



The White Guide

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CONTENTS

Chapter and Appendix

CHAPTER #1 – OVERVIEW AND KEY PRINCIPLES	2
CHAPTER #2 – ADVERTISING AND PROMOTIONAL LABELING	22
CHAPTER #3 – PROMOTIONAL INTERACTIONS WITH HEALTHCARE PROFESSIONALS	44
CHAPTER #4 – MARKETING PROGRAMS	52
CHAPTER #5 – HCP AND GOVERNMENT OFFICIAL CONSULTING ENGAGEMENTS.....	70
CHAPTER #6 – GOVERNMENT HEALTHCARE PROGRAMS.....	91
CHAPTER #7 – SUPPORT OF EXTERNAL ORGANIZATIONS	105
CHAPTER #8 – NON-PROMOTIONAL AND MEDIA ACTIVITIES	125
CHAPTER #9 – PFIZER-SPONSORED RESEARCH AND CLINICAL RESEARCH COLLABORATIONS (CRCs)	143
CHAPTER #10 – THE PFIZER PATIENT ASSISTANCE PROGRAM (PAP) AND DONATIONS TO INDEPENDENT CHARITABLE PATIENT ASSISTANCE PROGRAMS (ICPAPS).....	168
CHAPTER #11 – PRIVACY: PROTECTING PERSONAL INFORMATION	186
CHAPTER #12 – PROMOTIONAL INTERACTIONS WITH CONSUMERS	209
CHAPTER #13 – PROMOTIONAL INTERACTIONS WITH EMPLOYER GROUPS	221
CHAPTER #14 – STARTERS.....	227
CHAPTER #15 – STATE LAWS: HCP AND STATE EMPLOYEE RESTRICTIONS	243
CHAPTER #16 – FEDERAL EMPLOYEE INTERACTIONS AND LOBBYING	281
CHAPTER #17 – PUBLICATIONS	305
CHAPTER #18 – MEALS, EDUCATIONAL ITEMS, AND HCP PAYMENT DISCLOSURE.....	314
CHAPTER #19 – SAVINGS AND FREE TRIAL PROGRAMS	336
CHAPTER #20 – NON-DISCOUNT ARRANGEMENTS WITH SPECIALTY PHARMACIES AND OTHER ACCOUNTS	348
CHAPTER #21 – PATIENT SUPPORT ROLES.....	358
CHAPTER #22 – INDEPENDENT MEDICAL GRANTS.....	368



CHAPTER #1 – OVERVIEW AND KEY PRINCIPLES

Chapter**#1****Overview And Key Principles**

CONTENTS

Overview and Key Principles

Introduction	24
Key Compliance Points	25
Core Compliance Principles for Professional and Consumer Promotional Materials.....	25
Pre-Approval Interactions with Healthcare Decision Makers	26
Post-Approval Communication	27
Guiding Principle #1: Ensure Statements are Consistent with Product Labeling	27
Guiding Principle #2: Support All Claims with Adequately Substantiated Evidence	28
Guiding Principle #3: Be Accurate, Truthful, and Not Misleading	29
Guiding Principle #4: Provide Balanced Information about Benefits and Risks	31
Guiding Principle #5: All Promotional Materials Must Be Approved through Review Committee	32
Guiding Principle #6: Don't Make Claims About Investigational Products or Investigational Uses of Marketed Products.....	32
Requirements of Promotional Labeling and Advertising.....	33
Use of Reprints in Product Promotion.....	37
Direct-To-Consumer and Internet Advertising	38
Direct-To-Consumer Advertising	38
Patient Testimonials	38
Usage of Animals in Advertising.....	39
Internet and Social Media Promotion	40
Pfizer Biopharmaceuticals Group: Paid Media	40
For More Information.....	43

Chapter #1 Overview and Key Principles

Introduction

Living out our value of Equity requires that we act with integrity. One way we demonstrate our commitment to integrity is by complying with laws and regulations that govern 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 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; and
- Federal and State Pharmaceutical Disclosure and Compliance Laws.

Other Key Laws

- False Claims Act;
- Privacy Laws;
- State Consumer Protection Laws; and
- 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; and
- Pfizer's Corporate Integrity Agreement and State Attorneys General Agreements.

Anti-Kickback Laws:

Makes 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 covered outpatient 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.

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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), District Business Managers (DBMs), 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

“Sales Colleagues” generally 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, and educate 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. Sales Colleagues include, but are not limited to, Sales Representatives, Territory Managers, Area Business Managers, and Regional Business Directors. Sales Colleagues’ focus on individual HCPs and the way Sales Colleagues are compensated differs 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 health systems, Integrated Delivery Networks (IDNs), 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 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, or region. Account Managers includes, but are not limited to, Account Directors, Key Account Managers (KAMs), HIT Account Directors 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 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”), Field Access Specialists (“FASs”) Patient Access Coordinators (“PACs”), 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 externally facing 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.	Health Systems, 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 or virtual 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), 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

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, knowingly and willfully, offer, pay or provide anything of value 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 (FMV)

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, 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 should be contacted to discuss each arrangement or activity that potentially implicates the Anti-Kickback statute.

U.S. Department of Health and Human Services (HHS)

United States federal administrative agency that oversees Medicaid, Medicare, and other federally funded healthcare programs.

Office of Inspector General (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, purchase 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 Drug Pricing 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 covered outpatient products to a customer (excluding certain customer types). 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.

Food and Drug Administration (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: Interactions with HCPs and Health Systems, 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 starter. 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 Orange Guide Chapter 10, White Guide, Chapter 14.

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, mid-levels and teaching hospitals under the transparency provisions of the Sunshine Act and the SUPPORT 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: Interactions with HCPs and Health Systems, 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 (e.g., advertising and promotion agencies) perform various services 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 U.S. federal law that prohibits corrupt or improper payments to non-U.S. 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 U.S. 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 \(MAPP\) when entering such transactions](#). MAPP, which applies to all colleagues globally, 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 U.S. 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](#)

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.

Pfizer adopts and follows the PhRMA Code on Interactions with HCPs and the guiding principles on Direct to Consumer Advertising.

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 (5) 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

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 did not comply with federal law.

Pfizer's CIA Requirements: The CIA sets certain compliance-related requirements, most of which were already reflected in Pfizer's Compliance Program. Some of our CIA obligations include:

- Annual compliance training for U.S. colleagues;
- CEO, CCQRO, Management and other 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 your manager, another manager, Human Resources, Legal, **Compliance or via the Compliance Helpline (1-866-866-7349 or online at <https://pfizer.ethicspoint.com>)**, or directly via e-mail at 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 manager, another manager, Human Resources, Legal, or the Compliance Division. Pfizer has open door, anti-retaliation, and confidentiality policies to encourage and protect all Pfizer colleagues who raise valid concerns.

For More Information

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



CHAPTER #2 – ADVERTISING AND PROMOTIONAL LABELING

Chapter**#2****ADVERTISING AND PROMOTIONAL LABELING****CONTENTS****Advertising and Promotional Labeling**

Introduction	24
Key Compliance Points	25
Core Compliance Principles for Professional and Consumer Promotional Materials.....	25
Pre-Approval Interactions with Healthcare Decision Makers	26
Post-Approval Communication.....	27
Guiding Principle #1: Ensure Statements are Consistent with Product Labeling	27
Guiding Principle #2: Support All Claims with Adequately Substantiated Evidence	28
Guiding Principle #3: Be Accurate, Truthful, and Not Misleading	29
Guiding Principle #4: Provide Balanced Information about Benefits and Risks	31
Guiding Principle #5: All Promotional Materials Must Be Approved through Review Committee.....	32
Guiding Principle #6: Don't Make Claims About Investigational Products or Investigational Uses of Marketed Products.....	32
Requirements of Promotional Labeling and Advertising.....	33
Use of Reprints in Product Promotion.....	37
Direct-To-Consumer and Internet Advertising	38
Direct-To-Consumer Advertising	38
Patient Testimonials	38
Usage of Animals in Advertising.....	39
Internet and Social Media Promotion	40
Pfizer Biopharmaceuticals Group: Paid Media	40
For More Information.....	43

Chapter #2 Advertising and Promotional Labeling

Introduction

A fundamental basis for our promotional interactions with **Healthcare Professionals (HCPs)** and consumers is to promote our products and educate about the disease states they treat. Pfizer's Guiding Principles pertaining to Promotional Materials and Communications are intended to ensure that the development, review, approval and use of those materials comply with all applicable laws, regulations, policies, and procedures while optimizing efficiency, effectively mitigating risks, and leveraging Pfizer's scale.

These Guiding Principles should always be followed when developing, reviewing, approving, and using promotional materials:

- Ensure Statements are Consistent with Product Labeling;
- Support All Claims with Adequately Substantiated Evidence;
- Be Accurate, Truthful, and Not Misleading;
- Provide Balanced Information about Benefits and Risks;
- All Promotional Materials Must Be Approved through Review Committee;
- Don't Make statements of efficacy or safety about Investigational Products or Investigational Uses of Marketed Products.

In addition to these guiding principles, each Local Country is accountable for establishing and employing processes that will ensure that its promotional activities and materials comply with this Policy, all applicable local laws and regulations and industry standards. Additionally, the local country is accountable to ensure that local procedures are implemented and documented to support this policy.

These principles and process requirements are set forth in detail in [1.01 Pfizer's Global Content Policy: Commercial Standards for Promotional Materials](#), [2.01 Global Content Policy Addendum](#), and [7.01 US Policy Addendum](#).

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

Any exceptions to the following policies/principles must be first discussed with RC, and also discussed with BURC as appropriate.

Key Compliance Points



- A brand Review Committee (RC) may approve clinical reprints for promotional use by Field Commercial Colleagues only if they are consistent with the product's label, as detailed later in this Chapter. Only RC approved reprints should be used by Field Commercial Colleagues.
- Like other forms of promotion, **Direct-to-Consumer (DTC) and other consumer facing** communications must comply with FDA regulations and Pfizer's guiding principles as well as PhRMA's Guiding Principles. Consumer facing communications should educate patients and consumers and encourage them to seek guidance from healthcare professionals.
- As outlined in White Guide Chapter 4: Marketing Programs, Customer Engagement Programs (CEPs) must be designed, reviewed, approved, and conducted in compliance with Corporate Policy (CP) #902: Management of Safety Information for Customer Engagement Programs (CEPs) and Corporate Procedure (CP) #902a: Management of Safety Information for CEPs.
- As it does with other forms of advertising and promotional labeling, the FDA regulates Pfizer's use of the Internet, social media, and other digital channels to promote its products. Websites that contain promotional product information must comply with all the laws, regulations, and principles that govern promotional materials created for traditional media in addition to relevant Pfizer policies and guidelines, including those guidelines pertaining to digital communications. See DRT.pfizer.com and Advertising & Promotion Guidelines [here <link to http://opsource.pfizer.com/Pages/Advertising---Promotion-Guidelines.aspx >](http://opsource.pfizer.com/Pages/Advertising---Promotion-Guidelines.aspx) for guidelines associated with the appropriate use of the Internet, social media, and other digital channels in advertising and promotional labeling.

