licensed physicians, the awards or grants would be indirect payments to covered recipients and thus subject to the reporting requirements, even if Pfizer did not influence or know which physicians would receive a grant or award.

### 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 consulting and advisory boards, promotional speaking, clinical trials, and other studies or projects. Pfizer may also compensate HCPs by paying or reimbursing reasonable travel expenses incurred in connection with these activities and others, such as employment interviews, including airfare, hotel accommodations, and ground transportation. Disclosable travel expenses reflect either the actual sums expended for a specific HCP's accommodations or, if the activity or event requires the attendance of multiple HCPs, may reflect a proportionate allocation of travel expenses.

All compensation to U.S. HCPs is required to correspond to **bona fide services** provided pursuant to **written agreements**. See White Guide Chapter 5: HCP and Government Official Consulting Engagements and the Clinical Research and Investigator-Sponsored Research (ISR) Chapter in this Guide for more information on common engagements involving monetary compensation.

### Disclosure of the Value of Meals



As described in this Chapter, colleagues are permitted to provide occasional modest 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 or Pfizer policy, Pfizer's disclosures include all meals provided to U.S.-licensed HCPs, regardless of value. Although not treated as "meals," snacks and refreshments of nominal value (\$10 or less per attendee) must be appropriately recorded in expense reports, as directed in this Chapter.

When meals are provided in connection with an informational presentation to a group, the disclosable value is calculated by taking into account both actual and expected attendees. Therefore, to ensure appropriate



accounting for the per-person value, all attendees who partake in the meal (HCPs and non-HCP office staff), as well as all expected attendees and those who do not partake in the meal but did attend, should be tracked. (See Pfizer's Field Force T&E Expense Procedure is available on [MyPfieldNet](#).)

#### Disclosure of Snacks and Refreshments Provided at Exhibit Booths

	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 (\$10 per attendee or less) available. Do I need to track and report the refreshments provided to U.S.-licensed HCPs visiting the Pfizer booth?
	No. As a general rule, snacks and refreshments of nominal value do not need to be tracked at an exhibit booth when conducted in a large-scale convention or conference setting (greater than 50 attendees).

#### 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 \$100 or less may be provided on occasion to U.S.-licensed HCPs. The value of these educational items (such as textbooks) is included in Pfizer's public disclosures. Note that reprints and other educational materials that enhance an HCP's skills are considered reportable transfers of value under the Sunshine Act.

Generally, Pfizer-created branded and unbranded promotional materials, literature and other leave-behind written materials are **NOT** subject to disclosure under the Sunshine Act. Likewise, items that are to be used by or with patients, such as an anatomical model or patient education materials, are **NOT** disclosable under the Sunshine Act. However, some of these items are subject to disclosure under state laws (e.g., Vermont). Accordingly, all of these items must be tracked for business purposes. Such items include:

- Co-pay cards;
- Savings cards;
- Pill dispensers;
- Brochures;
- Vouchers;
- Prescription stamps; and
- Pamphlets.



### Recording Disclosable Payments and Items

Colleagues must properly record **all** payments, meals (including the number and classification of attendees), and other items that may be disclosable, **regardless of value**, as part of the regular expense reporting process. Colleagues are expected to:

- Obtain **full and complete names, titles, addresses, and state license numbers 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 **information about payments and non-cash items** given to U.S.-licensed HCPs is accurately recorded in the appropriate system (e.g., Ariba ePay and Purchase Orders; PT&E's "My HCP", "HCP", "Other HCP" categories; Centris's "Attendee" section; CVENT Attendee registry; Veeva CRM);
- Classify budgets and expenses using 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 lack full names and appropriate expense allocation.

### Identifying HCP Meal Attendees in Sales Colleague Expense Reports



A Sales Colleague has provided an in-office meal to a mixed group including both physicians who are on and not on her TCL, as well as office staff. Which individuals must the Sales Colleague identify by name in her meal expense report?



All individuals who are **licensed to prescribe medicines in the United States** must be identified by name in the meal expense report, regardless of whether they appear on the colleague's TCL. These include doctors of medicine or osteopathy, medical residents, dentists, podiatrists, optometrists, chiropractors, and advanced practice nurses, such as nurse practitioners and physician assistants, who are legally authorized to prescribe by the state in which they practice. Non-prescribers, including registered nurses and office staff, do not need to be identified by name, except for any individuals who are licensed to provide healthcare or are employees or agents of licensed prescribers in Nevada, Massachusetts or Washington, D.C. (including non-prescribing nurses, pharmacists and office staff) must be named for state reporting purposes. For meals taking place in Washington D.C. where the total cost per person exceeds \$25 all individuals partaking in the meal must be listed individually. For further information regarding appropriate use of the travel & expense system, Sales Colleagues should consult the Pfizer Travel & Expense guidelines available on [MyPfieldNet](#). Please also see the State Laws: HCP and State Employee Restrictions



### Identifying HCP Meal Attendees in Sales Colleague Expense Reports

Chapter in this Guide, for further details on who qualifies as an HCP in Nevada, Massachusetts and D.C.

### Opting Out of Receiving Disclosable Items

If a U.S.-licensed HCP expresses a desire to opt out of receiving food, beverages, or other disclosable items, the notified colleague must: (1) immediately make Pfizer aware of the opt out by e-mailing all relevant information to [PTI@Pfizer.com](mailto: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](mailto:PTI@Pfizer.com).

It is critical for Pfizer colleagues to 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**.” An HCP who does not want to have items reported should not be *offered* – and must not *accept* – any payments, food, or other disclosable items from Pfizer. Pfizer maintains a record of HCPs who have “opted out” of receiving disclosable items from Pfizer on [MyFieldNet](#) and [Global Policy Xchange on GCO On Demand](#).

**If a U.S.-licensed HCP accepts a disclosable payment or item of value**, that information will be subject to disclosure **regardless of any prior opt out request**.

If an HCP who has opted out subsequently chooses to opt back in, the notified colleague or the HCP should contact [PTI@Pfizer.com](mailto:PTI@Pfizer.com).

### Access and Use of Open Payments and other Transparency Data for Analytics

The Transparency team has created resources, which include CMS Open Payments competitor and Pfizer internal payment datasets, that enable certain analyses and business insights. For specific data requests or information regarding access to these datasets and dashboards for analytics, please visit the [Payment Transparency Portal](#) or contact the Transparency team directly at [GlobalTransparencyAnalytics@pfizer.com](mailto:GlobalTransparencyAnalytics@pfizer.com). If you have questions about the appropriate use of data please consult your BU, Divisional or Functional Compliance Lead.

### Understanding the Opt Out Process







Can a Sales representative provide a meal to an office with multiple HCPs, if some HCPs have opted out and others have chosen not to opt out?







Generally, yes. However, any HCPs in the office who have opted out may not consume the meal.



### Understanding the Opt Out Process

	What happens if an HCP who has previously opted out eats a meal that was provided for other HCPs in the office or at a joint meeting or event?
	The HCP must be informed that any meals consumed will be reported, and the HCP's name must be included in the list of attendees in the relevant expense system (e.g., PT&E), so that an appropriate portion of the meal expense can be allocated to that HCP.
	An HCP is willing to provide consulting services for zero compensation, including no travel expense reimbursements. Will this arrangement be subject to disclosure?
	Probably not. The HCP should still sign a "zero fee" consulting agreement to memorialize the terms. Please contact <a href="mailto:ENGAGE2@pfizer.com">ENGAGE2@pfizer.com</a> or your team attorney with any questions.

### The Disclosure Process

	Will U.S.-licensed HCPs have the opportunity to review their Sunshine Act data before it is posted on the CMS Open Payments website?
	Yes. After Pfizer submits data to CMS, and prior to the information becoming public, HCPs have a 45-day period to review their data and raise inquiries with Pfizer. Pfizer then has an additional 15 days to investigate and respond.
	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?
	Pfizer has a dedicated staff to address transparency questions and concerns. Colleagues should email questions to <a href="mailto:PTI@pfizer.com">PTI@pfizer.com</a> . If the HCP has a concern about a particular transaction disclosed on Open Payments, please direct the HCP to raise a dispute in the Open Payments portal directly or send an email to <a href="mailto:HCPDispute@pfizer.com">HCPDispute@pfizer.com</a> .



### For More Information

- For more information about the PhRMA Code, refer to the PhRMA website at <http://www.phrma.org/codes-and-guidelines/phrma-code-on-interactions-with-healthcare-professionals>.
- For more information on Pfizer's meal and educational item guidelines based on the PhRMA Code, including an FAQ on the PhRMA Code, refer to the [PhRMA Guidelines tab on Global Policy Xchange on GCO On Demand](#), or e-mail [StateHealthcareLawCompliance@pfizer.com](mailto:StateHealthcareLawCompliance@pfizer.com)
- For more information regarding processes for capturing and recording promotional meals in PT&E, refer to the guidance available on MyPfieldNet at [http://MyPfieldNet.pfizer.com/workspace/Documents/PTE\\_Entering\\_in\\_a\\_Promotional\\_Meal\\_Expense.pdf](http://MyPfieldNet.pfizer.com/workspace/Documents/PTE_Entering_in_a_Promotional_Meal_Expense.pdf).
- To determine whether an HCP is licensed in Massachusetts, Minnesota, New Jersey or Vermont, Sales representatives should consult the physician profile within Veeva CRM, and other colleagues should consult the [HCP Lookup Tool](#). Additional information on state law restrictions and other tools is available under the [Compliance tab on MyPfieldNet](#) and under the [State Healthcare Law Compliance tab on Global Policy Xchange on GCO On Demand](#).
- For more information on Pfizer's HCP transparency practices, including its U.S. HCP Payment Disclosure and State Reporting SOP, refer to the [HCP Payment Disclosure tab on Global Policy Xchange on GCO On Demand](#) or e-mail [PTI@Pfizer.com](mailto:PTI@Pfizer.com).
- For more information on the National Physician Payment Transparency Program (Open Payments) under the Affordable Care Act of 2010, commonly known as the Sunshine Act, and its implementing regulations, refer to the guidance available on the [CMS website](#).
- For more information on Open Payments, please see <https://www.cms.gov/OpenPayments/About/Law-and-Policy.html>.
- More information on Pfizer's Field Force T&E Expense Procedure is available on [MyPfieldNet](#) and by [clicking here](#).



## **CHAPTER #19 – HEALTH INFORMATION TECHNOLOGY ENGAGEMENTS**





**Chapter**

**#19**

**HEALTH INFORMATION TECHNOLOGY  
ENGAGEMENTS**

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## Chapter #19 Health Information Technology Engagements

### Introduction

Pfizer's customers are increasing their use of Health Information Technology ("HIT"), particularly Electronic Health Records ("EHR") systems. Pfizer engages with customers regarding their EHR systems in many ways, offering both branded and unbranded resources ("HIT Tools") and associated messaging. HIT engagements seek to provide education about products or disease states, to promote Pfizer products, or to expand the market in therapeutic areas where Pfizer has a public health goal as well as a business interest.

In order to manage legal risks appropriately, it is important for all Field Commercial Colleagues to understand: (a) what HIT Tools Pfizer may provide to customers; (b) which Pfizer Field Commercial Colleagues may provide HIT Tools to customers; and (c) appropriate messaging about HIT Tools:

- If a colleague gives – or could be perceived as giving – a customer a HIT Tool or expertise as an inducement for prescribing or recommending a Pfizer product, then that could implicate state and federal anti-kickback statutes.
- Further, if an offering of value inadvertently affects or could appear to affect the prices of Pfizer products that a customer is purchasing, that could cause Pfizer to inaccurately report the price of its products in its submissions to the federal government under the Medicaid Drug Rebate Program and other health care programs (e.g., Best Price).
- Field Commercial Colleagues should deploy only those HIT Tools approved by the relevant RC specifically for their role. RC approval of HIT Tools is tailored to both the customer type and the role of the Pfizer colleague delivering the Tools based on their HIT expertise. Some HIT Tools are intended for Sales Colleagues, while others are only appropriate for use by Account Managers. Implementation of and messaging about these Tools should remain within the scope of their intended audience and purpose.
- Discussion around and implementation of both branded and above-brand HIT Tools must be consistent with any relevant Pfizer product's FDA approved labeling.
- Pfizer has payment disclosure obligations under the federal Sunshine Act and in some States. Generally, the HIT Tools are designed not to have value that would require a disclosure. In certain circumstances involving HIT Specialists, the provision of HIT Tools and expertise may constitute a reportable transfer of value to the customer. When a disclosure may be necessary, you should discuss the matter with the customer prior to the provision of the Tools in question.



Since HIT engagements with customers carry legal risk, require proper training and expertise, and potentially require a disclosure, Field Commercial Colleagues must always take care to ensure that any customer engagement regarding HIT is consistent with Pfizer policy and is properly implemented.

#### **Key Points to Ensure Compliance**

- You may use approved HIT Tools. It is your responsibility to ensure the material you intend to use has received appropriate approval before use with customers, and that the material remains current and approved for your intended use. Additionally, ensure that you use the materials in accordance with any guidance or instructions relating to the use of such materials.
- When offering or providing approved HIT tools or resources, do so without any expectation of financial return to Pfizer. Do not condition the offer or provision of a program on increased prescribing or improved formulary status.
- To avoid the potential implication of pricing and/or Kick-Back risks, avoid combining different types of transactions. Do not discuss HIT tools and resources in connection with formulary discussions. Do not attempt to leverage any additional (e.g., non-formulary) arrangements in order to secure preferential formulary status.
- Ensure that your use of HIT Tools is consistent with their approved purpose and your role as a Field Commercial Colleague. Do not engage in HIT related medical activities that MOS or FMD Colleagues typically engage in, such as discussing appropriate diagnostic codes/clinical content. Similarly, Sales Colleagues and Account Managers should not engage in technical discussions around HIT Engagements that HIT Specialists typically conduct.

#### **Core Compliance Principles for HIT Engagements**

The Core Compliance Principles apply to HIT engagements. As a reminder, those Core Compliance Principles as applied here are as follows:

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



### ***Use only RC-Approved Materials***

Both Pfizer and you could be held responsible for what you say or show to customers in the scope of your employment, and that could include HIT Tools and related messaging. When engaging a customer on any HIT topic, whether branded or unbranded, you must adhere to the following guidance:

- Use with customers only materials that have been approved by the relevant Review Committee (RC) for that use.
- HIT Tools should be used only by the Field Commercial Colleagues for whom they are approved. Sales Colleagues should only use RC-approved HIT Tools available to them through [PROMOSprime](#) or Veeva CRM. Similarly, Account Managers and the members of their Account Team (which can include Medical Outcome Specialists or your Business Unit's equivalent) and HIT Specialists should only use RC-approved HIT Tools. Colleagues may not alter RC-approved materials except where specifically authorized by the RC. For example, an RC approved template may permit a colleague to customize a HIT resource by inserting the customer's name.
- Approval for one purpose does not mean approval for all purposes. Resources approved for a particular customer may only be used with that customer.
- Customer discussion and implementation of some HIT Tools will require input from Medical colleagues. See below for further discussion and consult your team attorney if you require guidance on when to involve field-based Medical.
- In limited circumstances, your team attorney may allow for the use of certain customized resources that have not been RC approved. This will occur most frequently in the context of workflow assessments collaborations, and discussions leading to a collaboration. See below for additional information on workflow assessments and collaborations with an HIT component.

### ***Stay On-label***



Pfizer may only promote FDA-approved products and FDA-approved uses and dosing of its products, and you may only discuss approved products, indications, and dosing in accordance with RC-approved materials. This guidance applies to your discussions with customers about HIT Tools.

Some HIT Tools are branded and mention a specific Pfizer product. Other HIT Tools will be “above-brand” and have no Pfizer product mentioned but rather discuss a therapeutic area or HIT generally. It is essential that you adhere to the RC-approved messages when using HIT Tools, whether the HIT Tool contains branded content or is unbranded but addresses a therapeutic area for which a Pfizer product might be prescribed. Remember that it is possible to promote a Pfizer product inappropriately without mentioning the product and when speaking “above-brand.” Therefore, Field Commercial Colleagues must not encourage or implicitly suggest off-label use of a Pfizer product in any unbranded HIT discussion. In all



cases, HIT Tools have been RC-approved to help ensure consistency with the FDA-approved labels for our products.

#### Listing of Pfizer Products in an EHR System

	I understand that for launch products, one of the challenges is to get the product listed in the customer's EHR system so that the HCP can find it easily on their screen. I know that a Pfizer product is expected to be approved by the FDA in the near future. Am I permitted to speak with the customer about how to list the product in the EHR, so it will be listed in their EHR system as soon after it has been approved as possible?
	Generally, it is not appropriate for commercial colleagues to discuss a product with a customer prior to FDA approval. If no RC-approved materials or messaging exist, such discussions are not permitted.

#### ***Fair Balance***

The FDA requires that product presentations include “fair balance” and therefore presentations about Pfizer’s products must include a discussion of a product’s benefit and risks. Similarly, HIT Tools that are branded, and some that are not branded but are closely associated with a product, may also require that Field Commercial Colleagues provide the relevant safety information to “balance” any statements regarding a product’s efficacy. For example, a conversation about securing the listing of a product in an EHR may include express or implied statements about the efficacy of a product. In those instances, fair balance would be required. The HIT Tool and any associated implementation guidance provided by the relevant RC should provide instructions on whether fair balance is necessary.

#### ***Never Engage in Actual or Perceived quid pro quo***

You must never offer nor appear to offer any remuneration, service, or item of value to induce or influence an HCP to prescribe a product or position it on formulary. The decision to prescribe or recommend a product must be based on the best interests of patients and not on anything of value offered by or on behalf of Pfizer. This is of particular concern when engaging customers on HIT.

You may only provide customers with HIT Tools for reasons consistent with the purpose for which the resource was approved. Branded HIT Tools may be offered to educate customers about the appropriate use of our products. Above brand HIT Tools may educate customers about improving patient outcomes and promoting quality healthcare without referring to particular Pfizer products.





HIT Tools have been RC-approved to ensure that they do not constitute an inappropriate quid pro quo when delivered in a manner consistent with implementation guides and other RC-approved instructions. Under



no circumstances should any Pfizer colleague, including a HIT Specialist, conduct any programming, coding, or actual operation of the customer's HIT system.

You must not present or characterize HIT Tools as assisting customers in obtaining financial incentives, reimbursements, or increased revenue.

#### HIT Engagements and MIPS/MACRA Requirements

	<p>I'm a KAM and I'd like to work with a customer to develop an improved workflow for identifying smokers and providing smoking cessation treatment where appropriate. I've consulted with my HIT Specialist and would like to engage the customer on the HIT-related aspects of this project. The customer is unsure if it wants to work with us on this. In explaining why this might be of interest, can I or the HIT Specialist explain how Pfizer can help the customer improve its ability to satisfy MIPS/MACRA requirements?</p>
	<p>No. Providing HIT Tools or expertise with the express or implied purpose of aiding the customer in satisfying MIPS/MACRA requirements could expose Pfizer to liability under the anti-kickback laws. In this instance, the proper approach would be to avoid the topic of MIPS/MACRA, except where expressly permitted in RC-approved materials and instead focus on how Pfizer and the customer can work together to ensure better care for the customer's patients.</p>
	<p>I understand that I cannot proactively initiate that discussion, but what if the customer asks about how Pfizer can help it satisfy MIPS/MACRA requirements? At that point, can we discuss MIPS/MACRA strategies?</p>
	<p>No, this would <b>not</b> be an appropriate activity. Whether proactive or reactive, Pfizer cannot provide assistance for the purpose of aiding customers in achieving any financial incentives, including MIPS/MACRA. Although the appropriate use of some Pfizer resources could potentially affect whether a customer meets some MIPS/MACRA criteria, Pfizer should never deliver these resources with the purpose of helping the customer to increase its revenue, reimbursements, or eligibility for financial incentives. See the FAQs in Chapter 5 for additional details on Collaborations that could positively impact a customer's reimbursement.</p>






## Your Role in an HIT Engagement

As our customers' breadth and depth of EHR use increases, Pfizer seeks to educate customers about its products and improve patient care through appropriate and compliant engagement on HIT issues. This section provides an overview of how different Field Commercial Colleagues may pursue these HIT engagements. If you are unsure whether a certain activity might be in scope for your role, contact your team attorney.

### Sales Colleagues

Traditional Sales Colleagues – most notably sales representatives and district business managers – may only engage customers on HIT topics in two ways. They may deploy RC-approved HIT Tools approved specifically for use by Sales Colleagues. Examples may include pieces that explain how to place Pfizer products in their bookmarks or favorites list. All HIT Tools approved for Sales Colleagues are available on [PROMOSprime](#). If a Branded resource is not available on [PROMOSprime](#), it is not approved for use by Sales Colleagues. Secondly they may engage a customer on HIT issues in identifying leads and introducing Account Team colleagues to key customer contacts. Sales Colleagues may play a critical role in connecting Account Team colleagues with the key individuals at customers who have account management responsibilities, which may include responsibilities directly or indirectly related to HIT. This role may require limited discussion of HIT to gauge interest and determine the appropriate contact, but it should not involve the use of any HIT Tools not approved for Sales Colleagues.

#### Sales Colleagues Role in Introductions

	I am a sales representative, and I recently learned that a HCPI have called on for years has taken on a key HIT role in her medical group. May I ask her if she would be interested in discussing HIT and quality initiatives with a Pfizer KAM? Could I sit in on the meeting?
	This would be a good example of where it is appropriate for the sales representative to assess the HCP's interest in meeting with the Account Team to cultivate a lead. And to the extent it would help facilitate the meeting, the representative may show up in person at the first meeting to introduce the KAM.
	I am a sales representative and I was speaking with a KAM in the lobby of a hospital when an HCP I know with HIT responsibilities came walking by. I introduced the HCP to the KAM, and the two of them agreed to meet next week to discuss HIT issues. May I join them for that first meeting?



### Sales Colleagues Role in Introductions



No. At this point, the KAM and the HCP have already met each other, and the presence of the sales representative at the scheduled meeting would not do anything further to facilitate the introduction. There is no other proper justification for the sales representative to sit in on the meeting, so he/she should not attend.

### Account Managers

As discussed in Chapter 1, Account Managers are Field Commercial Colleagues with account management responsibilities, such as KAMs, Oncology KAMs, and VAMs. Account Managers may deliver branded and unbranded HIT Tools and associated messaging approved for their use and consistent with the training they have received. An example of a branded HIT Tool is a piece to educate HCPs on how to bookmark a Pfizer product in an EHR system. An example of an unbranded HIT Tool is a value proposition deck about incorporating above-brand screeners and patient education materials into an EHR. All customer-facing content must be RC-approved for use by account managers. This means that the resource in question should be available on [PROMOSprime](#).

Account Managers should take care to ensure that the piece they would like to use is RC-approved and is not expired.

### Using Approved HIT Resources



In discussing a quality initiative relating to smoking cessation, one of my fellow KAMs recently told me that she had a positive experience sharing a particular RC-approved resource with the customer. She sent it to me by e-mail and told me that it is approved to show a customer on the iPad, but it is not approved to leave behind. May I show this to my customer at my next meeting about fibromyalgia?



Maybe, but you should not use an e-mailed copy. Before using the resource, you should first check to see that the piece is currently available on [PROMOSprime](#). It may be that the piece has expired or otherwise been replaced with a more current version. Always be sure to get your content directly from [PROMOSprime](#).

Some of the HIT Tools approved for Account Manager use are designed to spur discussion about how Pfizer can work with the customer to improve patient care. These HIT Tools may set the stage for more advanced discussions that may require the involvement of an HIT Specialist. To ensure consistency and availability, Account Managers should always confer with their HIT Specialist before proposing the use of any HIT Tools to a customer.







### **HIT Specialists**

HIT Specialists are a type of Account Manager and member of the Account Team with advanced HIT expertise as well as account management training in relevant therapeutic areas. Accordingly, there are certain HIT Tools, including some unbranded, disease-state specific resources that only an HIT Specialist may share with a customer. Except as described below, these HIT Tools must be RC-approved for the intended use. These Tools may include value proposition decks focusing on a particular therapeutic area, as well as screeners, questionnaires, and patient education materials that may be incorporated into a customer's workflow and/or EHR system.

HIT Specialists work with Account Teams to build on discussions initiated with a customer by the Account Team. Accordingly, Account Team Colleagues must consult with their HIT Specialist to anticipate those situations where the HIT Specialists' expertise may be necessary to engage the customer on topics involving HIT. This consultation ensures that the Account Team and the HIT Specialist are providing an appropriate, consistent, and compliant HIT message, and it also confirms that the HIT Specialist will be available to work with the customer in a timeframe that works for all parties.

HIT Specialists are **not** intended to be general HIT consultants for customers. Instead, HIT Specialist engagements with customers should be limited to approved HIT Tools and messaging. In many cases, this means the deployment of RC-approved HIT Tools found on [PROMOSprime](#). In other instances, a HIT Specialist may participate in the development of customized solutions for the customer under an approved collaboration agreement. Furthermore, while they may discuss with the customer how best to develop, build, and deploy these HIT Tools, Pfizer HIT Specialists are not authorized to perform the actual computer programming or coding necessary to implement the resource.

#### **Appropriate Interaction with HIT Specialists**



	I am a district manager, and I want my representatives to learn more about HIT so that they may properly deploy approved HIT Tools as well as identify leads for the Account Team. May I invite an HIT Specialist to provide training to my sales representatives team on EHRs and other HIT topics?
	No, that would not be an appropriate request of an HIT Specialist. Field Commercial Colleagues seeking additional HIT training should reach out to the training team to find the appropriate training resources and to identify additional learning needs.