Core Compliance Principles for Professional and Consumer Promotional Materials***Pre-Approval Communication***

Prior to approval, the **Food and Drug Administration (FDA)** permits only two types of advertisements for drugs: “**Institutional Advertising**” and “**Coming Soon**” advertising. Institutional Advertising may announce that a drug company is conducting research in a particular therapeutic area to develop a new drug, but the name of the investigational drug must not be mentioned and any representation (written, verbal, or graphic) that directly or indirectly identifies the drug must not be included in the advertisement. Coming Soon advertising, announces the name of the product that will be available soon without any information (written, verbal, or graphic) relating to the therapeutic area, safety, efficacy, or intended use of the drug. Coming Soon advertisements are permissible only if the drug is not expected to have a boxed

warning. Coming Soon advertisements must meet the requirements of a reminder advertisement (described further below) and therefore must not contain any representations, direct or implied, about the product. For a particular product, Pfizer can choose only one of these two types of advertising during the pre-approval time period. Companies are not permitted to use both types simultaneously or to alternate between these approaches during the pre-approval time period. Other than these two types of advertising, no promotion may be conducted for a product prior to FDA approval.

Pre-Approval Communication

	When am I permitted to meet with customers to begin discussing a new product or new indication?
	<p>Pfizer is not permitted to promote a new product or indication prior to receiving FDA approval. This means that Pfizer is not permitted to make claims about the safety and efficacy profile of the product until after FDA approval. In limited circumstances it may be appropriate to discuss an unapproved product or indication with certain customers as part of a non-promotional interaction (e.g., advisory board, scientific exchange, and certain payer communications). All colleagues must receive appropriate approvals before proactively discussing any unapproved product or unapproved indication with an HCP or consumer or other customer. See White Guide Chapter 8: Non-Promotional and Media Activities, and U.S. Guidance for Interactions with Healthcare Decision-Makers and Payers Pre-FDA Approval for more information.</p>

Pre-Approval Interactions with Healthcare Decision Makers

In limited circumstances, Medical Colleagues and Commercial Colleagues (not including sales representatives) may engage in communications with Healthcare Decision-Makers (e.g., formulary decision-makers, payers, and other similar entities) related to investigational assets and Investigational Uses of Approved Products (**PIE - Preapproval Information Exchange**). Communication of PIE must be designed and executed for the specific purpose of facilitating a Healthcare Decision-Maker's planning and budgeting in preparation for the potential approval and market availability of a Pfizer investigational product or use. Examples of a Healthcare Decision-Maker's business planning and budgeting processes may include, among others: benefit design analysis and modification, identification of disease prevalence within a population, potential medical policy modification, treatment pathway considerations, and evaluation of new to market policies.

Whether Pfizer should execute a PIE should be determined on a case-by-case basis, in consultation with the relevant Global Product Counsel (GPC).

Any PIE communications to a Healthcare Decision-Maker must be unbiased, factual, accurate, truthful, non-misleading, objective and non-promotional in content, presentation, and tone. Material presented during a PIE communication is not considered promotional in nature; therefore, the post-approval requirements pertaining to submission of promotional materials at time of first use to FDA's **Office of Prescription Drug Promotion (OPDP)** do not apply in these circumstances.

Disclosures:

The investigational nature of the product or use must always be clearly and prominently disclosed and should be unambiguous throughout the PIE communication.

The regulatory status of the investigational product or use should be similarly disclosed (e.g., disclosure that FDA has not evaluated the safety and effectiveness of the product or use, or that the product or use is currently under FDA review).

A caveat should be included (as applicable) that the sought-after label and indication(s) for the product are subject to change, should the product or use be FDA approved at all.

PIE **must not** be used to:

- claim that an investigational product or use is effective or safe
- recommend or encourage off-label uses
- encourage future prescribing or engage in actual or perceived quid pro quo

Please refer to [U.S. Guidance for Interactions with Healthcare Decision-Makers and Payers Pre-FDA Approval for more information on how to compliantly engage in a PIE and the process and procedure for obtaining approval to engage in a PIE.](#)

Post-Approval Communication**Guiding Principle #1: Ensure Statements are Consistent with Product Labeling**

Regulatory authorities in each country typically dictate the content of the approved product labeling. Colleagues must ensure that all statements in Pfizer Promotional materials and communications are consistent with the locally approved product label and local regulations, or otherwise authorized by law.

When creating global and/or regional materials (any materials created for more than one country) that will be distributed to multiple local markets for their review and approval, the Core Data Sheets may be used as the reference label.

Pfizer, like all pharmaceutical companies, is permitted to promote only FDA-approved uses of its products in the United States. All advertising and promotional labeling statements or communications made about

a Pfizer drug must be consistent with the information contained in the product's FDA approved labeling. In certain circumstances RC and BURC may approve content that is not specifically contained in the label while not inconsistent with the label. Uses that remain under investigation or are under FDA review, and therefore have not been FDA approved, are considered off-label and claims about such uses are not to be made in promotional communications.

Communications about products or uses that have received Emergency Use Authorization from FDA are limited in scope and depth. Consult <insert here> for additional information.

Guiding Principle #2: Support All Claims with Adequately Substantiated Evidence

Promotional communications and the claims they contain must be directly substantiated either by reference to the approved labeling or by adequate scientific evidence. Safety and efficacy claims must be supported by an up-to-date evaluation of evidence that is scientifically appropriate, statistically sound, and consistent with the approved product label. Quotations must be referenced. Claims must not be stronger than the evidence warrants. Any non-clinical data or studies must be identified clearly as non-clinical and not used in a misleading manner (i.e., to suggest or imply clinical relevance where none can be established). When substantiation consists of data-on-file, the data must be readily available and retrievable to be provided upon request. Such requests are subject to review and approval by Legal.

Standards for Claims

"Claims" are characterizations of a Pfizer product, whether related to efficacy, safety, dosing, or drug class. All product claims must be consistent with label and supported by adequately substantiated and statistically sound scientific evidence. Local laws and regulations may also have additional standards or requirements for making claims and the level of scientific substantiation required to make a claim.



Under FDA regulations, a drug is considered "**misbranded**" if its labeling or advertising contain claims that are not supported by **substantial evidence**. Substantial evidence generally means two randomized, double-blind, placebo-controlled clinical trials, although the required evidence may vary in certain disease areas or situations). These are often referred to as "**adequate and well controlled**" clinical trials. In most cases, any statement that could impact an HCP's decision to prescribe a Pfizer product, or not to prescribe a competing product, should be considered a claim that needs to be supported by substantial evidence or scientifically appropriate and statistically sound evidence. Moreover, consistent with guiding principle #1, such a claim must be consistent with the approved labeling. Additionally, RC teams should consider all FDA feedback (e.g., from labeling discussions, OPDP or APLB "preclearance"/advisory comments, or FDA enforcement action letters, etc.) when determining the appropriateness of a specific claim for use in advertising or promotional labeling..

Appendix III from [Global Content Policy: Commercial Standards for Promotional Materials](#) provides further information about substantiation requirements for various types of claims.

¹ Healthcare Economics or Pharmacoeconomic Claims are generally limited to use with formulary decision makers

In addition, as a reminder, product claims must be supported by scientifically appropriate and statistically sound data that is consistent with FDA approved labeling. Any exceptions to this rule must be carefully reviewed so that the claim does not inappropriately imply greater efficacy or fewer risks than otherwise established by scientific or medical evidence. It is also important that each claim is only as strong as the evidence that supports it. In other words, each product claim must be narrowly tailored to match the findings of the data and to not overstate what is known about the product.

Superlative Claims

	Is it ever appropriate to use superlatives like “best” or “safest?”
	It is almost never appropriate to use unqualified superlatives such as “best” or “safest” since such claims can rarely, if ever, be supported by substantial evidence. For example, to establish that a product is the best or safest would require successful head-to-head trials against all existing therapies.

Guiding Principle #3: Be Accurate, Truthful, and Not Misleading

- First and foremost, promotional materials must be accurate, truthful, not misleading and sufficiently complete to help enable the recipient to form his or her own opinion of the therapeutic value of the Pfizer product.
- Information contained in Promotional Materials and Promotional Communications must be based on all relevant evidence and should reflect that evidence clearly. Materials must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. Every effort should be made to avoid ambiguity.
- Visual representations, including graphics in promotional materials must not be used in a misleading manner. Graphics and images selected for use should also reflect appropriate local market cultural sensitivities.



Advertising and promotional labeling **must not be false or misleading**. Accordingly, all Pfizer promotional materials must accurately and truthfully present all material information, which includes the product’s important risk and safety information. Materials are false and misleading when they make a claim that is not supported by scientifically appropriate and statistically sound data or that is not consistent with the product label.

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

- Promotes the drug for an unapproved use or indication;

- Overstates the product's efficacy or claims it is effective in a broader range of conditions or patients than has been demonstrated by substantial evidence;
- Uses favorable data derived from patients treated with dosages different from those recommended in the approved labeling;
- Minimizes the product's safety risks;
- Suggests that a drug is safer or more effective than another drug when the claim has not been demonstrated by substantial evidence;
- Markets two or more products in a way that falsely or misleadingly conflates the various properties of the respective products;
- Contains or relies on outdated or selective ("cherry-picked") clinical or other data;
- Inaccurately reflects or incompletely communicates the methodology used to conduct the clinical study;
- Provides favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions;
- Uses the concept of statistical significance to support a claim that has not been demonstrated to have clinical significance or medical validity;
- Fails to reveal the range of variations around quoted average results;
- Uses statistical analyses and techniques on a retrospective basis to discover and cite findings not soundly supported by the study or to suggest scientific validity and rigor for data from studies, the design, or protocol of which are not amendable to formal, and sound, statistical evaluations;
- Presents information from a study in a way that implies that the study represents larger or more general experience with the drug than it actually does; or
- Uses statistics on numbers of patients or counts of favorable results or side effects derived from pooled data from various insignificant or dissimilar studies, in a way that suggests that such statistics are valid even if they are not.

Visual Representations

	<p>A brand team wants to include photographs of families (children and parents) in their promotional materials. Are there any concerns with doing this?</p>
	<p>Visual representations, artwork, and graphics must be taken into consideration when determining whether material may be deemed false and misleading. Visuals can imply claims about the product and must be consistent with the product's labeling. For example, if a product is indicated for adults, including pictures focusing on children in the advertising could lead viewers to mistakenly believe that the product is indicated for use in children. Accordingly, all visuals must be reviewed to help ensure they are not misleading in light of the product's indication or any claim made about the product.</p>

Guiding Principle #4: Provide Balanced Information about Benefits and Risks

Promotional Materials and Promotional Communications must present an appropriate balance between information relating to efficacy and information relating to safety of the product.



Each piece must have fair balance as a whole in terms of content and format. The word “safe” must not be used in promotion. When characterizing the safety profile of a product, the information must be substantiated and include appropriate safety context and balance, such as warnings, contraindications, and other significant safety information.

Essential product safety information, such as contraindications, precautions, and side effects, must be presented fairly, accurately, and according to local laws and regulations.

To be truthful and not misleading, all advertising and promotional labeling must present a **“fair balance”** of the promoted product's potential benefits and risks. This means that significant risk and safety information must be presented together with efficacy claims in comparable prominence.

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

Fair Balance

	Can promotional materials for a product claim that the product is “safe?”
	No. The word “safe” cannot be used since all products have risks. The safety profile of a product maybe described using its safety data including appropriate safety information, such as boxed warnings, contraindications, warnings/precautions, and side effects t.

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

All materials intended to promote our products for use in the United States must be approved through the RC review process prior to use. Branded materials are required to be submitted with the FDA’s **Office of Prescription Drug Promotion (OPDP)** or **Advertising and Promotional Labeling Branch (APLB)** by Date Of First Use. The RC review process should also be applied to all pieces being submitted to OPDP or APLB for advisory comments and to disease awareness for pre-launch materials prepared in anticipation of FDA approval For more information on the RC Process, see [Global Commercial Content: Review & Approval Procedure for Promotional Materials \(U.S. Addendum\)](#).. The GCO Policy Xchange on GCO on Demand available [here](#) also provides links to general and platform specific guidelines as well as communications from **Pfizer’s U.S. Advertising and Promotional Policy Committee (PPC)**.

Pfizer RC teams are encouraged to initiate an “**In-Context Training**” platform or to provide Implementation Guidance to provide specific guidance to field colleagues regarding key promotional content, such as visual aids, clinical reprints, or pieces where brand RC deems additional guidance is necessary. Implementation Guides and/or In Context training should outline the boundaries of what representatives “can and cannot say” about a product based on the content of the piece. For more information regarding what types of pieces must include in-context training or Implementation Guidance and how it should be provided, consult the brand’s team attorney.

Guiding Principle #6: Don’t Make Claims About Investigational Products or Investigational Uses of Marketed Products

Neither Pfizer nor any person acting on its behalf may make a promotional claim about an investigational product, or an investigational use of a marketed product, before the product or indication/use has been approved by a local Regulatory Authority, including FDA, unless otherwise permitted by local law. This prohibition applies even if the medical community widely accepts the use of an approved product for an unapproved indication. This requirement is not intended to restrict non-promotional communications and activities as permitted by local law and regulation.

Requirements of Promotional Labeling and Advertising

The FDA regulates two categories of promotional materials which have slightly different requirements: **promotional labeling** and **advertisements**. The FDA uses the term promotional labeling to apply to a broad array of materials used in marketing a product, including, for example, brochures, mailing pieces, detailing pieces, websites, social media platforms, exhibits, literature reprints, and similar pieces of printed, audio, or visual matter descriptive of a drug.

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

Both promotional labeling and advertising for a drug must include a **fair balance** between efficacy and risk information and must not be false or misleading in any respect. With some exceptions, promotional labeling and advertisements must also typically include:

- **Proprietary (Brand) Name & Established (Generic) Name;**
- Approved indication(s) for use (including any limitations of use);
- At least one dosage form(s) and at least one dosage(s);
- Quantitative amounts of active ingredients in combination products;
- Name of the company responsible for marketing the product and its agent (co-promote partner);
- Boxed warning (where applicable), contraindications, warnings/precautions, and side effects; and
- Appropriate labeling: 1) Full prescribing information, including Patient Package Insert (or **Medication Guide** and/or Instructions for Use) for promotional labeling; 2) appropriate brief summary for print advertisements; and 3) adequate provision for broadcast advertisements such as television, radio, and telephone. Pfizer strongly encourages the use of Consumer-friendly language in consumer materials. Consumer Brief Summary should be used in lieu of the full prescribing information in consumer print material with RC agreement.

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

- Professional print advertisements must include a **Professional Brief Summary**. Consult with your brand regulatory RC colleague for the content needed in a Professional Brief Summary.
- Consumer print advertisements must include the Consumer Brief Summary, **Important Facts Brief Summary**, the **Patient Package Insert**, or the **Medication Guide**, as determined by the brand RC.
- Broadcast advertisements (television, radio, or telephone) must include the **Major Statement** and ensure **adequate provision** of the full prescribing information.

Moreover, the full prescribing information – both the **Package Insert (PI)** and the **Patient Package Insert (PPI)** or **Medication Guide and/or Instructions for Use**, as appropriate – must accompany promotional labeling directed to HCPs (with the exception of some reminder ads – consult your brand regulatory RC colleague for the exceptions). Consumer Brief Summary should be used in lieu of the full prescribing information in consumer print material with brand RC agreement. These concepts are explained in the tables on the following pages.



- **Proprietary (Brand) Name & Established (Generic) Name** is required on all promotional labeling and advertising. The established (generic) name must be included at least once with the proprietary (brand) name where the proprietary name is featured and at least once per page or spread.
 - There must be no intervening matter between the brand and generic name. The generic name must be displayed in at least one-half the prominence of the featured proprietary name. For example, in a logo, the generic name must be included, and the prominence (including type size, character weighting) used must be at least half the prominence of the type used for the brand name.
 - On any page of an advertisement or promotional labeling in which the brand name or designation is not featured but is used in the running text, the generic name shall be used at least once in the running text, typically at first mention or otherwise prominently.
 - In television advertisements, the generic name should be included immediately following the most prominent display of the brand name on the screen (i.e., through “supers” that are used as headlines or taglines).
 - In radio advertisements and telephone scripts, the generic name should be included at the first mention of the brand name.
 - In electronic media, the generic name should accompany the brand name at the most prominent mention, and the generic name should also appear at least once in the running text. For electronic media, including websites and presentations, the generic name must be visible at least once per desktop screen or slide..

- **Professional Brief Summary** typically includes all risk information from the full prescribing information regarding the product including, but not limited to, boxed warning (where applicable), contraindications, warnings/precautions, and side effects, and information under headings such as cautions, special considerations. The Brief Summary typically excludes the pharmacokinetics, pharmacology, and dosage information from the full prescribing information unless there is important risk information included in these sections or if a brief summary was submitted for OPDP advisory comment with this content included. Consult with your brand Regulatory RC team member for further guidance.
- The Consumer Brief Summary is generally derived from the PPI (or Medication Guide) and is used in consumer DTC print advertisements and promotional labeling. [Labeling Requirements for Consumer Directed Print Material](#).<this is linking incorrectly to DRT. The correct link is: <http://opsources.pfizer.com/TORCDocuments/Consumer%20labeling%20March%202019%20Final.docx>>
- **Major Statement** conveys a drug's most important risk information in consumer-friendly language during a broadcast advertisement. A product's Major Statement is typically crafted with significant input from the FDA's OPDP or APLB through their responses to requests for advisory comments.
- **Adequate Provision** is applicable in the context of broadcast advertisements only. The term refers to providing the audience with a reasonably convenient way to obtain the drug's full prescribing information. Pfizer's approach to disseminating the product's approved labeling for broadcast advertisements is to include each of the following components:
 - Providing a toll-free telephone number in the advertisement for consumers to call to request the full prescribing information or to have it read to them over the phone;
 - Providing an Internet web page (URL) address where the full prescribing information can be viewed;
 - Disclosing that HCPs may provide additional product information.

Please note that Pfizer no longer requires reference to a print publication provided that the three components delineated above are satisfied. For further information regarding Adequate Provision and alternative approaches to fulfilling that requirement, see the [PPC memorandum regarding "Adequate Provision" and the "Book of Record" in Broadcast Advertisements](#) dated August 26, 2016 available on GCO Policy Xchange on GCO on Demand.

- Reminder Promotional Materials** are promotional pieces that contain a drug’s proprietary (brand) name and established (generic) name and may contain dosage form and strength, as well as pricing information or formulary coverage. A reminder cannot mention or imply the drug’s indication, effectiveness, safety, uses, or dosing regimen. Nor can a reminder give any representation of the drug, either direct or implied. The inclusion of any such information could transform a reminder into a full advertisement or promotional labeling, and be subject to FDA advertising & promotion requirements for a full product advertisement or full promotional labeling communication. Because reminders call attention to the name of the drug product but do not include indications or dosage recommendations, they are not required to carry the full prescribing information or brief summary. Reminder promotional materials also do not include safety disclosures since there are no efficacy or other claims to balance. **Pursuant to FDA regulations (with a limited exception for “price reminders” subject to strict requirements including disclosure of the price paid by the consumer), reminder promotional materials cannot be used for products that carry a boxed warning.** Boxed warning products may be advertised or communicated in promotional labeling using a “reminder-like” approach, where the communication complies with reminder rules, but also carries the full prescribing information or Brief Summary. See Pfizer Guidance on Promotional Labeling and Advertising for Products with a Boxed Warning available here: <http://opsource.pfizer.com/TORCDocuments/FINAL%20boxed%20warning%20treatment%20in%20advertising%20and%20promotion8.12.doc>
- Help Seeking or Disease Awareness Advertisements** are communications disseminated to consumers or HCPs that discuss a particular disease or health condition, but do not mention any Pfizer drug or make any representation or suggestion concerning a particular Pfizer drug.

FDA Submission of Promotional Materials

	When do promotional materials need to be sent to the FDA?
	All branded promotional materials for Pfizer drugs must be submitted to the FDA’s OPDP or APLB before or at the time that Pfizer first uses the materials. Except in the case of drugs approved via the Subpart H accelerated approval process or biologics and vaccines approved under Subpart E, Pfizer is not required to submit any materials to OPDP or APLB prior to first use. A company may choose to seek advisory comments from the FDA on materials prior to use. This is typically done prior to the launch of a new product or new indication so that the company may receive guidance from OPDP or APLB on the promotional presentation including efficacy claims and fair

balance when particular claims are made. Moreover, pursuant to the PhRMA DTC Guiding Principles and FDA's draft Guidance for Industry Direct-to-Consumer Television Advertisements – FDAAA DTC Television Ad Pre-Dissemination Review Program, <insert link to <https://www.fda.gov/media/82590/download>> Pfizer has committed to seek advisory comments on new television broadcast advertising campaigns.