### ***Role of Medical in Account Team Activities Involving HIT***

Some HIT engagements may require discussion of clinical topics with the customer. In those instances, the Field Medical Colleagues for your Business Unit (such as a MOS) should be involved early in the process to ensure that they can provide appropriate input. For example, if an HIT Specialist is providing an RC-approved screener to the customer for insertion into the EHR, and the screener requires the customer to make certain clinical decisions about what kinds of information should be factored into the screening process, then it would not be appropriate for the HIT Specialist to discuss those clinical decisions. The HIT Specialist and the account manager have a duty to work with their MOS to anticipate those situations where the MOS's clinical expertise may be necessary to assist the customer with the proper implementation of the Pfizer resource.

#### **Consultation with MOS**

	How do I know if the implementation of a screener might require clinical decisions?
	In the absence of specific RC guidance on this topic, always consult your MOS before working with the customer to implement the screener. There may be instances where decisions have to be made about clinical content and clinical context along with diagnostic codes that provide appropriate sources of data, and the MOS may be best equipped to make those decisions.

### **HIT Engagements**

The length, structure, and complexity of an HIT Engagement can vary with the objectives of Pfizer and the customer. A simple HIT Engagement may consist of one face to face meeting using a single approved HIT Tool. A more complex engagement may require the expertise of a HIT Specialist. The complexity of the HIT Engagement will most often depend on the customer's level of sophistication with regard to HIT. Below outlines a typical HIT engagement where the involvement of a HIT Specialist is necessary to determine whether opportunities exist to implement a HIT Tool.

#### ***Account Engagement***

In this first step, an Account Manager will work with the customer to understand customer needs, and whether those needs overlap with Pfizer business objectives. In the event the customer and Pfizer can agree upon mutually aligned business objectives intended to improve patient care (e.g. NVAf), the Account Manager will further determine whether an opportunity exists to engage the customer around HIT. It is at





this point the Account Manager should coordinate with the HIT Specialist to determine what steps, if any, may be taken towards an HIT engagement.

### **Workflow Assessments**

Assuming customer agreement and proper coordination between the customer, Account Manager and HIT Specialist, the next step may be for the HIT Specialist to conduct a workflow assessment. A workflow assessment is an evaluation of how a customer's patients flow through its HIT system and how the use of the system affects the identification and management of patients in a designated therapeutic area. The HIT Specialist conducts the workflow assessment to identify opportunities to incorporate Pfizer-approved HIT Tools designed to improve patient care in the therapeutic area in general. The workflow assessment should not be remunerative and should not constitute a transfer of discernible value to the customer. It is not appropriate for HIT Specialists or Account Team Colleagues to provide expertise on the overall use of the customer's HIT system or otherwise provide general HIT consulting services. Rather, the HIT Specialist should narrowly tailor the assessment and its recommendations to customers to further the implementation of approved HIT Tools in a relevant therapeutic area.



#### **Workflow Assessment and HIT Specialist**

	Who may conduct an HIT workflow assessment?
	Only an HIT Specialist may conduct a workflow assessment. While other Account Team members may possess substantial experience with HIT, only the HIT Specialists have the training, guidance, and experience to perform this assessment.

To conduct the workflow assessment, the HIT Specialist will likely meet with the customer in person and review how the customer interfaces with the electronic health record for a hypothetical patient (i.e., test patient) in the therapeutic area in question. Under no circumstances should a HIT Specialist observe the treatment of actual patients or view the Protected Health Information ('PHI') of any patient. It is the responsibility of each Pfizer colleague to ensure that he or she is not exposed to PHI. A confidentiality agreement will not address patient privacy concerns and does not permit Pfizer employees to receive PHI. Furthermore, Pfizer generally does not act as a business associate for purposes of HIPAA, and Pfizer colleagues should never agree to enter into a business associate agreement individually or on Pfizer's behalf. If you are asked to sign a confidentiality agreement or business associate agreement, contact your team attorney. For more information about HIPAA, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.



### Purpose of a Workflow Assessment

	<p>I'm an HIT Specialist, and I worked with a KAM to schedule an assessment of an integrated delivery network's workflow for patients with atrial fibrillation, a therapeutic area for which Pfizer has approved HIT Tools and resources. The customer has also asked that we provide feedback on the workflow for obesity as well as interoperability across the sites of the IDN. Can I provide the customer the information it seeks?</p>
	<p>Absent an approved collaboration or other unique arrangement approved by management and legal for the proposed purpose, a HIT Specialist should not provide the requested feedback on obesity and interoperability. The HIT Specialist should confine the workflow assessment to the topic of atrial fibrillation, where Pfizer has an appropriate interest in patient care and also has approved tools and resources. A workflow assessment for obesity would likely be inappropriate, as it is not a therapeutic area aligned to Pfizer interests, nor do approved tools and resources exist. Workflow assessments should focus on opportunities to implement approved HIT tools. Similarly, addressing general interoperability is neither aligned to Pfizer strategy nor tailored to improving patient care. Instead, assessments in those areas could be construed as inappropriate HIT consulting services that could expose Pfizer and the HIT Specialist to liability under the anti-kickback laws.</p>

Upon completion of a workflow assessment, the HIT Specialist may draft a report of the findings. The report should be high-level, describing opportunities where Pfizer and the customer might work together to improve patient care, but it should not contain detailed recommendations or solutions. Workflow assessment reports should not contain any guidance regarding the achievement of MIPS/MACRA guidelines, earning or obtaining financial incentives, or otherwise improving reimbursement. The scope of the workflow assessment report should be limited to the relevant therapeutic area and should not go beyond the implementation of Pfizer approved HIT Tools or the use of existing functionality necessary to implement the approved HIT Tool.

Workflow assessment reports do not require RC approval, but they must be approved by the appropriate team attorney. HIT Specialists also should consult the other Account Team members to ensure that the report: (1) is consistent with Pfizer strategies in the relevant therapeutic area; (2) contains accurate and appropriate feedback with respect to any clinical or medical topics; and (3) work with MOS colleagues to ensure appropriate clinical content and clinical intent when appropriate.



### ***Post-Workflow Engagement***

Once completed, the workflow assessment will be delivered to the customer and assist the Account Team and customer in identifying next steps in the engagement. In many instances, the workflow assessment will recommend delivery of one or more RC-approved materials available on [PROMOSprime](#). When this occurs, the HIT Specialist, in consultation the other Account Team members may provide those HIT Tools to the customer. Where implementation of an approved HIT Tool requires discussion of clinical or disease concepts with the customer, the MOS should be consulted. As always, Account Team coordination is key.

In other instances, the workflow assessment may identify broader opportunities for customer engagement. When the workflow assessment suggests a more complex arrangement, requiring numerous approved tools, customization of existing tools, or significant time investment from both Pfizer and the customer, the Account Team should consider a collaboration. A collaboration, including one with a HIT component, is an activity or project undertaken by Pfizer with an organization to advance public health goals\_of interest to both Pfizer and the organization. Chapter 5 of the Orange Guide sets out the factors by which one determines whether an engagement is a collaboration that requires Intake Committee approval and a collaboration agreement between Pfizer and the customer. Account teams should refer to Chapter 5 and consult with their team attorney to determine if a HIT engagement would be a collaboration and, if so, the process for ensuring compliance. In the absence of a collaboration agreement, HIT Specialists may only deliver RC-approved HIT Tools found on [PROMOSprime](#) and associated messaging.

Collaborations are intended to be unbranded. Where a proposed collaboration may implicate a Pfizer product (for example, where the Pfizer product is the only product on the market with an approved indication in the relevant therapeutic area, or where the Pfizer product is the exclusive option for that customer's patients), the Account Manager should consult with his or her team attorney before proceeding with the engagement.

Regardless of whether they are acting pursuant to a collaboration agreement with a customer, neither the HIT Specialists nor any other Account Team colleague may conduct any programming, coding, or actual operation of the customer's HIT system. They may offer guidance to the customer regarding the design, build, and/or implementation of HIT Tools, but they must remain in an advisory role.

Additionally, HIT Specialists must be aware that their interactions with customers may, in certain instances, be subject to disclosure requirements under the federal Sunshine Act and State laws, and therefore subject to compliance with Chapter 17, of the Orange Guide. HIT Specialists should make sure that the customer is aware that Pfizer may have to disclose the time and value of their work, and they also should be sure to keep appropriate records of their time and the nature of their work. In order to assess the fair market value of programs, an interactive Excel based worksheet tool has been developed to quantify the value of certain activities. HIT Specialists should contact their team's point of contact for assistance with use of the tool and to establish the value of a program.



### For More Information

- For more information about when an engagement may become a collaboration, see Orange Guide Chapter 5: Interactions with Health Systems and Medical Groups.
- For more information about collaborations and collaboration agreements involving KAMs, including how to get them approved and prepared, see the [Organized Customer Collaborations Process Guidelines](#).
- For information on the appropriate use of patient information, please see Orange Guide Chapter 8: Privacy – Protecting Personal Information.
- For more information on state laws, see Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions.



## **CHAPTER #20 – SPECIAL TYPES OF SERVICES AGREEMENTS – INTERACTIONS WITH SPECIALTY PHARMACIES**



**Chapter**

**#20**

**SPECIAL TYPES OF SERVICES  
AGREEMENTS – INTERACTIONS WITH  
SPECIALTY PHARMACIES**

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## Chapter #20 Special Types of Services Agreements – Interactions with Specialty Pharmacies

### Introduction

Recently, there has been an increase in the development of “specialty” medications. Specialty medications often have specialized administration, storage, or distribution requirements commonly have a higher cost of therapy than traditional medications and may be subject to additional regulatory requirements (i.e. FDA mandated Risk Evaluation Mitigation Strategies (REMS) requirements). Specialty drugs are generally dispensed by “Specialty Pharmacy Providers” (SPPs), which are distinct from traditional retail pharmacies in their more comprehensive coordination of many aspects of patient care, disease management, and patient access to therapy. SPPs have developed expertise in overcoming payer access challenges and have been shown to help improve clinical and economic outcomes for patients with complex, often chronic or rare conditions. SPPs employ health care professionals, including both pharmacists and nurses, provide patient education, help ensure appropriate medication use, promote clinically appropriate adherence by identifying drug-drug interactions, or by referring patients back to their prescribing physician when a therapy is not working as expected. SPPs can help patients gain access to therapy by: performing prescription intake and dispensing, conducting benefits investigation, providing clinical support for inbound patient calls, providing eligible patients with information about third party funding sources (e.g., out-of-pocket assistance with co-pay resources and contact information for third party co-pay foundations), providing prior authorization and appeals support, and a number of other services as part of their normal business operations or “core services.”

As discussed in Orange Guide Chapter 15 and Orange Guide Chapter 12, Pfizer enters into a variety of non-discount and discount contractual arrangements with certain customers when it procures services. Pfizer enters into non-discount arrangements with specialty pharmacies to participate in Defined Specialty Pharmacy Provider (SPP) Networks and/or to provide Supplemental Services to patients that have been prescribed a Pfizer product dispensed by such specialty pharmacies. All of these arrangements raise specific legal risks if not handled by Pfizer colleagues in an appropriate manner.

### Key Compliance Principles Governing Specialty Pharmacy Interactions

Because of the nature of the relationship and the influence health care professionals employed by SPPs often develop with patients, it is important to ensure that Pfizer’s interactions with SPPs are managed appropriately and Pfizer colleagues do not interfere with the independent clinical judgment of the SPP HCPs. Therefore, Pfizer colleagues must ensure such interactions remain appropriate and compliant with Pfizer’s policies by **never** directly or indirectly:



- Interfering with the carefully defined contractual arrangements between Pfizer and the SPP, including by providing any items of value to SPP personnel other than as expressly stated in Pfizer's contract with the SPP;
- Interfering with the independent clinical judgment of HCPs (including both prescribers and SPP clinicians);
- Interfering with the relationship between the patient and his/her HCP (including both prescribers and SPP clinicians);
- Encouraging SPP personnel to suggest to patients or a prescribing HCP that the patient should switch to a Pfizer product from their existing therapy;
- Steering HCPs or patients to one particular SPP to the exclusion of other SPPs; or
- Using SPP personnel (including SPP clinicians or sales representatives) as an extension of the Pfizer sales force, or as a mechanism for delivering Pfizer promotional messaging to either HCPs or patients.

These principles apply to all Pfizer colleagues who engage with SPPs.

#### ***Types of Contractual Relationships Between Pfizer and SPPs***

**Defined Distribution Networks:** Through distribution agreements, Pfizer contracts with certain SPPs that meet pre-defined objective inclusion criteria to dispense a particular Pfizer as part of a 'Defined SPP Network'. Defined SPP Networks are designed to ensure consistent and high-quality patient care and facilitate patient access across payers and geographic regions. Defined Distribution Network inclusion criteria are determined by the SAS COE and CSP Legal. All pharmacies seeking access to a Defined Distribution network must be reviewed by the SAS COE against such pre-defined objective inclusion criteria.

**Supplemental Services Contracts:** Through service agreements, Pfizer contracts with SPPs to provide specific services to help support patients prescribed a Pfizer product. These services – known as 'Supplemental Services' – are in addition to a SPP's 'Core Services' (i.e., services that the SPP provides to its patients as part of its normal business practice). Supplemental Services may include, but are not limited to, the SPP's dissemination of Pfizer patient educational materials, product adherence counseling, or provision of data or information to Pfizer about product usage.



## Field Commercial Colleagues and Interactions with SPPs

### ***SAS NAD Interactions with SPPs***

SPPs are sometimes owned or affiliated with other healthcare organizations. For SPPs aligned to payers, pharmacy benefits managers and similar organizations (collectively, “Organized SPP Customers”), the SAS NADs serve as the primary Pfizer contact for Organized SPP Customers. A listing of such Organized Customers can be found at the following link on [MyPfieldNet](#). SAS NADs also manage relationships through aggregators that contract with the non-Organized SP Customers for Supplemental Services.



### ***Other Field Commercial Colleague Interactions with SPPs***

In addition to Organized SPP Customers, certain SPPs may operate independently or may be affiliated with Integrated Delivery Systems (IDNs) or academic medical centers that are approved to dispense Pfizer brands. These institutions may be supported by KAMs or similar Account Management roles. In order to ensure effective understanding and implementation of the Key Compliance Principles listed above, Field Commercial Colleagues other than SAS NADs (e.g. Sales, KAMs, and other Account Management roles) must receive prior approval from their BU management, PCA, the global product counsel and CSP Legal before engaging with SPP personnel. The process for obtaining such approval is described in White Guide Chapter 20.

### ***HCP Request for a Pharmacy Recommendation***

Steering is defined as showing preference for one pharmacy or pharmacies over another pharmacy or pharmacies within a defined distribution or open network. In addition to explicit steering, there may be implicit steering if a sales representative jointly calls upon HCPs with SPP personnel or carries any pharmacy branded materials, including business cards or SPP prescription sheets or price lists.

#### **Request for Pharmacy Recommendations**

	How should a Pfizer Sales Representative respond if an HCP asks if there is a pharmacy or several pharmacies that the sales representative or Pfizer recommends to the HCP?
	The Pfizer Sales Representative may not show a preference for any particular pharmacy(ies) over other pharmacy(ies) regardless of whether the product is in a defined network. If the product is part of a defined network, all pharmacies who are part of the defined network must be presented to the HCP without directing an HCP or any particular pharmacy in that network.



### ***Sales Interactions with Specialty Pharmacy HCPs and SPP Office Staff***

As a general rule, subject to the approval identified above, Pfizer Sales Representatives may engage with HCPs and office staff at SPPs (including SPPs at IDNs/COEs) consistent with the requirements of Chapter 2 of this Guide. Any such interactions must arise from and be narrowly tailored to 1) educate an SPP HCP about the clinical profile of a Pfizer product, 2) educate SPP office staff about patient support programs available to patients, or 3) further an otherwise approved purpose. Such interactions should be for educational purposes only and must not include express or implied requests for the SPP personnel to recommend Pfizer products either to patients or prescribing HCPs. Sales Representatives must not attempt to influence the SPP personnel's decision-making and may only use materials and messaging specifically approved for use with SPPs during these interactions. In addition, Sales Representatives must not make any express or implied requests for the SPP personnel to recommend Pfizer products either to patients or HCPs.

Pfizer Sales Representatives are not permitted to discuss product discounts, rebates, reimbursement details to SPPs, participation in Pfizer's SPP Defined Networks, or Purchase or Service Agreements with any personnel at an SPP. In the event that a Pfizer Sales Representative learns that the SPP wishes to discuss such a contractual arrangement, the matter must be referred to the SAS NAD covering the SPP.

Finally, Sales Representatives must not share complaints about SPP performance issues that are relayed to them by customers (e.g., slow dispense times, inadequate inventory, etc.) to any SPP personnel directly or indirectly. Rather, the Sales Representatives must elevate potential SPP performance issues that they learn about to their sales manager, who can share the information with the appropriate SAS NAD.

### ***Interactions with Specialty Pharmacy Sales Representatives***

SPPs employ their own sales representatives to call on HCPs and promote the services of the SPP to encourage referrals.



Subject to the approval process referenced above, Pfizer Sales Representatives may have limited interactions with SPP sales representatives on a periodic, infrequent basis, where there is a legitimate business purpose to share appropriate information. Pfizer sales representatives must not use these contacts for relationship building with the SPP, to gather general payer information regarding Pfizer products, or to seek information about market shares of competitive products within the SPP, top prescribers, product volumes and utilization information on specific products, as this information may be subject to restrictions on further use by Pfizer or third parties. Moreover, Pfizer Sales Representatives must not share call or HCP target lists with SPP sales representatives and must not jointly meet with the SPP representative and a prescriber or HCP office.

In addition, Pfizer Sales Representatives must not provide Pfizer materials to the SPP sales representative. In the event that a SPP sales representative reaches out to a Pfizer Sales Representative with a product



question or request for product information, the Pfizer Sales Representative should refer the SPP sales representative to the SPP's own clinical personnel to answer the product-related question. SPP sales representatives must not attend educational presentations provided by Pfizer Sales Representatives or by Pfizer medical colleagues for SPP HCPs.

#### Request for Patient Brochures or Welcome Kits

	How should a Pfizer Sales Representative respond if an SPP sales representative requests patient brochures or welcome kits for Pfizer products?
	The Pfizer Sales Representative should advise the SPP sales representative that Pfizer will follow-up with the SPP's <b>clinical personnel</b> regarding the request. If the SPP is in a Pfizer Defined Network for the product, or the SPP is providing Supplemental Services for the product, the Pfizer Sales Representative should refer the request to the assigned SAS NAD for follow-up rather than following up directly.

In interactions with SPP sales representatives, Pfizer Sales Representatives must never share or discuss patient-specific information (even if de-identified), including information regarding the status of fulfillment of prescriptions at the SPP or with a payer. Pfizer Sales Representatives are also prohibited from sharing information about an HCP's prescribing patterns or coordinating targeting of or visits to HCPs with the SPP business representative; such actions may be perceived as inappropriately "steering" business to a particular SPP.

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

#### For More Information

General Questions regarding this chapter should be referred to your manager and/or your Global Product Counsel and the [CSP Legal team](#).



## **CHAPTER #21 – PATIENT SUPPORT ROLES**



Chapter

#21

PATIENT SUPPORT ROLES

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## Chapter #21 Patient Support Roles

### Introduction

Pfizer is committed to supporting patient access to the medicines prescribed by healthcare providers (“HCPs”) in a manner consistent with all applicable laws and regulations. As part of this commitment, some Pfizer brands may offer brand-specific reimbursement and patient support activities that are carried out by field-based colleagues (hereinafter “Patient Support Roles”). Generally, Patient Support Roles are field-based commercial roles that seek to expand access to, reimbursement of and education about Pfizer products in a non-promotional and appropriate manner. As of the publication of this chapter, Patient Support Roles include Field Reimbursement Managers (“FRMs”), Clinical Educators (“CEs”) and Patient Affairs Liaisons (“PALs”). Patient Support Role activities are intended to facilitate patient access to Pfizer medicines and associated patient support programs when a Pfizer medicine is prescribed by a patient’s HCP, or to provide training and/or education regarding relevant Pfizer products or therapeutic areas. Although Patient Support Roles are commercial roles, they are separate from the sales organization and are not intended to promote Pfizer products. This Chapter provides guidance for Patient Support Roles, and supplements all existing policies and SOPs governing Patient Support Role activities, including the [Blue Book](#) and the [White Guide](#).

To ensure compliance with applicable laws, the following governs Pfizer Patient Support activities:

- Patient Support Roles must not provide substantial, independent value to HCPs, HCP practices, patients or their caregivers;
- Patient Support Role activities must be made available in a non-discriminatory fashion to all appropriate HCPs and eligible patients; and
- Patient Support Role offerings must be unrelated to the volume or value of business generated by any HCP or healthcare facility or to any decision by a patient to use a Pfizer medicine.

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

### Role Descriptions

#### ***FRMs***

Pfizer’s FRMs are subject-matter experts on reimbursement, access, and coverage issues affecting Pfizer products. FRMs educate HCPs and their staff on matters relating to reimbursement, access and coverage to facilitate appropriate patient access to prescribed Pfizer products. FRMs may also respond to patient-





specific access and reimbursement questions from HCPs and office staff. FRMs may engage commercial and government payers, including Medicare Administrative Contractors and Medicare Carrier Advisory Committees, to discuss systemic obstacles to and support policy-level decisions about patient access to Pfizer products. FRMs may attend relevant state and regional society and association meetings to keep apprised of reimbursement and coverage developments that may affect Pfizer products. FRMs can also coordinate with Pfizer Hubs concerning individual patient cases.

### ***HCP-Facing CE's***

Pfizer's HCP-Facing CEs educate HCPs and relevant office staff on topics such as relevant disease states, proper administration of Pfizer medicines, safety and tolerability matters (including monitoring and management), contraindications, warnings, and other relevant Product characteristics. HCP-Facing CE's must provide this education in a manner that is non-promotional, fair and balanced, consistent with the relevant product's Prescribing Information, and without claims as to a product's efficacy.

### ***Patient-Facing CE's***

Patient-Facing CE's are responsible for educating patients who have been prescribed a Pfizer product and their caregivers on disease awareness and management and providing basic information on proper use and administration of Pfizer medicines and related devices. Such education may be provided individually or in group settings depending on the guidance developed by the brand team in partnership with Legal and Compliance. Consistent with their non-promotional role, Patient Facing-CE's may not promote Pfizer products to patients or caregivers.

### ***Patient Affairs Liaisons***

PALs are field based, non-promotional, community-facing colleagues who serve as educational resources for both local advocacy groups and individual patients and caregivers. The PALs primary function is to engage in proactive outreach to local advocacy and patient groups to understand their goals, objectives and needs, and to develop strong working partnerships to help advance the needs of the patient community. PALs may staff exhibits and displays at patient meetings and conferences, as well as educate patients and their caregivers on disease awareness and management. In addition to this chapter, PALs should refer to Orange Guide Chapter 16: Consumer, Patient, and Employee Interactions for guidance on their activities and interactions.



### ***Key Points to Ensure Compliance for Patient Support Roles***

- Provide only limited and appropriate support to HCPs, offices, patients and caregivers:
  - Do not provide reimbursement support to HCPs or office staff that replaces services they would otherwise pay office staff or a third party to perform.
  - Do not provide any HCPs, offices, or accounts with routine business support activities.
  - Do not engage in activities that address practice-level issues (e.g., issues not connected to Pfizer products such as office administration).
  - Do not directly or implicitly provide medical advice to patients or recommend switching to HCPs or patients; direct all medical questions to the patient's HCP.
- Do not engage in sales activity:
  - Do not engage in product promotion.
  - Limit interactions with Sales Colleagues and Account Managers.
  - Do not leverage Patient Support Role interactions to gain access for Sales Colleagues and Account Managers to inaccessible or difficult-to-see accounts.
  - Do not engage in joint customer meetings with Sales Colleagues or Account Managers except introductory meetings.
- Avoid off label discussions:
  - Use only materials approved by the relevant Review Committee (RC) for use with the appropriate audience.
  - Only arrange contacts with HCPs and offices practicing in specialties that are likely to prescribe the relevant Pfizer products for on-label uses.
  - Refer all off-label questions to the appropriate resource (off-label coverage, coding and payment questions to the Hub and off-label clinical questions to Medical Information).



### ***Key Points to Ensure Compliance for Patient Support Roles***

- Privacy and patient information:
  - Do not record patient-specific information, including PHI, except as required to execute approved Patient Support Role activities.
  - Do not engage in patient-specific discussions without first confirming that patient authorization was obtained, such as enrollment in the relevant hub.
  - Do not share PHI with anyone other than the treating provider, treating facility, Pfizer Hub or as otherwise required to conduct approved activities.
- Always disclose to HCPs, staff, and patients that you are compensated by Pfizer.
- Follow applicable e-mail guidelines.

### **Guiding Principles for Patient Support Roles**

#### ***Provide Only Limited Support***

As discussed in Chapter 1, federal and state anti-kickback laws prohibit payments -- or any other exchange of in-kind value -- intended to induce someone to purchase, prescribe, endorse, or recommend a product that is reimbursed under federal or state healthcare programs. Patient Support Roles may implicate anti-kickback laws if used to induce patients to request or HCPs to prescribe Pfizer products. To mitigate this risk, Patient Support Roles must never offer patients, caregivers or HCPs services that have “independent value,” which is defined as “more than limited support in connection with the purchase or prescription of a Pfizer product.” Any activities that defray costs that the HCP, patient or caregiver may otherwise incur could be seen as providing independent value and are prohibited. Similarly, repeated engagements with the same audience can appear as an effort to provide “independent value.” Patient Support Roles should ensure the frequency of their interactions with an HCP, office, patient or caregiver is consistent with the limited support mandate.