Use of Reprints in Product Promotion

A brand Review Committee may approve clinical reprints for promotional use by Field Commercial Colleagues. Most reprints approved for use will be consistent with the product's label. Occasionally, other types of reprints may be RC approved for use, if deemed compliant with FDA's Guidance for Industry: Distributing Scientific and Medical [Publications](#) on Risk Information for Approved Prescription Drugs and Biological Products or [Distributing Scientific and Medical Publications on Unapproved New Uses](#). In order for a reprint to qualify as "consistent with the product's label," (for indication, efficacy, and safety) it must satisfy **ALL** of the following conditions:

The primary message must fall within the product's label;

It contains, at most, only an insignificant amount of information that is inconsistent with the label; and

Any information that is inconsistent with the label must not be reasonably likely to be used to support an inappropriate promotional message.

Further, in accordance with agreements between Pfizer and certain state Attorneys General, the following additional requirements and restrictions apply when an RC is considering approval of a reprint for promotional use:

Pfizer is prohibited from disseminating information regarding an off-label use of a Pfizer product if that use was submitted to the FDA for approval and the FDA either: (1) refused to approve the application; or (2) indicated that FDA-identified deficiencies must be resolved before approval can be granted, unless the information clearly and conspicuously discloses to the recipient that the FDA has issued that advice regarding the off-label use.

Pfizer is prohibited from distributing reprints containing off-label information about any Pfizer product to physician specialties who do not customarily prescribe the product if the distribution of the reprint, combined with other promotional activities, promotes off-label use of the product.

Opioid-specific restrictions: Reprints relating to the use of opioids for chronic pain should be accompanied by information relating to the potential risks of addiction, abuse, and misuse associated with extended-release opioids.

Before approving a reprint, the product Review Committee should carefully consider additional risk mitigation measures that may be appropriate, such as, implementation guides, carriers, wrappers, backgrounders, and/or enhanced training, on a case-by-case basis. In accordance with [Global Commercial Content: Review & Approval Procedure for Promotional Materials \(U.S. Addendum\)](#) any reprint reviewed for approval under this guidance may also be referred by the product Review Committee to the relevant **Business Unit Review Committee (BURC)**.

Direct-To-Consumer and Internet Advertising

Direct-To-Consumer Advertising

Pfizer has adopted the [PhRMA Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines](#) and Pfizer's [Guidance for the Implementation of the Updated PhRMA DTC Principles](#). These principles support the use of DTC advertising to communicate information about medical conditions and potential treatments so that patients can make informed choices. Like all promotion, DTC communications must comply with FDA regulations and Pfizer's guiding principles, as stated above.

In addition to the guiding principles, PhRMA's Guiding DTC Principles serve to ensure that DTC communications educate patients and consumers and encourage them to seek guidance from their healthcare professionals. All Pfizer DTC materials should be consistent with the PhRMA Principles. In the event of any inconsistency, Pfizer guidance takes priority over the PhRMA Principles.

Opioid-specific requirements: Advertising of Pfizer opioids should also include information concerning the potential risks of addiction, abuse, and misuse of the products when used in accordance with their FDA-approved prescribing information.

Patient Testimonials

Like all other advertising and promotion, testimonials must follow the guiding principles outlined above. Any testimonial used by Pfizer must be consistent with the product label and must include and/or be accompanied by fair balance. Testimonials must not include any claims that Pfizer could not make directly. Moreover, in accordance with our agreements with state Attorneys General, Pfizer cannot disseminate in a promotional context any patient testimonial relating to a Pfizer product that does not clearly and conspicuously disclose what the generally expected performance would be in the depicted circumstances or clearly and conspicuously disclose the limited applicability of the experience described by the patient testimonial to what consumers may generally expect to achieve. Please refer to the [Guidance for the Implementation of the Updated PhRMA DTC Principles](#). Please also refer to [Testimonials: Patient Recruitment and Engagement](#), available on GCO Policy Xchange on GCO on Demand, for further guidance on specific requirements for using patient testimonials in promotion.

Usage of Animals in Advertising

Introduction

Because respect is a key tenet in our use of animals, Pfizer has established standards regarding the use of animals in the marketing of Pfizer products. If advertisements (print, digital or television) featuring animals are used, any animal shown should be healthy and in a natural or appropriate setting. Non-human primates must not be used in the advertising of Pfizer products, and other wild animals will also not be used unless they are shown in their natural setting or portrayed through animation or computer-generated graphics. These standards are part of [Pfizer's Corporate Policy # 901](#). The summary below is intended only as an overview, and colleagues are responsible for referring to and following all applicable portions of CP #901.

Planning Guidance

For promotional planning, if you are considering a campaign or promotional tactic that may feature an animal or animals the following steps are required:

Animals in TV Advertising: If a Pfizer television promotional campaign will contain any **use of animal** (including domesticated animals such as dogs, cats, birds, etc.), please include Gloria Gaito, Global Animal Welfare, at the concept stage – before market research or testing. All storyboards must be reviewed and approved by Gloria Gaito in conjunction with Global Product Counsel.

Animals in Print and Digital Promotion: If a Pfizer promotional print or digital campaign will feature any animal, and in the absence of a storyboard, please outline use as follows:

- Provide a detailed overview paragraph outlining animal(s) use;
- Specify the medium: print, digital, or both;
- Clarify whether the animal(s) depicted are from stock photography, existing Pfizer photo archive, from an existing DTC TV advertisement that went through the process for TV advertising above, or will be part of a new photo shoot;
- List the type and number of animal(s) being used (itemize all animals being depicted – dog, cat, horse, etc.);
- Describe the setting (for non-wild animals this can be a natural or appropriate setting);
- Describe what the animal will be doing;
- Explain the objective of the promotional tactic; and
- All outlines must be reviewed and approved by Gloria Gaito, Global Animal Welfare in conjunction with Global Product Counsel.

Use of Wild Animals in Any Promotion: If any wild animal is being considered for use in promotion (including bears, porcupines, sea lions, etc.) these animals must only be shown in their natural setting (a zoo is not considered a natural setting) or portrayed through animation or computer-generated graphics. At concept stage and prior to market research, their use for TV advertising should be drafted in a Storyboard, and for print and digital work (in the absence of a storyboard) should be provided in a detailed overview. Both require a concept review by Gloria Gaito, Global Animal Welfare, in conjunction with Global Product Counsel.

To view Corporate Policy # 901, please click [here](#).

If you have additional questions, please contact Gloria Gaito or your Pfizer legal contact for your promotional work.

Internet and Social Media Promotion

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

Pfizer websites that contain product information that is deemed promotional must comply with the laws, regulations, and principles that govern promotional materials created for traditional media. This means that any discussion of the product's uses or indications on websites must adhere to FDA-approved labeling. Websites must appropriately balance any claims of efficacy with the relevant risk information, and the risk information should be presented in a manner similar to the presentation of efficacy information. For example, if the efficacy presentation is active (e.g., an audio component), then the risk information should likewise have an active element. Similarly, if efficacy or benefits claims are made on a page, balancing safety information must be incorporated into that page with comparable prominence. Having risk information "one click away" is generally not acceptable; rather, risk information must be incorporated into the body of any webpage that includes any benefit claims. Branded webpages may not include or imply any product claims (including the indication) unless fair balance is provided on that same page. In addition, the webpage must include a link to the product's package insert.

Detailed information on the requirements of Internet promotion, including Facebook (social media), can be found under the [Advertising & Promotion Guidelines](#) tab on Global Policy Xchange on GCO on Demand.

Pfizer Biopharmaceuticals Group: Paid Media

As part of our advertising and promotional efforts, the Pfizer Biopharmaceuticals Group (PBG) purchases media placements for advertisements or other marketing content. This activity is referred to as **PAID MEDIA** and includes related media services and vendors. Examples of paid media include placing a TV

commercial on CBS or YouTube, banner ads on Medscape, a sponsored article in The New York Times, paid search on Google, or newsfeed placements on Facebook. Media services includes data and tools for media activation and optimizations, and Pfizer’s external media agencies. See table below for additional details on paid media related definitions.

While paid media efforts are an important tool to reach patients and HCPs, there are also multiple risks including compliance, fraud, privacy, and reputation. To protect Pfizer, PBG policy requires that PAID MEDIA be centrally led and governed by the Pfizer MEDIA LAB. Centralized media ensures media activity adheres to Pfizer policies and guidelines, and achieves the following Pfizer requirements:

- **Control and Tracking:** visibility of all media spend and practices, and ability to pause/stop.
- **Protection of Media Spend:** fair market value, auditing, appropriate terms and conditions.
- **Media Vendor Management:** single Pfizer voice and process, and proper vendor vetting.
- **Respect Privacy:** adherence to Pfizer’s Privacy Policy, and privacy laws and regulations.
- **Reputation:** media practices and placements consistent with Pfizer values and policies.

Paid Media Procedures

This policy applies to all colleagues (across functional areas/BUs/divisions) that are engaging in paid media and media services **that are funded by and for the benefit of PBG**. To be compliant with this policy, colleagues are required to follow these standard operating procedures.

OVERALL	All PBG paid media and media services must be initiated and implemented through the Media Lab and its processes, guidelines, and tracking systems.
PURCHASING	Only the Media Lab can implement, negotiate or purchase paid media or media services on behalf of PBG. <ul style="list-style-type: none"> • Colleagues must not sign contracts for paid media or media services
VENDORS	Relative to media vendors for paid media and media services: <ul style="list-style-type: none"> • The Media Lab is the single point of contact for all media vendors • The Media Lab is responsible for vetting and approving media vendors
VENDORS WITH MULTIPLE OFFERINGS	For vendors that have media and non-media offerings: <ul style="list-style-type: none"> • Refer vendors to the Media Lab for paid media and media services offerings • Non-media colleagues must not engage in media related discussions, sign contracts, or bundle media with non-media offerings

AGENCIES	<p>The Media Lab selects and manages external media agency resources which must be utilized for all PBG paid media and media services.</p> <ul style="list-style-type: none"> Other agencies (i.e., creative, digital, PR) cannot engage in media activity
DATA & TOOLS	<p>The Media Lab is responsible for all media services related to data, tools, and analytics used for media activation, optimizations, reporting, and measurement.</p>
CO-PROMOTES	<p>For co-promotes, where the co-promote's media agency is leading media (not the Pfizer Media Lab), Pfizer brand teams are responsible for ensuring core media requirements are met for compliance, privacy, auditing, FMV, and vendors.</p>

Media Related Definitions

Paid Media: refers to efforts, where Pfizer is paying to place ads or other content, on media and other platforms not owned or controlled by Pfizer. Paid media is used to reach patients, HCPs or other targets.