For example, FRMs may not provide general advice on billing or coding issues unless specifically related to the reimbursement of Pfizer products, any consultant-type services for which the HCP's office would ordinarily pay a third party, or routine business operating services, such as performing medical literature research, filling out clinical or diagnosis portions of forms, submitting claims, coding records, processing bills, or compiling documentation for appeals and/or submitting written appeals. Similarly, CEs and PALs



may not provide “on call” medical services and are prohibited from providing medical advice to HCPs, patients or caregivers. Patient-Facing CEs and PALs must direct the patient to refer any treatment-related questions, including questions about side effect management and discontinuation of a Pfizer product, back to his or her treating HCP.

CEs and PALs may not provide “on call” medical services and are prohibited from providing medical advice to HCPs, patients or caregivers. Patient-Facing CEs and PALs must direct the patient to refer any treatment-related questions, including questions about side effect management and discontinuation of a Pfizer product, back to his or her treating HCP.

#### FRM Individual Patient Benefit Investigation

	Can an FRM conduct a benefits investigation for an individual patient?
	Yes, when appropriately trained, the FRM may conduct a benefits investigation on behalf of an individual patient to determine whether the Pfizer product will be covered, as well as any relevant copays, prior authorizations, step edits and other coverage policies. This may be done by researching publicly available information as well as contacting the patient’s insurer. However, the investigation request must not be solicited by Pfizer, and must be for an on-label use of a Pfizer product. The FRM must not do things such as accessing a patient record or filling out clinical parts of statements of medical necessity, prior authorization forms, or appeals forms. The FRM should also be sure to respect patient privacy. The FRM must confirm that the patient has authorized the FRM’s involvement, and the FRM should not disclose any of the patient information to anyone other than the patient’s HCP, treating facility, the relevant payer for the patient or Pfizer Hub, as applicable.

#### Non-Promotional Nature of Patient Support Roles

Patient Support Roles, while commercial roles, are prohibited from promoting Pfizer products. FRMs may not promote or detail any Pfizer product, and may not discuss clinical product information with HCPs or office staff. If asked an on-label clinical question about a Pfizer product, the FRM may refer the question directly to the responsible Sales Colleagues or Account Managers. Similarly, while PALs, HCP- and Patient-Facing CEs are responsible for delivering some product-related information, it must be delivered in a manner that is non-promotional, and without claims as to a product’s efficacy or safety.

In addition, Patient Support Role activities should not have promotional tactics, goals or objectives. Patient Support Role operating plans, tactical plans and goals should be consistent with their non-promotional nature and independent from commercial goals. Lastly, Patient Support Roles performance metrics and



accountabilities must be independent of commercial objectives and goals. Patient Support Roles may not be measured by prescription, sales or revenue generation. And in no instance should a “return on investment (ROI)” calculation be done or the “value” of Patient Support Roles be determined by comparing pre- and post- Patient Support Role interaction prescribing patterns.

Patient Support Roles should ensure their activities do not prompt or solicit off-label discussions. Engaging in an off-label discussion of Pfizer products, proactively or reactively, or engaging in activities likely to prompt or otherwise solicit off-label questions from HCPs and office staff, is prohibited. Patient Support Roles that receive clinical off-label questions must refer those questions to Medical Information. Like all customer facing Pfizer colleagues, Patient Support Roles may only use RC-approved materials for the purposes and audiences for which they were approved.

Patient Support Roles should ensure the frequency of their interactions with an HCP, office, patient or caregiver is consistent with that audience's need for Patient Support Role information. Repeated engagements with the same audience concerning the same information can appear promotional even when they are not. Patient Support Roles are responsible for ensuring the frequency of their engagements is commensurate with the audience's need for the information they provide.

All Patient Support materials for use with HCPs, patients and caregivers must be reviewed and approved by the applicable Review Committee. While these materials are not intended to promote Pfizer products, inclusion of certain information or formatting (i.e., brand name, brand colors) may trigger the need for product safety information and filing with the FDA. The Review Committee will make the necessary determinations and filings.

### ***Limited Interactions with Sales Colleagues and Account Managers***

Patient Support Role interactions with Sales Colleagues and Account Managers can pose significant risks to Pfizer if executed inappropriately. Patient Support Roles must be independent from sales-related activities and influence, and Sales Colleagues and Account Managers may not direct Patient Support Roles. Patient Support Roles may only interact with Sales Colleagues and Account Managers consistent with the guidance in this chapter. Interactions between Patient Support Roles and Sales Colleagues and Account Managers should be limited in frequency and limited to logistical discussions and background discussions about HCPs on which Patient Support Roles call. Discussions between Patient Support Roles and Sales Colleagues and Account Management must not include discussion of patient-specific cases, HCP prescribing behavior information, or sales messaging or strategy.



### ***Internal Meetings***

With approval from the relevant Patient Support Role Team Lead, Patient Support Roles may participate in internal Sales and Account Management teleconferences or meetings, including regional and district sales meetings, but only for purposes of providing or receiving information relevant to the Patient Support Role. Patient Support Roles should only attend the part of the internal meeting that is directly related to the purpose of their role. For example, FRMs may, with the approval noted above, attend a regional sales meeting to discuss reimbursement and patient access issues. FRMs may also present at such meetings to provide Sales Colleagues and Account Management an overview of the relevant payer landscape for a given product or region. Patient Support Roles should not attend meetings, or meeting portions, that focus on sales or promotional strategy, prescription volume, or sales performance.

### ***External Meetings***

Due to their non-promotional nature, Patient Support Roles should not attend meetings that have a promotional purpose, such as promotional speaker programs conducted by Marketing or Sales. Furthermore, joint customer meetings between Patient Support Roles and Sales Colleagues or Account Managers are prohibited except for one-time, in-person introductions. Such meetings must be for introduction purposes only and must not be used to hold a substantive joint meeting with the customer. If, during a joint introductory meeting, the HCP or office staff initiates a product-related discussion with the Sales Colleague or Account Manager, the Patient Support Role colleague should excuse him or herself. Similarly, the Sales Colleague or Account Manager should excuse him or herself if the HCP or office staff initiates a discussion with the Patient Support Role colleague, such as a discussion about patient access with an FRM.

In instances where an HCP or institution limits access by pharmaceutical companies, Patient Support Roles and Sales Colleagues or Account Managers may schedule one Pfizer meeting with the customer, but should use the allocated time to conduct consecutive, separate, independent discussions with the customer (outside the presence of the other Pfizer colleague). For these permitted adjacent meetings, the Patient Support Role and Sales Colleagues or Account Manager can exchange logistical information such as key office contact/staff information and visitation requirements for pharmaceutical representatives. The pre-meeting should not include any discussion of sales objectives, strategy or performance.

Patient Support Roles must always prominently disclose that they are a Pfizer colleague or contracted on behalf of Pfizer and must never state or imply that they are independent of Pfizer.



### ***Selecting Patient Support Role Customers/Audiences Appropriately***

Patient Support Roles should avoid off label discussions and select their audiences accordingly. Patient Support Roles should not seek to engage HCPs or patients and caregivers of HCPs practicing in specialties excluded from Sales Colleague or Account Manager call lists as those specialties generally prescribe the relevant product for off-label purposes.

Patient Support Role activities must be made available in a non-discriminatory fashion to all appropriate HCPs and eligible patients, unrelated to the volume or value of business generated by any HCP and any decision by a patient to use a Pfizer medicine. Rather, the decision to engage should be based on the customer's or patient's need for the information the Patient Support Role provides. Consistent with this, Sales Colleagues and Account Managers may not direct or influence Patient Support Role Colleagues to engage with certain audiences. In addition, Sales Colleagues and Account Managers must refer requests for inclusion on Patient Support Role call and contact lists to the applicable Patient Support Role Team Lead. Such requests may not be sent directly to the Patient Support Role colleagues. Sales Colleagues and Account Managers may also provide the relevant Patient Support Role colleague's contact information to HCPs and offices who request it. Patient Support Role Leads and Brand teams, in consultation with Legal, may identify additional methods for Sales Colleagues and Account Managers to pass along HCP referrals (i.e., iPad apps, e-mail templates, etc.).

While Sales Colleagues and Account Managers may not influence the selection of customers with whom Patient Support Roles engage, Sales Colleagues and Account Managers can notify Patient Support Role Colleagues if they learn an issue about an **ongoing** Patient Support Role engagement in an unsolicited manner. For example, if an HCP asks a Sales Colleague about the status of an ongoing benefit investigation by an FRM, the Sales Colleague may contact the FRM directly and alert the FRM to the issue about which the HCP is seeking follow up. In such instances, the Sales Colleague should not collect or transmit any of the patient's personal health information. And Sales Colleagues and Account Managers should not solicit such queries from Patient Support Role audiences.

A Patient Support Role team lead, in consultation with Legal and Compliance, may use HCP or office prescribing and diagnosis data – among other factors – to inform their decision on whether to include an HCP or office on the Patient Support Role contact list. This data may be used to determine whether Pfizer products are being prescribed, whether they are being prescribed for on or off label uses, and the eligible patient population seen by the HCP office with the goal of ascertaining the HCP or office's need for the approved information that the Patient Support Role is permitted to share. However, such data must not be



used to reward high prescribing HCPs with Patient Support Role engagement, or to target high prescribers of a competitor product for conversion of patients to a Pfizer product.

### ***Educating HCPs and Patients about Patient Support Roles***

Communication about the availability of Patient Support Roles can raise significant legal concerns if such communication seeks to induce the prescription, purchase or referral of Pfizer products. Therefore, Pfizer may not promote the availability of Patient Support Roles as a reason to prescribe Pfizer products. Furthermore, Pfizer should not use Patient Support Roles to differentiate Pfizer products from competitor products or suggest that Patient Support Role activities provide substantial independent value to any HCP, patient or caregiver. Lastly, Patient Support Roles may not be used as levers to gain access for Sales Colleagues or Account Managers, and the availability of Patient Support Role offerings may not be made contingent on providing access to other Pfizer colleagues. Field Commercial Colleagues should educate HCPs and their offices about Patient Support Roles using only RC -approved materials and talking points to help ensure compliance.

### **Privacy**

Applicable privacy laws impose strict limitations on the use and disclosure by HCPs and insurers of information that may be used to identify patients, including protected health information (PHI). With certain exceptions, such as for purposes of treatment, payment or health care operations, HCPs are generally permitted to use or disclose an individual's PHI only if the individual has authorized that use or disclosure in writing in advance. Most Pfizer colleagues do not need access to PHI for any reason and should not request, collect or retain any such information. Patient Support Role colleagues should not collect or retain patient-specific information unless necessary to conduct an approved activity **and** the necessary patient authorization has been obtained.

While some Patient Support Roles, including Patient-Facing CEs and PALs, are permitted to interact with patients, they are never permitted to meet with patients or caregivers at an HCP office or be present when a patient is receiving medical advice or treatment from a healthcare provider.

### ***Privacy and Individual Patient Support Activities***

FRM engagement on individual patient support activities will necessitate the FRMs having access to at least some PHI. FRMs should follow this guidance when conducting Individual Patient Support to help safeguard any PHI he or she may receive.





### ***Individual Patient Support of Hub Enrolled Patients***

Patients enrolled in Pfizer Hubs are required to sign an authorization that allows their HCP and insurer to share PHI with the Hub, enabling the Hub to assist individual patients. Patient Support Roles may provide individualized support for patients enrolled in a Pfizer Hub only after confirming the Hub enrollment form, which contains the necessary authorization for the Patient Support Role activity, has been filled out and signed by the HCP. If such confirmation is not received, a new enrollment form and/or patient authorization must be submitted to the Hub before the Patient Support Colleague can provide any individualized patient support. Once the Patient Support Colleague has the necessary confirmation they may conduct activities consistent with the guidance provided in this Chapter and any relevant brand guidance. Thereafter, PHI may be received from and provided to the Hub representatives, clinicians, case managers, or authorized individuals as required to coordinate and support reimbursement of or access to Pfizer products.

### ***Individual Patient Support for Patients Not Seeking Hub Support***

Before investigating an individual patient's benefits, FRMs must obtain from the patient's HCP a signed form attesting to the patient's authorization for the patient support provided by the Patient Support Role. The brand team will provide FRMs with the appropriate form template. FRMs may not receive PHI prior to completion of the required form.

Due to privacy concerns, FRMs should avoid conducting reimbursement support activities over e-mail and text. In the event it is necessary, FRMs should ensure that the appropriate authorizations have been received and that they do not disclose patient information to individuals other than those authorized to receive it.

## **Meals**

FRMs may provide to HCPs occasional in-office and out-of-office meals in connection with presentations and discussions. Meals must be limited to those HCPs and staff with roles relevant to the topic on which the FRM is presenting. Any meal provided, whether in or out-of-office, must be modest by local standards and the cost may not exceed the applicable limits set forth in Chapter 18 of the Orange Guide. The meal cannot serve as the primary focus of the interaction.

Prior to providing any meal, the FRM must obtain information about the state licensure and opt-out status of the relevant HCPs. It is important to note that certain state laws apply when providing meals to HCPs licensed in those states, regardless of where the HCP actually practices or where the meal takes place. In addition, there are strict rules which prohibit on-site meals at Department of Veterans Affairs (VA) facilities as well as dollar limitations applicable to any HCP employed by the federal government.



PALs are permitted to offer a modest meal in conjunction with an unbranded, non-promotional, educational consumer presentation subject to applicable laws, federal rules, and Pfizer policy governing the provision of meals. A meal cannot serve as the primary focus of the interaction, and any meal should be modest as judged by local standards, with the cost not to exceed the applicable limit set forth in Chapter 18 of the Orange Guide.

PALs are also permitted to provide coffee or a light snack (for under \$10) to opted-in patients, caregivers and consumers on a limited and infrequent basis, when meeting in person to discuss issues related to the Patient Support Role.

CEs may not provide food, beverages, or other items of value to HCPs/offices.

For more information, see the Orange Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure.

#### Considerations Related to Independent Charity Patient Assistance Programs (“ICPAPs”)

Pfizer colleagues should refer to the Pfizer [Corporate Policy and Procedure #803: Contributions to Independent Charity Patient Assistance](#) and the Orange Guide Chapter 11: The Pfizer Patient Assistance Program, Institutional Patient Assistance Program, Donations to Independent Charity Patient Assistance Programs, and Patient Support Programs for information regarding sensitivities and restrictions around copay assistance from independent charitable patient assistance funds.

#### For More Information

- For more information on Pfizer Hubs, see Orange Guide, Chapter 11: The Pfizer Patient Assistance Program, Institutional Patient Assistance Program, Donations to Independent Charity Patient Assistance Programs, and Patient Support Programs.
- For more information on providing meals to HCPs and for information on Pfizer’s HCP Disclosure Policy, see Orange Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure.
- For more information on privacy issues, see Orange Guide, Chapter 8: Privacy: Protecting Personal Information.
- Refer any questions to your manager, Legal, or Compliance.



## **CHAPTER # 22 – INDEPENDENT MEDICAL GRANTS**



Chapter

#22

INDEPENDENT MEDICAL GRANTS

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## Chapter #22 Independent Medical Grants

### Introduction

Independent Medical Grants (IMGs) must only be used to support bona fide independent initiatives (e.g., research, quality improvement, or education) that are scientifically and ethically sound, and aligned with Pfizer's medical and/or scientific strategies. Independent Medical Grant types include:

- Investigator Sponsored Research (ISR);
- General Research;
- Quality Improvement; and
- Medical Education.

#### ***Key Points to Ensure Compliance***

- IMGs must be conducted in accordance with all applicable local laws and regulations, applicable Pfizer policies and SOPs, as well as applicable country or region-specific industry and professional standards, and aligned with Pfizer's medical and/or scientific strategies.
- All decisions to support an IMG must be made by colleagues in a medical, clinical, or scientific function.
- Funding of an IMG may never be provided to:
  - Establish, maintain, or improve Pfizer's relationship with an HCP or Account;
  - Gain or improve access to an HCP or Account;
  - Reward past or present, or induce future, prescribing or purchasing; or
  - Influence an upcoming formulary decision or reward a past formulary decision.
- Do not attempt to influence a decision by Medical or Clinical colleagues to hire Clinical Investigators or award grants for ISRs based on the potential impact to Pfizer sales.
- Do not provide starters (samples) to HCPs for use in ISR studies.
- There must be no involvement of commercial colleagues (including sales, marketing, account management, commercial development, and access colleagues) in any aspect of the review and approval of the project, project design, set-up, recruitment, and execution, including providing any funding directly from a commercial budget.



IMG requests are managed by the Global Medical Grants group in Pfizer's Worldwide Medical & Safety organization. With the exception of Pfizer's Competitive Grant Program, requests for independent medical grant support must be initiated by an external organization, not solicited by Pfizer. [Refer to GNT01-GSOP – Independent Medical Grants for more information.](#)

Each request is evaluated based on objective criteria including the institution's ability to properly oversee and conduct the study/project/education in compliance with applicable regulations and guidelines, design, budget, and scientific rationale. Whether Pfizer will benefit from the outcomes of the study/project/education in any way cannot be a basis for approval. Thus, all IMGs are reviewed by Medical Affairs, Research Unit colleagues and/or Global Medical Grants colleagues, and sales and marketing personnel may not influence any decision-making.

In addition to increased scrutiny of clinical trial conduct and payments to HCPs in recent years, the HHS **Office of Inspector General (OIG)** has issued compliance guidance addressing independent medical grants. This guidance and government investigations reinforce that funding must not be used to induce or reward the purchase of a manufacturer's products. Further, ISR or General Research studies must not be used as "seeding" studies for unapproved indications. Buttressing fraud and abuse laws, trade organizations including the **Advanced Medical Technology Association (AdvaMed)** and the **Pharmaceutical Research and Manufacturers of America (PhRMA)** have issued compliance guidelines regarding ISR studies. All relevant local, anti-corruption, and anti-kickback laws also apply.

Why support ISR studies? ISR studies expand therapeutic area and product knowledge, including safety information. Researchers may identify new ways of using existing treatments or investigational compounds, or they may focus on under-studied patient populations.

As a result of this regulatory framework, and because they are independent, Pfizer employees should not be involved in the design, conduct, supervision, management, or monitoring of any study/project/education that is supported by an IMG. Any of these actions would be out of compliance with the SOP governing IMGs, GNT01-GSOP – Independent Medical Grants.

**Non-compliance with the policies in this guide puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination of employment.**

#### ***Investigator-Sponsored Research Grants***



Pfizer may not design, conduct, assist with recruitment, or monitor ISR studies. Rather, they must be conducted independent of any influence or management by Pfizer. The evaluation of an ISR request cannot be influenced by an investigator's, institution's or organization's generation of past, present, or potential



future business for Pfizer, nor by any decisions the investigator or institution has made or may make in the future regarding Pfizer or Pfizer products.

All inquiries regarding an ISR grant should be referred to the Global Medical Grant System (“GMGS”) (as required by [GNT01](#)-GSOP Independent Medical Grants). The review and approval process cannot include any Commercial (e.g., Sales or Marketing) colleagues. This reduces the risk that an HCP’s past support of Pfizer products or future prescribing habits might be considered in any grant decision.

#### Investigator-Sponsored Research Grant

	<p>I am a Commercial colleague developing a relationship with an HCP customer who is an expert in her field and who does a significant amount of clinical research involving a Pfizer drug. She told me that she is seeking funding for a research proposal. Is it OK for me to suggest she submit a proposal to Pfizer for an ISR grant?</p>
	<p>Yes, if an HCP independently expresses interest in applying for research funding, you may suggest submitting a proposal for an ISR grant. If you do speak with the HCP about Pfizer’s ISR program, do not make any promise or suggestion that the ISR proposal will be supported, nor assist in any way in drafting the ISR proposal or submitting it through the <a href="#">GMGS web portal</a>. The HCP can access information about the requirements and application process for ISR grants at <a href="http://www.pfizer.com/purpose/independent-grants">www.pfizer.com/purpose/independent-grants</a>. Note, Pfizer colleagues must not proactively solicit the submission of ISR proposals by Pfizer customers. In addition, you may have no other involvement in the request or funding decision, and you must not attempt to influence, or foster the impression that you can influence, the funding decision. It is your responsibility to ensure that the HCP understands that all funding decisions are made without your input, based upon assessment of the medical and scientific merits of the proposal as well as the investigator’s eligibility to conduct the research.</p>

#### ISR Protocols

Per [GNT01-SOP](#), the investigator requesting ISR support is responsible for drafting the ISR protocol independently. You may not write, suggest, or comment on protocols for independent Clinical Investigators to submit to Pfizer for ISR support. If you receive a request from a sponsor or Clinical Investigator for assistance with drafting a protocol, you should direct them to the Global Medical Grants website [www.pfizer.com/purpose/independent-grants](http://www.pfizer.com/purpose/independent-grants) for information on the GMG program. Under the [GNT01](#) SOP, Clinical Investigators are responsible for drafting their own protocols.



### **Requests for Study Product or Pure Substance**

A request for study product or pure substance (for pre-clinical studies) to support legitimate medical research should be referred to the GMGS web portal ([www.pfizer.com/purpose/independent-grants](http://www.pfizer.com/purpose/independent-grants)). Starters (samples) may never be used for clinical trials or as support for ISR studies, and it would be inappropriate for you to try to obtain or promise samples for any research purposes.

## **General Research Grants**

### **General Research vs. ISR Grants**

General Research grants support the development or refinement of specific and defined medical knowledge based upon medical and scientific merit. This grant type is used to support research that would otherwise not be defined as an ISR, including support for an institution's general research fund, Health Services Research, Registry Development and/or Queries, Outcomes Research, and Research Fellowships. A General Research grant *cannot include a Pfizer asset, nor can it support research that involves the study of a Pfizer asset.*

These grants support interventional, non-interventional, outcomes, registry or other types of research that does not involve a Pfizer asset (drug, compound). And like ISRs, General Research grants must follow [SOP GNT01 – Independent Medical Grants](#) requirements. All General Research protocols must be developed by the external investigator and/or institution and, as the sponsor of the independent research, the grantee must assume all legal and regulatory responsibilities. Pfizer may not be involved in any aspect of study protocol development, nor may Pfizer be involved in the conduct or monitoring of the research. General Research grant requests must be submitted by the external investigator and/or institution through the GMGS.

## **Independent Medical Education and Quality Improvement Grants**

### **Overview**

Pfizer provides non-promotional funding to third-party organizations in the form of **Independent Medical Education (IME) and Quality Improvement (QI) grants**. An IME grant refers to funding given to a third-party entity to support an activity or initiative which serves to maintain, develop, or increase the knowledge, skills, and/or professional performance of Healthcare Professionals (HCPs). A QI grant refers to funding given to a third-party entity for QI which consists of systematic and continuous actions that lead to measurable improvement in healthcare services and the health status of targeted patient groups. These grant types are covered by [SOP GNT01 – Independent Medical Grants](#).





Legitimate professional and educational initiatives that can be supported with IME grants include, but are not limited to, activities like certified Continuing Medical Education (CME)/Continuing Education (CE) for HCPs. IME grants are permissible only if they are “independent,” which means that colleagues may not influence the development or content of the supported activity or how it is conducted. For example, colleagues cannot choose nor have any input on the topic, or the speakers who participate in the activity. Additionally, if Pfizer colleagues are solicited by external organizations to serve as faculty, colleagues are required to ascertain whether funding has been provided by Pfizer for the specific medical education activity. Any independent CME/CE activity supported by Pfizer precludes Pfizer colleagues from serving as faculty for that CME activity.

The review and approval of requests for IME and QI grants in the U.S. (and Puerto Rico) is managed by the office of Global Medical Grants (GMG). GMG, a part of WMS, works with therapeutic area representatives from BU Medical and Legal to develop IME and QI strategies for clinical areas of interest. To be considered for funding, a grant request should align with these strategies and must meet all of the criteria of an appropriate educational activity or QI initiative, including that it is independent, and information provided is balanced, accurate, and not misleading, delivered to a broad audience, and reasonable in cost. Additional criteria must be met when responding to a request for proposal (RFP) prepared by GMG in collaboration with External Review Panels and/or in partnership with other third party organizations

**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 an IME or QI grant.** By requiring the review and approval of these requests by GMG (or when applicable, by External Review Panels), Pfizer seeks to minimize the risk that an IME or QI grant could be approved, or perceived to have been approved, for an improper purpose.

Industry support of IME 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](#).

### ***Application Submission***

All requests for U.S. IME or QI grants must be submitted by the external organization directly to GMG via Pfizer's online Grant Management System (GMS) at [www.pfizer.com/independentgrants](http://www.pfizer.com/independentgrants). All submissions, required documentation, and decisions are recorded and archived in GMS.

Types of organizations eligible to apply for grants include hospitals, academic medical centers, schools of nursing or pharmacy, professional societies and associations, and other institutions specializing in specific healthcare-related disciplines (e.g., public health, quality improvement). Eligible organizations may submit a request for support of QI/health services initiatives and independent accredited or non-accredited





professional educational programs and activities. Requests for accredited IME must be submitted by accredited organizations. Examples of qualified accreditations include ACCME, AAFP, and AOA, ACPE, ANCC, AANP, AAPA, and NCOA. Providers must be in compliance with Pfizer standards as well as the guidelines of the OIG, ACCME, and other relevant bodies, as applicable. 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 HCPs have a proprietary or ownership interest in the organization will not be eligible to apply for IME or QI grants from Pfizer. Additionally, funding from GMG may not be used to support food and beverage for learners or audience participants.

### ***Application Review, Notification, and Payment***

GMG will review application submissions for completeness, alignment with IME or QI goals, compliance with Pfizer policies, and other requirements. For those requests submitted in response to an RFP, final decisions will be rendered by External Review Panels. 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. Funds are sent directly to the requesting organization.