- Pfizer Content for paid media includes branded or unbranded communications, in standard ad units (i.e., TV commercial, banner ad) or non-standard/custom formats.
- Paid Media Platforms: includes all existing and emerging media platforms and tactics:

Examples of platforms and tactics for paid media:

<i>TV</i>	<i>Radio, Streaming Audio</i>	<i>Programmatic</i>	<i>Local Media</i>
<i>Video</i>	<i>Interest Based Advertising</i>	<i>Sponsorships</i>	<i>Geolocation</i>
<i>Digital Display</i>	<i>Smartphones, Tablets</i>	<i>Paid Native</i>	<i>Newspapers</i>
<i>Social</i>	<i>Electronic Health Records (ads)</i>	<i>Out-of-Home</i>	<i>Paid Podcasts</i>
<i>Magazines</i>	<i>Multicultural Media</i>	<i>Point-of-Care</i>	<i>3rd Party Apps</i>
<i>Journals</i>	<i>Search (paid, organic)</i>	<i>Direct Response</i>	<i>3rd Party Emails</i>

Media Services: related to paid media, includes the following

- Data and Analytics for media targeting, optimizations, reporting, and return-on-investment
- Programmatic Technology such as demand side and data management platforms
- Implementation Tools for ad serving, verification, fraud detection
- Emerging Media Applications such as artificial intelligence, machine learning, automatic content recognition, blockchain, and automation tools
- Media Agencies-of-Record used for planning and purchasing PBG media

Media Vendors: are companies or organization and their respective sales representatives, that sell paid media or media services.

Key activities that are **out-of-scope** for this policy include Pfizer Corporate funded paid media, paid media that is included in HCP congresses/conferences, and in-pharmacy.

For questions related to the Paid Media policy, please contact the [Media Lab](#).

For More Information

- Refer any questions to your team's Regulatory colleague or product attorney.
- [1.01 Global Content Policy: Commercial Standards for Promotional Materials](#)
- [2.01 Global Content Policy Addendum](#)
- [Global Commercial Content: Review & Approval Procedure for Promotional Materials \(U.S. Addendum\)](#)
- [PhRMA Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines.](#)
- [Pfizer's Guidance for the Implementation of the Updated PhRMA DTC Principles.](#)
- CEP Resource Center at <http://cep.pfizer.com>.
- Global Policy Xchange on GCO on Demand internal website [here](#).
- The Digital Review Team website at <http://drt.pfizer.com/>.
- Compliance Division internal website (for state Attorney General agreements) at <http://corporatecompliance.pfizer.com/Resources/Pages/StateAGAgreements.aspx>.



CHAPTER #3 – PROMOTIONAL INTERACTIONS WITH HEALTHCARE PROFESSIONALS

Chapter

#3

Promotional Interactions with Healthcare
Professionals

CONTENTS

Promotional Interactions with Healthcare Professionals

Introduction	46
Key Points to Ensure Compliance	46
Four Core Compliance Principles for Successful Product Promotion	48
Use Only RC-Approved Materials and Selling Statements	48
Stay On-Label and Discuss Only Approved Products and Indications	48
Provide an Accurate and Balanced Presentation.....	50
Patient Access / Reimbursement Support Resources	50
Never Engage in Actual or Perceived Quid Pro Quo Arrangements.....	51
For More Information.....	51

Chapter #3 Promotional Interactions With Healthcare Professionals

Introduction

Pfizer Sales Colleagues have primary responsibility for promoting our products to **Healthcare Professionals (HCPs)**. However, non-Sales colleagues, including Marketing and Medical colleagues, may also interact with HCPs in various settings where activities governed by promotional standards may take place. These settings may include congresses, conventions, symposia, and field rides with Field Commercial Colleagues. Other interactions with HCPs may also be considered promotional, depending on the content and context of the interaction. The “**Four Core Compliance Principles**” reviewed in this Chapter are applicable to any Pfizer colleague engaged in a promotional interaction with an HCP. For a more detailed discussion of the policies applicable to Sales Colleagues, see Orange Guide Chapter 2: Interactions with HCPs and Health Systems.

Key Points to Ensure Compliance

- Use only Pfizer Review Committee (RC) approved materials when engaging in promotional interactions with HCPs.
- All promotional statements must be on-label (consistent with the product's package insert) and consistent with RC-approved materials/messaging. All inquiries about off-label information or unapproved clinical data must be referred to Pfizer U.S. Medical Information (USMI) (1-800-438-1985)
- Do not discuss new products or indications before they are FDA-approved unless you have approval to do so.
- Always ensure accurate and balanced presentations of the risks and benefits of any Pfizer product for the relevant approved indication are given.
- Never engage in any actual or perceived quid pro quo arrangement.
- Key Points to Ensure Compliance use only Pfizer Review Committee (RC) approved materials when engaging in promotional interactions with HCPs.
- All promotional statements must be on-label (consistent with the product's package insert) and consistent with RC-approved materials/messaging. All inquiries about off-label information or unapproved clinical data must be referred to Pfizer U.S. Medical Information (USMI) (1-800-438-1985)

- Do not discuss new products or indications before they are FDA-approved unless you have approval to do so
- Always ensure accurate and balanced presentations of the risks and benefits of any Pfizer product for the relevant approved indication are given
- Never engage in any actual or perceived quid pro quo arrangement

Key Points to Ensure Compliance

- Four Core Compliance Principles for Successful Product PromotionKey Points to Ensure ComplianceUse only Pfizer Review Committee (RC) approved materials when engaging in promotional interactions with HCPs
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- Do not discuss new products or indications before they are FDA-approved unless you have approval to do so
- Always ensure accurate and balanced presentations of the risks and benefits of any Pfizer product for the relevant approved indication are given
- Never engage in any actual or perceived quid pro quo arrangement

Four Core Compliance Principles for Successful Product Promotion

Your interactions with HCPs always must be based on providing accurate and balanced information. Pfizer has Four Core Compliance Principles that protect you and the Company when you are engaged in promotional interactions 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 arrangements.

Use Only RC-Approved Materials and Selling Statements

Each promoted Pfizer product has a multi-disciplinary **Pfizer Review Committee (RC)** that reviews and approves all sales and marketing materials for the product and associated disease states. Any written materials that you use in a promotional interaction, whether a marketing visual aid, a clinical reprint, or any other resource or tool, must be approved by the relevant RC. RC-approved materials are prepared in accordance with FDA-approved product labeling. You may not alter RC-approved materials in any way. In addition, any materials marked “DO NOT DETAIL” or “Internal Use Only” must not be shared with HCPs or other customers. For more information on the review and approval of promotional materials, see [White Guide Chapter 2: Advertising and Promotional Materials](#).

It is critical that you only make promotional statements that are RC-approved, and follow all guidance and direction contained in any relevant product Implementation Guide or other RC-approved guidance to help ensure appropriate execution.

Stay On-Label and Discuss Only Approved Products and Indications

All promotional statements about a drug must be consistent with the product’s labeling and must be consistent with information contained in RC-approved materials. **Off-label promotion** is taken extremely seriously by Pfizer and the government.

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

Detailing and Promotional Materials: Examples of On-label vs. Off-label Claims	
On-label Claims (Appropriate)	Off-label Claims (Inappropriate)
Statements that accurately reflect an approved indication	Statements that inappropriately broaden an indication <i>E.g.</i> , “Eliquis is effective in reducing strokes and blood clots for all patients”
Statements about a product’s efficacy for the approved indication, consistent with labeling	Statements about a product’s efficacy for an unapproved use <i>E.g.</i> , “Ibrance 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 label	Statements about a product’s efficacy within a population of patients that are not consistent with the product labeling or where the safety and efficacy in that population has not been established <i>E.g.</i> , “Chantix 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 misstate, minimize, or are inconsistent with the information in the package insert <i>E.g.</i> , “Patients taking Xeljanz do not really experience side effects”

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

Additionally, you may only make comparative claims (comparing an attribute of one product to an attribute of another product) when you use Pfizer RC-approved promotional materials that expressly make such claims and you follow all directions provided in any applicable implementation guidance. The FDA considers promotional materials and 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 without “substantial evidence” to support

such statements or suggestions. It is not appropriate to make comparative safety or efficacy claims based solely on the data in products' package inserts (i.e. "label-to-label" comparison). Similarly, because of differences in clinical trial designs, inclusion criteria, and other factors, it generally is not permissible to compare results from two separate clinical trials.

If an HCP asks you an unsolicited question about an unapproved product or use, or asks for information outside of, or inconsistent with, a product's approved labeling or Pfizer RC-approved materials, the question must be referred to Pfizer U.S. Medical Information (1-800-438-1985).

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

Provide an Accurate and Balanced Presentation

All promotional materials, selling statements, and presentations about Pfizer products must be truthful, accurate and not misleading, be supported by substantial scientific evidence, and appropriately "balance" product claims with risk and safety information. Promotion is false or misleading if it does not include relevant risk and safety information or if it is not supported by appropriate scientific evidence.

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

Patient Access / Reimbursement Support Resources

Pfizer is committed to supporting access to the Pfizer medicines prescribed to patients by their doctors. As part of this commitment, some Pfizer brands offer reimbursement and patient access resources such as copay cards, hubs, and other programs to help patients get access to their prescribed Pfizer medicine. When communicating about these resources to doctors, you should not communicate that these offerings are a reason to prescribe the product, that they differentiate the product from competitors, or that these resources provide independent value to a doctor by relieving administrative burden or otherwise providing a service to the doctor. As with efficacy and safety claims, all communications about these resources must be consistent with RC-approved materials and implementation guides.

Some Pfizer brands may offer brand-specific reimbursement and patient support activities that are carried out by field-based colleagues. See White Guide Chapter 21 Patient Support Roles for further guidance on appropriate interactions regarding these patient support activities.

Never Engage in Actual or Perceived Quid Pro Quo Arrangements

Never offer or appear to offer any payment or item of value in exchange for prescribing or formulary placement of a Pfizer product. The decision of an HCP to prescribe or recommend a Pfizer product, or put it on a formulary, must be based on the clinical data and the best interest of the patient, and not on any payment or value offered by Pfizer.

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

For More Information **Key Point Regarding Meals, Educational Items, and Other Transfers of Value to HCPs**

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

Never give something of value – even something of nominal value – to influence an HCP, directly or indirectly, to prescribe or recommend a Pfizer product, or to influence its formulary positioning. Doing so could put both you and Pfizer at substantial risk and subject you to disciplinary action.