### **Colleague Roles in Grant Process**

	May a Field Commercial Colleague communicate with grant requestors regarding the status of grant requests?
	No. These colleagues must not be part of the submission, review, or approval process. Requestors must communicate only with members of the GMG team regarding grant requests, funding, or denials. Colleagues must direct requestors to the GMG website at <a href="http://www.pfizer.com/independentgrants">www.pfizer.com/independentgrants</a> , or the dedicated e-mail address <a href="mailto:GMG@pfizer.com">GMG@pfizer.com</a> .





### ***Pfizer May Not Influence Grant-Funded Activities***

Colleagues may not offer suggestions regarding topics, content, or speakers to a CME/CE provider, program sponsor, or speaker at a CME/CE medical education activity. Even if colleagues are asked to provide input on topics or speakers, colleagues must decline. If a provider or speaker were to implement Pfizer suggestions, the independence of that medical education program could be compromised. Additionally, colleagues must not provide logistical support at an IME or QI activity.

On occasion, Pfizer may be offered promotional opportunities in connection with an IME or QI activity, 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 activities, see the section below.



### Colleagues' Role in Preserving Independence

	May 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?
	No. To preserve independence, colleagues, including those in GMG, must not provide input or in any way influence the content of a CME/CE activity.
	May a colleague provide input on the content of a non-CME/CE activity funded through GMG? Similarly, can a colleague provide logistical assistance for a non-CE event funded through GMG?
	No. Pfizer considers all grant-funded activities, even non-CME/CE activities, to be independent. Colleagues may not influence any grant-funded activity in any way.

### Promotional Opportunities at Medical Education Conferences

You may not under any circumstances fund or provide a meal or any other type of expense associated with a third party's medical education conference or activity where CME/CE credit is being offered.

If Pfizer is offered the opportunity to conduct a speaker program in connection with an accredited medical education activity (ACCME, AAFP, or AOA), this may be done *only* under the following conditions:

- The Pfizer program must be conducted in a room physically separated from the space where CME/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 certified 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 GMG.



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, Sales Colleagues must still follow all applicable Pfizer policies for promotional speaker programs (including the policies outlined in Orange Guide Chapter 9: Speaker Programs for HCPs).

### ***Complimentary Exhibit or Display Space***

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

### **For More Information**

- More information on Independent Medical Grants can be found on the GMG website, [www.pfizer.com/purpose/independent-grants](http://www.pfizer.com/purpose/independent-grants). More information about requests for pure drug substance alone can be found at the Compound Transfer Program website [www.pfizer.com/ctp](http://www.pfizer.com/ctp).
- For more information on SOPs please refer to the [eSOP portal](#).
- Questions may be referred to a Medical colleague, your manager, or Pfizer Legal counsel.



## APPENDIX – ACRONYM LIST



Acronym	Definition
<b>3PL</b>	Third Party Logistics Provider
<b>A</b>	
<b>ABM</b>	Area Business Manager
<b>ACA</b>	Affordable Care Act
<b>ACCME</b>	Accreditation Council for Continuing Medical Education
<b>ACO</b>	Accountable Care Organization
<b>ACPE</b>	Accreditation Council for Pharmacy Education
<b>ADE</b>	Adverse Drug Event
<b>ADR</b>	ADR – Adverse Drug Reaction
<b>AE</b>	Adverse Event
<b>AER</b>	Adverse Event Report
<b>AfME</b>	Africa/Middle East
<b>AGC</b>	Assistant General Counsel
<b>AHP</b>	Animal Healthcare Providers
<b>AI</b>	Active Ingredient
<b>AKS</b>	Anti-Kickback Statute
<b>AMA</b>	American Medical Association
<b>AMCP</b>	Academy of Managed Care Pharmacy
<b>AMP</b>	Average Manufacturer Price
<b>ANCC</b>	American Nurses Credentialing Center
<b>AP</b>	Accounts Payable
<b>A&amp;P</b>	Advertising & Promotion
<b>APC</b>	Ambulatory Payment Classification



Acronym	Definition
<b>API</b>	Active Pharmaceutical Ingredient
<b>APN</b>	Administrative Professionals Network
<b>ARIBA</b>	Pfizer Accounts System
<b>ASC</b>	Administrative Services Contract
<b>ASP</b>	Average Sales Price
<b>A/V</b>	Audio Visual
<b>AWP</b>	Average Wholesale Price
<b>B</b>	
<b>BA</b>	Business Analytics
<b>BAA</b>	Business Associate Agreement
<b>BAMs</b>	Biosimilars Account Managers
<b>BB</b>	Blue Book
<b>BI</b>	Benefits Investigation
<b>Big 4</b>	Department of Veterans Affairs, Department of Defense, Public Health Service & Coast Guard
<b>BLA</b>	Biological License Application
<b>BP</b>	Best Price
<b>BRE</b>	Business Rules Engine
<b>BRF</b>	Business Rationale Form
<b>BT</b>	Business Technology
<b>BU</b>	Business Unit
<b>BV</b>	Benefits Verification
<b>C</b>	
<b>CAP</b>	Consumer Assistance Program



Acronym	Definition
<b>CBO</b>	Chief Business Office <u>or</u> Congressional Budget Office
<b>CBOCs</b>	Community Based Outpatient Clinics
<b>CCQRO</b>	Chief Compliance, Quality, and Risk Officer
<b>CDA</b>	Confidentiality Disclosure Agreement
<b>CDC</b>	Center for Disease Control and Prevention
<b>CDE</b>	Customer Data Evaluation
<b>CDHC</b>	Consumer-Direct Health Care
<b>CEs</b>	Clinical Educators
<b>CE</b>	Continuing Education
<b>CE&amp;E</b>	Customer Events & Engagement
<b>CEO</b>	Chief Executive Officer
<b>CEP</b>	Customer Engagement Program
<b>CERF</b>	Contract Execution Request Form
<b>CFO</b>	Chief Financial Officer
<b>CFR</b>	Code of Federal Regulations
<b>CFU</b>	Criteria-For-Use
<b>CH</b>	Consumer Health
<b>CHC</b>	Community Health Centers
<b>CHIP</b>	Children's Health Insurance Program
<b>CI</b>	Clinical Investigator <u>or</u> Competitive Intelligence
<b>CIA</b>	Corporate Integrity Agreement
<b>CISRs</b>	Contracted Inside Sales Representatives
<b>CLM</b>	Contract Lifecycle Management or Closed Loop Marketing





Acronym	Definition
<b>CMCDs</b>	Clinical and Medical Controlled Documents
<b>CMD</b>	Chief Medical Director
<b>CME</b>	Continuing Medical Education
<b>CMP</b>	Comprehensive Medical Plan <u>or</u> Civil Monetary Penalty
<b>CMS</b>	Centers for Medicare & Medicaid Services
<b>CO</b>	Commercial Operations <u>or</u> Contracting Officer
<b>COB</b>	Coordination of Benefits
<b>COBRA</b>	Consolidated Omnibus Budget Reconciliation Act
<b>CoE</b>	Center of Excellence
<b>COT</b>	Class of Trade
<b>CP</b>	Corporate Policy
<b>CPA</b>	Capital Project Appropriations
<b>CPI-U</b>	Consumer Price Index – Urban
<b>CPT</b>	Current Procedural Terminology
<b>CRCs</b>	Clinical Research Collaborations
<b>CRGs</b>	Colleague Resource Groups
<b>CROs</b>	Contract Research Organizations
<b>CSA</b>	Cross-Site Access <u>or</u> Clinical Supply Agreement
<b>CSO</b>	Contract Sales Organization
<b>CSP</b>	Commercial Solutions Platform (Legal)
<b>CV</b>	Cardiovascular
<b>D</b>	
<b>DAEO</b>	Designated Agency Ethics Official



Acronym	Definition
<b>DataXfer</b>	Designated Agency Ethics Official
<b>DBM</b>	District Business Manager
<b>DDQ</b>	Due Diligence Questionnaire
<b>DEs</b>	Director of National Employer Accounts
<b>DFG</b>	Digital for Growth
<b>DHHS</b>	Department of Health and Human Services
<b>D&amp;I</b>	Diversity & Inclusion
<b>DL</b>	Distribution List
<b>DLA</b>	Defense Logistics Agency
<b>DMC</b>	Data Monitoring Committee
<b>DME</b>	Durable Medical Equipment
<b>DoD</b>	Department of Defense
<b>DOJ</b>	Department of Justice
<b>DP</b>	Direct Price
<b>DRA</b>	Deficit Reduction Act of 2005
<b>DRG</b>	Diagnosis-Related Group
<b>DSA</b>	Distribution Services Agreement
<b>DSCSA</b>	Drug Supply Chain Security Act
<b>DSH</b>	Disproportionate-Share Hospital
<b>DSU</b>	Drug Safety Unit
<b>DTC</b>	Direct-to-Consumer
<b>DTCA</b>	Direct-to-Consumer Advertising
<b>E</b>	



Acronym	Definition
<b>EA</b>	Expanded Access
<b>EAC</b>	Estimated Acquisition Cost
<b>ECP</b>	Essential Community Providers
<b>E&amp;D</b>	Exhibit & Display
<b>EFR</b>	Electronic File Room
<b>EGWP</b>	Employer Group Waiver Plans
<b>EHB</b>	Essential Health Benefits
<b>EHR</b>	Electronic Health Record
<b>EH&amp;S</b>	Environmental Health & Safety
<b>ELT</b>	Executive Leadership Team
<b>EMB</b>	Pfizer Established Medicines (EMBU)
<b>EMR</b>	Electronic Medical Record
<b>EOB</b>	Explanation of Benefits
<b>EPO</b>	Exclusive Provider Organization
<b>eRIM</b>	Enterprise Records and Information Management
<b>ERISA</b>	Employee Retirement and Income Security Act of 1974
<b>ERP</b>	Emerging Risk Program
<b>ESI</b>	Employer-Sponsored Insurance
<b>ETMS</b>	Electronic Territory Management System
<b>EU</b>	European Union
<b>F</b>	
<b>FAQs</b>	Frequently Asked Questions
<b>FCP</b>	Federal Ceiling Price



## Orange Guide – Acronym List

Acronym	Definition
<b>FCPA</b>	Foreign Corrupt Practices Act
<b>FDA</b>	U.S. Food and Drug Administration
<b>FDB</b>	First Data Bank
<b>FF</b>	Field Force
<b>FFS</b>	Fee-For-Service
<b>FMAP</b>	Federal Medical Assistance Percentage
<b>FMV</b>	Fair Market Value
<b>FPL</b>	Federal Poverty Level
<b>FQHC</b>	Federally Qualified Health Center
<b>FRF</b>	Funding Request Form
<b>FRMs</b>	Field Reimbursement Managers
<b>FSS</b>	Federal Supply Schedule
<b>FTC</b>	Federal Trade Commission
<b>FTO</b>	Freedom To Operate
<b>FUL</b>	Federal Upper Limit
<b>G</b>	
<b>GC</b>	General Counsel
<b>GCMA</b>	Global Content Management and Approval Program
<b>GCN</b>	Generic Code Number (6-character, First Data Bank)
<b>GCO</b>	Global Commercial Operations
<b>GCP</b>	Good Clinical Practice
<b>GEP</b>	Global Established Pharma
<b>GG</b>	Green Guide



Acronym	Definition
<b>GH&amp;V</b>	Global Health and Value
<b>GIP</b>	Global Innovative Pharma
<b>GMG</b>	Global Medical Grants
<b>GMI</b>	Global Medical Information
<b>GMS</b>	Grant Management System
<b>GO</b>	Government Official
<b>GPC</b>	Global Product Counsel
<b>GPD</b>	Global Product Development
<b>GPI</b>	Generic Product Identifier (14-character, Medi-Span)
<b>GPM</b>	Global Performance Management
<b>GPO</b>	Global Purchasing Organization
<b>GPP</b>	Global Performance Plan
<b>GRD</b>	Government Relations Director
<b>GSOC</b>	Global Security Operations Center
<b>GTC</b>	Global Trade Controls
<b>H</b>	
<b>HAS</b>	Hematology Account Specialist
<b>HBU</b>	Hospital Business Unit
<b>HCEI</b>	Healthcare Economic Information
<b>HCP</b>	Healthcare Professional
<b>HCPCS</b>	Healthcare Common Procedure Coding System
<b>HCPMID</b>	Healthcare Professional Medical Identification
<b>HDAS</b>	Health Data Analytics Specialist