For More Information

- [Orange Guide Chapter 2: Interactions with HCPs and Health Systems.](#)
- [Green Guide: Governance for External Medical Activities.](#)
- [White Guide Chapter 5: HCP and Government Official Consulting Engagements.](#)
- [White Guide Chapter 15: State Laws: HCP and Government Employee Restrictions.](#)
- [White Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure.](#)



CHAPTER #4 – MARKETING PROGRAMS

CONTENTS

Marketing Programs

Introduction	54
Key Points to Ensure Compliance	54
Speaker Programs	55
Content Development	57
Speaker Programs Topics and Invitations	58
Speaker Recruitment & Contracting	59
Speaker Training	60
Program Execution	60
Promotional Opportunities at Third-Party Meetings and Conventions	61
Symposia Programs	61
Exhibit/Display & Other Advertising Opportunities	63
External Websites and Other Digital Activities	64
Customer Engagement Programs (CEPs)	64
Savings and Free Trial Programs	64
Hub Support Programs	65
Pfizer Patient Assistance Programs and RxPathways	65
Quality Programs	66
Commercial E-mails	67
For More Information	68

Chapter #4 Marketing Programs

Introduction

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

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

Key Points to Ensure Compliance

- Pfizer marketing programs, including those executed by an advertising agency or other vendor working on Pfizer’s behalf, must adhere to FDA regulations and other rules governing promotion and must be approved by the relevant Review Committee.
- The main objective of all speaker programs must be to meet an educational need by providing truthful and non-misleading, scientific and educational information consistent with FDA guidelines on the appropriate utilization of Pfizer products and/or on relevant disease areas.
- Each brand team must follow guidance related to the submission of a Speaker Program Needs Assessment to obtain approval and funding for the use of speaker programs as a promotional tool.
- Pfizer policy requires that speakers engage attendees at an out-of-office venue for a minimum of 45 minutes (inclusive of Q&A) or a minimum of 30 minutes (inclusive of Q&A) for programs that occur virtually or in an in-office setting. Marketing must be mindful of these requirements when developing content in order to ensure that a sufficient amount of content is provided to support program. duration requirements.

Key Points to Ensure Compliance

- Speakers may only be selected based on their expertise, credentials, and ability to communicate with the target audience.
- Prior to providing any speaking services, all speakers must be screened as part of a vetting process and must have a signed agreement with Pfizer which documents the fair market value rate to be paid.
- Prior to engaging in any speaker program, all new speakers are required to complete training on: (1) the brand's core product or topic slide kit (as applicable); and (2) Pfizer compliance policies (annually).
- Brand teams should design, review, approve, and conduct Customer Engagement Programs in compliance with [Corporate Policy \(CP\) #902: Management of Safety Information for CEPs](#) and [Corporate Policy \(CP\) #902a: Management of Safety Information for CEPs Procedure](#).
- At many third--party meetings and conventions, Pfizer may pay for space for an opportunity to promote its products (or, in some cases, to promote Pfizer), but Pfizer must not pay more than fair market value for the opportunity.

Copay savings programs, discount programs, direct purchase programs, voucher programs and free trial programs (collectively “Savings and Free Trial Programs”), and other similar programs offered by U.S. teams (including brand teams and non-brand teams, such as the U.S. Trade Group) must be developed and implemented in accordance with Chapter 19 of the White Guide: Savings and Free Trial Programs and the relevant standard operating procedure.

Speaker Programs

A **speaker program** is a promotional activity controlled by Pfizer in which a speaker (typically an external HCP) presents educational information on a product, disease state, or other healthcare topic, consistent with Pfizer's policies on advertising and promotion, to a group of invited HCPs or other appropriate attendees. Even though an external individual is engaged to speak, Pfizer is responsible for the conduct and content at speaker programs since the FDA considers speakers to be representatives of Pfizer. This section focuses on speaker programs for HCPs. For more information on speaker programs with a consumer audience, see [White Guide Chapter 12: Promotional Interactions with Consumers](#).

Speaker Programs are a way to present information in a peer-to-peer format on products, a disease state related to our products, or other quality of care topics to a group of HCPs and/or other appropriate attendees as applicable under local laws, regulations and industry codes. However, Speaker Programs also present a risk to Pfizer. Transfer of value to an HCP, such as speaker fees or meals to attendees, could be perceived as an attempt to improperly influence prescribing decisions. Presentation of inaccurate information (e.g. downplaying safety issues) can result in perceived or actual patient harm. Pfizer is responsible for Speaker Program activities conducted on its behalf, including all information the speaker presents, any payments related to the program, attendance by appropriate attendees, and the venue. As a result, minimum standards have been developed to ensure consistency across U.S. businesses:



- A legitimate business purpose exists for both individual programs and a brand's Speaker Program strategy
- Speaker selection is based on qualification and experience
- Appropriate HCP attendance
- Appropriate materials and content
- Appropriate event execution
- Appropriate expenditures are made
- Appropriate transparency of transfers of value

For more information regarding Global Speaker Program Policy minimum standards, please click on the [link](#).

If a brand team wishes to conduct speaker programs, it must coordinate with Legal, Compliance, and Medical to prepare a **Speaker Program Needs Assessment (SPNA)**. The SPNA must be approved and submitted along with the brand team's request for funding (typically as part of their proposed Operating Plan for the upcoming year) following the requirements and processes for the **SPNA**. Given the heightened risk associated with speaker programs, Brand Teams should assess the status of the product lifecycle and consider whether other promotional strategies with lower compliance risk would be sufficient to accomplish the Brand Team's educational goal. The SPNA must set forth the educational goal(s), topics planned to support the educational goal(s), respective justification for each topic planned, target audience, and any data/metrics that support the need for education in a peer-to-peer format. **It is against Pfizer policy to design a speaker program strategy for the purpose of inducing speakers to prescribe Pfizer products or to affect their placement on a formulary.**

Sales and Marketing can both plan speaker programs, although programs for most brands are more typically executed by Sales. All speaker programs, regardless of whether they are Marketing programs or Sales programs, must be implemented and executed in accordance with the SPNA and Pfizer policies and procedures.

Speaker Programs

	<p>If a Pfizer Sales or Marketing colleague initiates a speaker program, what responsibilities do they have?</p>
	<p>Regardless of who funds the event (Sales or Marketing), the program host is responsible for the overall compliant management of the event. Generally, the Sales or Marketing colleague chooses an appropriate venue and presentation topic (from the list of RC-approved topics in Centris), selects an appropriate speaker, and contacts that speaker. The program host must review Pfizer's speaker policies and the speaker's slide deck with the speaker prior to the event to ensure that the speaker understands that they must present the entire deck in accordance with the product's approved labeling and is using an approved slide deck without any additional, unapproved slides. Colleagues may e-mail slide decks to the speaker for the sole purpose of the pre-program review discussion with the speaker only if the speaker is not able to download the deck. The slide deck in this instance must be already RC-approved, locked, and available in Centris. The program host must monitor the program, make any needed corrections or clarifications, and identify any potential compliance violations that occurred at the program as part of the Centris close-out process. For more information on program host responsibilities when conducting a speaker program, see Orange Guide Chapter 9: Speaker Programs for HCPs.</p>

Content Development

All speaker program initiatives must be aligned to an approved SPNA which identifies the legitimate educational goals for a proposed speaker program series. Marketing, with input from Medical, is responsible for developing speaker program content which must align with the educational goals identified in the SPNA. Examples of legitimate educational needs are:

- Raise awareness of a disease state;
- Education on new product (within 24 months of FDA approval);
- Education on significant label update/expansion (within 24 months of FDA approval);
- Education on new data not associated with a new or subsequent FDA approval (within 12 months);
- Education on topics not related to product or specific disease state; or
- Education on patient support offerings.

Brand teams interested in conducting speaker programs outside these windows must obtain approval from a BU-level committee comprised of Legal, Compliance, Medical, and Marketing colleagues as part of the

SPNA process. The committee must be able to justify the ongoing educational need for the program based on objective criteria.

If there is no identifiable legitimate educational goal that warrants a real-time peer-to-peer presentation – for example, in cases in which the information is already well known and understood by the target audience – then it may be appropriate to leverage other promotional activities instead (e.g., detailing, DTC, etc.).

All speaker program content must be reviewed and approved by the relevant RC, be designed to meet the educational goal identified in the SPNA and comply with Pfizer policies on advertising and promotion. All speaker program decks must also include a mandatory introductory compliance slide which notifies attendees of certain key Pfizer speaker program policies (e.g., speakers are presenting on Pfizer's behalf; content is required to be consistent with FDA-approved labeling; etc.). Even when Pfizer hires a third-party vendor to assist with the development or execution of a program or series of programs, Pfizer remains responsible for the content and message.

Speakers must use only Pfizer RC-approved slides when speaking on behalf of Pfizer, and the slides used must be approved for the audience (HCPs or consumers). Pfizer policy requires that speakers engage attendees for a minimum of 45 minutes, inclusive of Q&A, for out-of-office programs, or a minimum of 30 minutes for programs in an in-office setting or conducted virtually. Marketing colleagues must be mindful of these requirements when developing content in order to ensure that a sufficient amount of content is provided to support program duration requirements. For more information on content development, see [White Guide Chapter 2: Advertising and Promotional Materials](#).

Pfizer policy prohibits speakers from modifying slides or inserting their own slides (including introductory, speaker bio, case study, and disease state slides). In limited circumstances, a speaker may present slides that are not contained in the standard approved speaker deck so long as RC approval of the speaker's slides is received prior to the speaker program. All slides for which a speaker seeks RC approval must be consistent with product labeling, accurate and truthful, supported by substantiated and scientifically-sound data, and appropriately balanced with information on both benefits and risks.

Speaker Programs Topics and Invitations

As part of the RC approval process, brand teams are required to provide a speaker program **topic name** for each presentation. This topic name typically mirrors the title within the slide deck itself. The topic name is also used to populate various materials and systems associated with speaker programs, including program invitations generated on behalf of colleagues hosting speaker programs, the program name that displays in Centris, as well as logistical communications used by the scheduling vendor when working with both speakers and Sales Colleagues.

Brand teams should generally avoid using product names (either branded or generic) in speaker program topics, since such references can trigger additional legal and regulatory requirements which

Pfizer's systems and processes are not routinely set up to manage. To be clear, although a speaker program title reflecting a product name (e.g., "Calmia: A Treatment for Mild Anxiety") may be appropriate as part of a slide deck containing balance and Important Safety Information, such a title could constitute an unbalanced product claim if it were populated into a stand-alone branded speaker program invitation that lacks Important Safety Information or is not accompanied by a PI.

If a brand team believes there is a compelling justification to use a product name in a speaker program topic/invitation (e.g., in the case of a new product launch), please discuss the matter beforehand with your team attorney, Regulatory, and the **Meetings & Events (M&E) team** to ensure that all legal, regulatory, and operational requirements are satisfied.

Regarding development and finalization of all program invitations for Marketing-Led Programs, including when working with an agency, it is imperative to adhere to the requirements outlined in the "Preparing and Distributing Invitations" section in Orange Guide Chapter 9: Speaker Programs for HCPs.

Speaker Recruitment & Contracting

A list of active and appropriate Pfizer speakers for given products and topics will appear in Centris. These are speakers that: (1) have been vetted by a third-party against an objective set of criteria that reflects evolving industry standards and accounts for reputational risks; (2) have been assessed based on their qualifications, license status and presence on internal and exclusion lists; (3) have a signed contract with Pfizer; (4) have completed compliance training; (5) have completed training on a core product or topic slide kit (in-person, virtually, or online on-demand, as applicable); and (6) have not yet reached Pfizer's annual promotional speaker payment cap or caps on frequency of utilization by individual sales representatives or sales district members. An HCP's promotional speaking contract with Pfizer is valid for one year and is typically renewed automatically.

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

Speakers may only be selected based on their expertise, credentials, and ability to communicate with the target audience. Speakers may not be selected to: establish, maintain, or improve a relationship with the speaker; gain or improve access to the speaker; or reward past prescribing or induce future prescribing. Although the speaker should have experience with the product or disease state, prescribing volume may not specifically be considered when selecting a speaker. In addition to doctors, speakers may be nurses, pharmacists, or any other person with the requisite subject matter expertise and credibility to speak on a particular topic. Consult the M&E team for more information on speaker nominations and validation.

Prior to providing any speaking services, all speakers must have a signed agreement in place with Pfizer that documents the speaker's fair market value (FMV) payment rate. FMV and appropriate tier status will be determined for each speaker during the nomination and vetting process. Speakers enter the speaker bureau with an annual speaker payment cap of \$50,000. Brand teams, with mandatory Medical consultation, must review and approve any Annual Cap Reclassification increase request prior to submitting the request through M&E to Legal and/or Compliance for final approval.

Only speakers may be paid in connection with speaker programs; attendees may not be compensated in any manner. Speakers may also be reimbursed for reasonable travel-related expenses associated with speaking at the program, such as out-of-pocket lodging, transportation, or parking costs, in accordance with the U.S. Consultant – Speaker Business Travel and Expense SOP. Pfizer's HCP Payment Disclosure and State Reporting SOP applies to all speaker and consulting fees, travel expenses, meals, and other items of value provided in connection with speaker programs.

Speaker Training

Prior to engaging in any speaking engagements, all speakers are required to complete training on: (1) Pfizer Promotional Speaker Compliance Guidelines Training (annually); and (2) the brand's Core Product or Topic Training Slide Kit, as applicable. Accordingly, all Pfizer brands that execute speaker programs must create Core Product and/or Topic Training Slide Kits that cover the key aspects of the product or topic, including Important Safety Information.

Depending on factors including the specific needs of the brand team, a speaker may complete training either online via Centris, via WebEx, or live in-person. In limited instances, separate individual training may be conducted by a **Field Medical Director (FMD)** for speakers who cannot complete training through other available means – consult your product attorney for guidance. If a speaker is paid for participation in training, they will be required to complete at least two speaker programs on the relevant product within a year of the paid training. For more information on speaker training, see Training resources available on the [Speaker Programs](#) tab in PolicyXchange. 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.

Program Execution

Regardless of whether it is a Marketing- or Sales-led program, all speaker programs must be executed consistent with the more detailed requirements outlined in [Orange Guide Chapter 9: Speaker Programs for HCPs](#) and [Orange Guide Chapter 16: Consumer, Patient, and Employee Interactions](#).

Promotional Opportunities at Third-Party Meetings and Conventions

Pfizer brand teams are often provided the opportunity to promote Pfizer products by paying for promotional opportunities at third-party meetings and conventions. These opportunities must always be Fair Market Value (FMV) and satisfy our tangible benefits requirements. Common promotional opportunities include, but are not limited to:

- Symposia Programs/Product Theaters;
- Exhibit/Booth Display Space;
- Advertisement Space in Conference Brochure;
- Delegate Bag Inserts.

Financial support in exchange for these opportunities can occur at a variety of venues and programs, but the key principle is that Pfizer is paying for the space or opportunity to promote its products (or, in some cases, to promote Pfizer) and must pay the same rate as other exhibitors and the fees must be appropriate based on the opportunity.

There are several factors to consider when deciding appropriateness with respect to promotional opportunities. Examples include the following:

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

Often, the event brochure lists the levels of support opportunities available and describes the space and services that are available at each level. This type of brochure should accompany the request for financial support whenever possible because it helps to validate the fair market value of the opportunity. Follow the procedures outlined in the [Funding Requests for Not-for-Profit Organizations SOP \(External Funding SOP\)](#) to facilitate funding for promotional opportunities at third-party meetings and conventions. All promotional materials used at a marketing program, such as exhibit panels, professional advertising, and consumer materials, must be approved by the appropriate brand RC.

Symposia Programs

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

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

- Symposia may be **open-door**, at which any congress/convention participant may attend, or **closed-door**, invitation-only events. For both, attendance is controlled with logistic support provided by meeting planners on the ET&M (Enterprise Travel & Meetings) team.

Open-door symposia take place at third-party events, such as congresses or conventions, with logistical support provided by Convention Housing & Logistics Meeting Manager on the ET&M Team, and in partnership with the Global **Congress Center of Excellence (CoE) group** within Global **Business Services (GBS)**. Closed-door symposia may coincide with, but typically do not take place at, third-party events such as congresses or conventions, with logistical support provided by the ET&M team.

There are three types of symposia:

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

Initiating Symposia Programs

The Global Congress CoE and Marketing teams are responsible for determining the annual Pfizer congress and convention open-door symposia plan. Any symposium, however, can be proposed, initiated, and conducted by any appropriately trained Pfizer colleague (“Project Owner”) responsible for the project management of symposia. The Project Owner must document the need for a symposium on a Business Rationale Form and follow the rest of the steps required by the HCP Engagements SOP.

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

Content Development

The content of a symposium, which includes any promotional materials that will be presented or handed out at the event, must be RC-approved. The Project Owner and the vendor are responsible for ensuring the symposium faculty follows Pfizer’s content requirements and processes. For symposia managed with

the support of the Global Congress CoE: Convention Housing & Logistics team, the Symposia Specialists are responsible for ensuring that all speakers have received compliance training.

Invitations, Logistics, and Meals

The Project Owner and the Symposia Specialist or ET&M Meeting Manager (as applicable) are responsible for logistics related to the program. Travel and lodging expenses may be provided for Pfizer speakers but not for attendees. Modest meals and refreshments may be provided, where appropriate. These and any other items of value conferred to certain HCPs are subject to disclosure in accordance with Pfizer's [HCP Payment Disclosure and State Reporting SOP](#) and may also be subject to disclosure or further restrictions in accordance with applicable state law. **HCP attendees who are licensed to practice in Minnesota or Vermont must not be provided a meal by Pfizer at these programs (although coffee or other light snacks at the convention/congress booth are permissible for Vermont HCPs).** For closed-door symposia events where a meal will be provided to all attendees, potential invitees should be screened in advance using the [HCP License Lookup Tool](#) on Policy Xchange so as not to invite those holding an MN or VT license. For additional information, see [White Guide Chapter 15: State Laws: HCP and Government Employee Restrictions](#) and [White Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure](#).

Exhibit/Display & Other Advertising Opportunities

Funding for an **exhibit or display** or other promotional opportunity at a congress or convention must not be greater than the fair market value of the opportunity. Likewise, brand teams cannot bypass the grant process administered by **Global Medical Grants (GMG)** by funding a promotional opportunity when the funding request is really for non-promotional aspects of a program. Promotional and non-promotional funding must always be separated, easily identifiable, and able to be tracked for auditing purposes. In addition, if an opportunity involves the distribution or provision of any items to conference attendees, brand teams may only fund opportunities involving PhRMA Code compliant educational items.

The process for funding sponsorship opportunities is outlined in the [Funding Requests for Not-for-Profit Organizations SOP \(External Funding Requests SOP\)](#), which is described in more detail in [White Guide Chapter 7: Support of External Organizations](#). Applicable Foreign Corrupt Practices Act due diligence must also be conducted by the FRF owner for sponsorships involving non-U.S. third-party congresses, conventions, and open-door symposia. In addition, all requests from managed care customers, regardless of amount, must be reviewed and approved by Legal before the date of the event and before Pfizer may pay for the exhibit/display or undertake any activities associated with the exhibit or display opportunity.

External Websites and Other Digital Activities

Like other forms of promotion, the FDA regulates Pfizer's use of the Internet to promote its products in the United States. This includes [PfizerPro](#) and product websites, as well as social media, banner, and other Internet advertisements. For more information, see [White Guide Chapter 2: Advertising and Promotional Materials](#). Detailed information on the requirements of Internet promotion, including on social media platforms, such as YouTube, Twitter and Facebook, as well as search engine optimization and search engine marketing can be found at the Digital Review Team [site](#).

Customer Engagement Programs (CEPs)

Pfizer has legal, regulatory, and ethical responsibilities to monitor the safety profile of its products through the collection, evaluation, and timely reporting of safety information to regulatory authorities. To meet these responsibilities, colleagues are required to submit Reportable Safety Information within 24 hours of becoming aware of any such information concerning Pfizer products, as stated in [CP #903: Your Responsibility to Report Information about the Safety, Quality, and Performance of Pfizer Products Policy](#) and associated training "[Your Reporting Responsibilities: Monitoring the Safety, Performance and Quality of Pfizer Products](#)" (YRR).

CEPs are broadly defined as Pfizer-sponsored programs that allow for two-way communication between Pfizer and its customers for Pfizer to gain insight from, or provide information or support to, its customers. Examples of CEPs are Pfizer-sponsored programs, such as: patient support programs, market research, disease awareness and screening programs, Pfizer-sponsored digital media with open text fields, and Pfizer-sponsored customer outreach programs. Because CEPs are a potential source of Reportable Safety Information, CEPs require a process to identify and report such information within required timelines.

CEP Program Owners are accountable for ensuring that the design, review, approval, and conduct of the CEP comply with [CP #902: Management of Safety Information for CEPs Policy](#) and [CP #902a: Management of Safety Information for CEPs Procedure](#), which also contain more detail on the types of programs that may be considered CEPs. See the CEP Resource Center at <http://CEP.Pfizer.com> for tools and other information.

Savings and Free Trial Programs

Pfizer is committed to encouraging patients to talk to their doctors about available treatment options and to helping patients better afford Pfizer medications. As part of this commitment, Pfizer has developed various copay savings programs, discount programs, direct purchase programs, and voucher programs and free trial programs (collectively, "Savings and Free Trial Programs") to help patients access or evaluate the safety and tolerability of their prescribed Pfizer medications. All communications about Pfizer Savings and Free Trial Programs are subject to RC approval.

Even though such programs are designed to benefit patients, if not carefully developed and implemented, they may raise a number of significant legal risks (such as under federal and state kickback laws, consumer protection laws, the “Best Price” Medicaid Drug Rebate Statute, state contract law, and state pharmacy laws). Savings and Free Trial Programs offered by U.S. teams (including brand teams and non-brand teams, such as the U.S. Trade Group) must therefore be structured and implemented in accordance with Chapter 19 of the White Guide, Savings and Free Trial Programs.