Acronym	Definition
<b>HDHP/SO</b>	High Deductible Health Plan with Savings Option
<b>HDL</b>	High-Density lipoprotein
<b>HHS</b>	U.S. Department of Health and Human Services
<b>HIE or HIX</b>	Health Insurance Exchange
<b>HIPAA</b>	Health Insurance Portability and Accountability Act
<b>HIT</b>	Health Information Technology
<b>HITECH</b>	Health Information Technology for Economic & Clinical Health
<b>HLOGA</b>	Honest Leadership and Open Government Act
<b>HMO</b>	Health Maintenance Organization
<b>HOPD</b>	Hospital Outpatient Department
<b>HR</b>	Human Resources
<b>HRoD</b>	HR on Demand
<b>HRSA</b>	Health Resources and Services Administration
<b>HSA</b>	Health Savings Account
<b>I</b>	
<b>ICD</b>	Informed Consent Document
<b>ICMJE</b>	International Committee of Medical Journal Editors
<b>ICPAP</b>	Independent Charity Patient Assistance Program
<b>I&amp;I</b>	Inflammation & Immunology
<b>IDE</b>	Investigational Device Exemption
<b>IDN</b>	Integrated Delivery Network
<b>IDP</b>	Individual Development Plan
<b>IEC</b>	Independent Ethics Committee



## Orange Guide – Acronym List

Acronym	Definition
<b>IGLC</b>	Independent Grants for Learning and Change
<b>IHS</b>	Indian Health Service
<b>IM</b>	Internal Medicine
<b>IMB</b>	Pfizer Innovative Medicines (IMBU)
<b>IME</b>	Independent Medical Education
<b>IND</b>	Investigational New Drug
<b>INDA</b>	Investigational New Drug Application
<b>IP</b>	Intellectual Property
<b>IPA</b>	Independent Practice Association
<b>IPAP</b>	Institutional Patient Assistance Program
<b>IPGS</b>	Intellectual Property Global Services
<b>IPSM</b>	Intellectual Property Strategy Management
<b>IRB</b>	Institutional Review Board
<b>ISP</b>	Internet Service Provider
<b>ISRs</b>	Investigator-Sponsored Research Organizations <u>or</u> Inside Sales Representatives
<b>K</b>	
<b>KAMs</b>	Key Account Managers
<b>KFF/HRET</b>	Kaiser Family Foundation/Health Research and Educational Trust
<b>KOL</b>	Key Opinion Leader
<b>KPI</b>	Key Performance Indicator
<b>L</b>	
<b>LCA</b>	Least Costly Alternative
<b>LDET</b>	Legal Division Executive Team



Acronym	Definition
<b>LIS</b>	Low Income Subsidy
<b>LMR</b>	Life Management Resources
<b>LOD</b>	Legal on Demand
<b>LOE</b>	Loss of Exclusivity
<b>LPAT</b>	Legal Planning Advisory Team
<b>LTC</b>	Long-Term Care
<b>LTD</b>	Long-Term Disability
<b>LVP</b>	Local Vet Policy
<b>M</b>	
<b>MA</b>	Medicare Advantage
<b>M&amp;A</b>	Merger & Acquisition
<b>MAC</b>	Maximum Allowable Cost <u>or</u> Medication Advisory Committee
<b>MA-PD</b>	Medicare Advantage-Prescription Drug Plan
<b>MAPP</b>	My Anti-Corruption Policy and Procedures
<b>MCC</b>	Managed Care Customer
<b>MCM</b>	Multichannel Marketing
<b>MCO</b>	Managed Care Organization
<b>M&amp;E</b>	Meetings & Events
<b>MedPAC</b>	Medicare Payment Advisory Commission
<b>MMA</b>	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
<b>MOS</b>	Medical Outcome Specialist
<b>MRC</b>	Medical Review Committee
<b>MSA</b>	Master Services Agreement





## Orange Guide – Acronym List

Acronym	Definition
<b>MYRA</b>	My Reporting App
<b>N</b>	
<b>NAD</b>	National Account Director
<b>NAMs</b>	National Account Managers
<b>NCD</b>	New Channel Director
<b>NCPAS</b>	Non-Clinical Publication Approval System
<b>NDA</b>	New Drug Application <u>or</u> Non-Disclosure Agreement
<b>NDC</b>	National Drug Code (11-character)
<b>non-FAMP</b>	Nonfederal Average Manufacturer Price
<b>NRx</b>	New Prescriptions
<b>NSAID</b>	Nonsteroidal Anti-Inflammatory Drug
<b>NYO</b>	New York Office
<b>O</b>	
<b>OAM</b>	Oncology Account Manager
<b>OAS</b>	Oncology Account Specialist
<b>OBRA 90</b>	Omnibus Budget Reconciliation Act of 1990
<b>OCP</b>	Organized Customer and Payer
<b>OFG</b>	Organizing For Growth
<b>OG</b>	Orange Guide (Field Guide)
<b>OGE</b>	Office of Government Ethics
<b>OIG</b>	Office of Inspector General (of the Department of Health & Human Services)
<b>OM</b>	Organization Manager
<b>ONC</b>	Oncology



## Orange Guide – Acronym List

Acronym	Definition
OOO	Office of Ombudsman <u>or</u> Out of Office
OOP	Out of Pocket
OPA	Office of Pharmacy Affairs (part of HRSA)
OPD	Outpatient Prescription Drug
OPE	Out of Pocket Expense
OPH	Office of Public Health
OOO	Office of the Ombudsman
OPPS	Outpatient Prospective Payment System
OTC	Over-the-Counter
<b>P</b>	
P2L	Power2Learn
P4P	Pay for Performance
PA	Prior Authorization
PAC	Political Action Committee <u>or</u> Program Activity Coordinator
PAL	Pfizer Authorization Limit
PALs	Patient Affairs Liaisons
PAP	Patient Assistance Program
PBG	Physician Buying Group <u>or</u> Pfizer Biopharmaceutical Group
PBM	Pharmacy Benefit Manager
PCA	Payer and Channel Access
PCCs	Pfizer Colleague Councils
PCEC	Pfizer Compliance Education Center
PCMH	Patient Centered Medical Home



Acronym	Definition
<b>PCP</b>	Primary Care Physician
<b>PCRs</b>	Pharmaceutical Company Representatives
<b>PDL</b>	Preferred Drug List
<b>PDMA</b>	Prescription Drug Marketing Act
<b>PDP</b>	Prescription Drug Plan
<b>PEH</b>	Pfizer Essential Health
<b>PEM</b>	Pfizer Established Medicines
<b>PERS</b>	Public Employees' Retirement System (e.g., California Public Employees' Retirement System [CalPERS])
<b>PFE</b>	Pfizer
<b>Pfizer CARES</b>	Pfizer Compassionate Access Request System
<b>PGRP</b>	Pfizer Global Recovery Program
<b>PGS</b>	Pfizer Global Supply
<b>PHI</b>	Patient Health and Impact <u>or</u> Protected Health Information
<b>PHR</b>	Professional Healthcare Representative
<b>PhRMA</b>	Pharmaceutical Research and Manufacturers of America
<b>PHS</b>	Public Health Service
<b>PI</b>	Package Insert <u>or</u> Prescribing Information
<b>PIE</b>	Preapproval Investigational Exchange
<b>PIGO</b>	Potentially Influencing Government Official
<b>PIH</b>	Pfizer Innovative Health
<b>PII</b>	Personal Identifying Information
<b>PLA</b>	Pfizer Legal Alliance
<b>PM</b>	Pfizer Medical



## Orange Guide – Acronym List

Acronym	Definition
<b>PMA</b>	Premarket Approval
<b>PMPM</b>	Per Member Per Month
<b>PO</b>	Purchase Order
<b>POC</b>	Point of Contact or Proof of Concept
<b>POI</b>	Position of Influence
<b>POS</b>	Point of Sale <u>or</u> Point of Service
<b>PPACA</b>	Patient Protection and Affordable Care Act
<b>PPAF</b>	Pfizer Patient Assistance Foundation
<b>PPARx</b>	Partnership for Prescription Assistance
<b>PPO</b>	Preferred Provider Organization
<b>PPS</b>	Prospective Payment System
<b>PRO</b>	Peer Review Organization
<b>PROMOS</b>	Marketing Materials
<b>PRxP</b>	Pfizer RxPathways
<b>PSAO</b>	Pharmacy Services Administrative Organization
<b>PSO</b>	Provider-Sponsored Organization
<b>P&amp;T</b>	Pharmacy and Therapeutics
<b>PT&amp;E</b>	Pfizer Travel and Expense
<b>PTE</b>	Patent Term Extension
<b>Q</b>	
<b>QEs</b>	Quality Events
<b>QGO</b>	Qualified Government Official
<b>QHP</b>	Qualified Health Plan



Acronym	Definition
<b>QIG</b>	Quality Improvement Grant
<b>R</b>	
<b>RAMP</b>	Risk Assessment Mitigation Plan
<b>RBD</b>	Regional Business Director
<b>RC</b>	Review Committee <u>or</u> Regional Coordinator
<b>RCD</b>	Regional Channel Director
<b>RCI</b>	Referable Compliance Issue <u>or</u> Reportable Compliance Issue
<b>RCP</b>	Retail Community Pharmacies
<b>R&amp;D</b>	Research and Development
<b>RD</b>	Rare Diseases
<b>RDS</b>	Retiree Drug Subsidy
<b>REG</b>	Regulatory, Environmental and Global Supply
<b>REMS</b>	Risk Evaluation and Mitigation Strategy
<b>RFP</b>	Request for Proposal
<b>RM</b>	Regional Manager
<b>ROI</b>	Return on Investment
<b>RP</b>	Reference Price
<b>RPA</b>	Robinson-Patman Act
<b>RPS</b>	Restricted Party Screening
<b>RRS</b>	Resource Reporting System
<b>RxPathways</b>	Pfizer's Patient Assistance Program
<b>S</b>	
<b>SAF</b>	Starter Activity Form



Acronym	Definition
<b>SAP</b>	Statistical Analysis Plan
<b>SARs</b>	Starter Activity Reports
<b>SAS</b>	Specialty Access Solutions
<b>SBL</b>	Skill Based-Learning
<b>SCHIP</b>	State Children's Health Insurance Program
<b>SCOD</b>	Specified Covered Outpatient Drug
<b>SD</b>	State Director <u>or</u> Sales Director <u>or</u> Senior Director
<b>SE</b>	Step-Edit
<b>SFA</b>	Sales Force Automation
<b>SFG</b>	Simplicity For Growth
<b>SMART</b>	Specific, Measurable, Actionable, Realistic, Time-Bound
<b>SMD</b>	Software Medical Devices
<b>SNF</b>	Skilled Nursing Facility
<b>SOC</b>	Standard of Care
<b>SOM</b>	State Office Manager
<b>SOP</b>	Standard Operating Procedure
<b>SOW</b>	Statement of Work
<b>SP</b>	SharePoint
<b>SPA</b>	Single-Point of Accountability
<b>SPAP</b>	State Pharmaceutical Assistance Program
<b>SPI</b>	Sensitive Personal Information
<b>SPNA</b>	Speaker Program Needs Assessment
<b>SPP</b>	Specialty Pharmacy Provider



## Orange Guide – Acronym List

Acronym	Definition
<b>SSA</b>	Social Security Administration
<b>SSI</b>	Supplemental Security Income
<b>StratCO</b>	Strategy and Commercial Operations
<b>STD</b>	Short-Term Disability
<b>SVP</b>	Senior Vice President
<b>T</b>	
<b>TBO</b>	Tactical Business Objectives
<b>TCL</b>	Territory Credit List <u>or</u> Territory Call List
<b>TIPPS</b>	Transparency in Drug Purchasing Solutions
<b>TMAC</b>	Therapeutic maximum allowable cost
<b>TPA</b>	Third-party (claims) Administrator <u>or</u> Third Party Agreement
<b>TPAA</b>	Third Party Access Agreement
<b>TPRM</b>	Third Party Risk Management
<b>TrOOP</b>	True Out-Of-Pocket
<b>U</b>	
<b>U&amp;C</b>	Usual and Customary (price)
<b>UCR</b>	Usual, Customary, and Reasonable
<b>UM</b>	Utilization Management
<b>UMR</b>	Unsolicited Medical Requests
<b>URA</b>	Unit Rebate Amount
<b>USFDA</b>	United States Food and Drug Administration
<b>URO</b>	Urology
<b>USMI</b>	US Medical Information



## Orange Guide – Acronym List

Acronym	Definition
<b>USP</b>	United States Pharmacopeia
<b>V</b>	
<b>VA</b>	Department of Veterans Affairs (Veterans Administration)
<b>VAC</b>	Vaccine
<b>VADs</b>	Vaccine Account Directors
<b>VAMs</b>	Vaccine Account Managers
<b>VANF</b>	VA National Formulary
<b>VP</b>	Vice President
<b>W</b>	
<b>WAC</b>	Wholesale Acquisition Cost
<b>WAMP</b>	Widely Available Market Price
<b>WBB</b>	Worldwide Biopharmaceutical Business
<b>WG</b>	White Guide
<b>WHO</b>	World Health Organization
<b>WL</b>	Warning Letter
<b>WMS</b>	Worldwide Medical and Safety
<b>WRDM</b>	Worldwide Research & Development and Medical
<b>Y</b>	
<b>YRR</b>	Your Reporting Responsibilities