Hub Support Programs

In addition to Savings and Free Trial Programs, Pfizer also contracts with third-party vendors to operate product-specific Hubs that support patients with certain prescription access and treatment needs. Hub offerings include, for example, reimbursement support (benefits verification, prior authorizations, appeals), product and disease state education, and nursing support. As with Savings and Free Trial Programs, Pfizer Hub services are designed to support patients, and Pfizer structures these programs to provide only limited support (in accordance with applicable Department of Health and Human Services Office of Inspector General guidance). Communications about Pfizer Hubs and their services are subject to RC approval. For more information about Hub operations and Pfizer’s compliance efforts, please refer to Chapter 10 of the White Guide.

Pfizer Patient Assistance Programs and RxPathways

Marketing materials that reference programs operated by Global Health & Patient Access (e.g., Pfizer **Patient Assistance Programs (PAPs)**, Pfizer **Institutional Patient Assistance Program (IPAP)**, and Pfizer **RxPathways (PRxP)**, including implementation guides, must be created in line with the below requirements:

- The PRxP team will make available through PROMOs Prime a set of unbranded PRxP materials that can be used by Marketing for purposes of discussing PRxP. The team will also make limited materials available on Pfizer PAPs.
- Marketing teams may include in their marketing materials the PRxP logo and PRxP pre-approved taglines and logo lock-ups without requiring the approval of the PRxP RC. The placement of the logo and tagline must be either at the bottom of the piece or in an area where it can be separated from the brand, therapeutic area or other messaging in the materials. Marketing teams should send samples of these materials to PRxP to keep on file.
- If a Marketing team wishes to include PRxP and/or Pfizer PAPs/IPAP information beyond the standard PRxP logo and tagline, those materials must be reviewed by the PRxP team and require the approval of both the PRxP RC and the brand, therapeutic area, or other relevant RC that normally approves these materials.

- Brand RCs must review and approve materials related to product-specific patient support hubs. Content that mentions services managed by Global Health & Patient Access (e.g. patient assistance programs, reimbursement support services) must be reviewed by a member of the PRxP Team, and PRxP RC if the content deviates from standard language provided. At a minimum, such materials must: (i) accurately and transparently describe the program offerings; (ii) clearly outline eligibility criteria; (iii) not guarantee coverage; (iv) not include unsubstantiated claims comparing Pfizer and competitor programs; and (v) not position the program as an inducement or reward for prescribing the relevant medication.

A note on Independent Charity Patient Assistance Programs (ICPAPs)

With the exception of certain colleagues engaged in reimbursement support and approved in advance by Legal, Commercial and Medical Affairs Colleagues must not discuss the following with Healthcare Professionals (HCPs) or patients: specific ICPAPs; the availability of funding in relevant disease states from ICPAPs; or that ICPAPs can overcome copay barriers. Approved reimbursement support colleagues may provide to HCPs materials approved by the relevant Brand RC that discuss generally the range of assistance options to which Pfizer RxPathways (or the relevant product Hub connects patients (including information about ICPAPs). See Corporate Policy and Procedure #803, Contributions to ICPAPs, for additional information.

Quality Programs

Quality programs refer to RC-approved activities that offer information and other resources relating to therapeutic areas, disease states, and patient care to healthcare organizations, such as medical groups, long term care, **health maintenance organizations (HMOs)**, **U.S. Department of Veterans Affairs (VA)**, **U.S. Department of Defense (DoD)**, and pharmacy benefit managers. Quality programs focus on addressing the overall quality of healthcare rather than promoting Pfizer products.

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

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

Quality programs improve patient care by providing customers with information about, for example, quality accreditation standards, HCP's patient interaction skills, and management of medical conditions.

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

Pfizer's quality programs **may never be offered to:**

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

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

Commercial E-mails

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

All commercial e-mail must include the following:

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

There is an exception from these requirements for certain specified transactional e-mails, including e-mails that: (i) facilitate or confirm an agreed-to commercial transaction; (ii) give warranty, recall, safety or security information; (iii) give information about a change in terms, features, or account balances for ongoing relationships; (iv) provide information about employment relationships or benefits; or (v) deliver already

purchased goods or services. A transactional e-mail may contain advertising if the primary purpose of the e-mail is transactional, not promotional. E-mails that are not primarily commercial or transactional (other e-mails) are also exempt from the above requirements.

The Act prohibits false or misleading information in the “From” and “Subject” lines of company e-mails. The “Subject” line should accurately reflect the content of the e-mail and the “From” line should accurately indicate the sender. This requirement can be challenging for some affiliate marketing and “forward to a friend” referral e-mails. There are also special rules for multi-party promotional content e-mails that enable one entity to be deemed the sole sender for disclosure and opt-out purposes. Consult with your team attorney if your program involves referral or multi-party e-mails.

The Act also prohibits falsifying header information, harvesting e-mail addresses, opening multiple e-mail accounts using false information and using open relays to transmit commercial e-mail. It pre-empts state commercial e-mail laws but does not pre-empt state fraud and trespass laws that can be applied to commercial e-mail.

Colleagues who are responsible for sending commercial e-mail should coordinate with GCO’s HCP/Patient Engagement Center and their team attorney to ensure compliance with all applicable laws and regulations.

For More Information

- For speaker programs, consult the **Enterprise Travel & Meetings (ET&M)** team, and for conventions / congresses / symposia consult the Global Congress CoE Leads.
- [Speaker Programs tab on Policy Xchange.](#)
- [Orange Guide Chapter 9: Speaker Programs for HCPs.](#)
- [Orange Guide Chapter 16: Consumer, Patient, and Employee Interactions.](#)
- [Co-Pay Savings and Free Trial Programs page on GCO Policy Xchange on GCO on Demand:](#)
 - Savings and Free Trial Policy and SOP.
 - [New Limitations Regarding Free Trial Voucher Programs \(Restrictions on Free Trial Vouchers – July 2011\).](#)
 - [Massachusetts Update on Loosened Copay, Coupon, and Free Trial Voucher restrictions.](#)
- HCP Consulting guidelines and resources available on [HCP Engagements](#) tabs on Policy Xchange.
- Digital Review Team E-mail [Guidelines.](#)
- CEP Resource Center at Customer Engagement Programs home page at <http://CEP.Pfizer.com>.
- [White Guide Chapter 2: Advertising and Promotional Materials.](#)

- [White Guide Chapter 5: HCP and Government Official Consulting Engagements.](#)
- [White Guide Chapter 7: Support of External Organizations.](#)
- [White Guide Chapter 12: Promotional Interactions with Consumers.](#)
- [White Guide Chapter 15: State Laws: HCP and Government Employee Restrictions.](#)
- [White Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure.](#)
- Refer other questions to your team's Regulatory colleague or team attorney



CHAPTER #5 – HCP AND GOVERNMENT OFFICIAL CONSULTING ENGAGEMENTS

Chapter

#5

HCP and Government Official Consulting Engagements

CONTENTS

HCP and Government Official Consulting Engagements

Introduction	72
Key Points to Help Achieve Compliance	74
Consulting Engagement Controls Overview	76
Requirements for a Bona Fide Consulting Arrangement	77
Legitimate Need for Services	77
Consultant Qualifications	78
Consultant Screening Requirements	78
Restricted Markets	79
Export Controlled Technology	80
Written Agreement	81
Meeting Venue	83
Output / Deliverables	83
Reimbursement of Expenses	83
Types of Consulting Arrangements	83
Advisory Board Meeting	83
Live Speaker Training Meeting	84
Focus Groups and Market Research	85
Preceptorships and Mentorships	85
Retaining Government Employees as Speakers or Consultants	86
Non-U.S. HCPs and Government Officials	86
U.S. State and Federal Government Officials	87
Retaining Government Employees in Connection with Their Official Duties	88
Retaining Government Employees Outside of Their Official Duties	88
For More Information	89

Chapter #5 HCP and Government Official Consulting Engagements

Introduction

Pfizer enters into consulting engagements with **Healthcare Professionals (HCPs)** for a range of services including business counseling, Pfizer colleague training, external HCP education and training, pre-clinical and clinical program design, post-launch regulatory compliance assistance, and marketing program development, among others. For this Chapter HCP is defined as members of the medical, dental, pharmacy and nursing professions and anyone else, who may in the course of their professional activities recommend, influence, manage or directly prescribe, supply, administer, or buy any medicines; researchers and investigators; and any other individuals engaged in healthcare-related practices or employed by a healthcare institution, as noted in the HCP Engagements SOP.

For U.S.-based business units, Corporate Affairs, and Medical colleagues, the HCP Engagements SOP is applicable to most HCP and non-U.S. HCP and non-U.S. government official (GO) consulting engagements. However, that SOP does not apply to Marketing and Sales speaker programs, clinical services, and other activities subject to other policies (see the Scope section of the SOP for more information). For U.S.-based WRDM, GPD, and Upjohn R&D colleagues (collectively, R&D colleagues), HCP engagements in support of Pfizer's Research and Development (R&D) activities are generally subject to the policies and procedures set forth in in SOP 201: R&D HCP/GO Engagements & Interactions. While all of Pfizer's HCP engagement policies reflect the same core principles and the core requirements are common across activity types, some of the specific requirements and controls detailed in this Chapter relate most directly to engagements covered by the HCP Engagements SOP, which is applicable to the U.S.-based business units noted above. Consult the relevant SOP for the specific requirements applicable to a particular engagement.

Because these interactions potentially implicate federal and state anti-kickback laws and other U.S. and international anti-corruption laws, it is important for Pfizer colleagues to establish that a proposed consulting relationship is bona fide prior to engaging the consultant. Any HCP consulting arrangement must meet the following requirements:

- The consultant is not a Restricted Party¹, in a [Restricted Market](#), or otherwise prohibited from being engaged by Pfizer²;

¹ See Corporate Policy (CP) #206, Compliance with Global Trade Control Laws (<http://policysource.pfizer.com/Corporate/PDFDocuments/206.GlobalTradePolicy.pdf>).

² Not on any applicable internal Pfizer exclusion lists; or lists of HCPs/GOs subject to state disciplinary actions, state licensing suspension or revocation, FDA Warning Letters, Independent Oversight Committee membership, or any international equivalent to the foregoing.

- There is a legitimate business need for the services;
- Each consultant is selected based on his or her expertise and knowledge and not to gain access or to influence prescribing habits;
- The number of consultants and duration of the engagement are appropriate to the business need;
- A written contract is executed that specifies the nature of the services and the basis of payment for those services;
- The term of the agreement is for at least one year (unless a shorter term is approved by a Legal colleague);
- The services are provided as outlined in the written contract; and
- Any compensation does not exceed Fair Market Value (FMV).

Consultants must provide an actual service. For example, passive activities, such as time spent merely listening to a marketing presentation, are not considered bona fide services and are not compensable. You must select consultants who possess experience or expertise relevant to the engagement. Consultants should never be selected to influence or reward their prescribing or recommendation of Pfizer products or to provide Pfizer with any other improper benefit or advantage. Consulting fee payments must not be determined in a manner that takes account of the past, present, or future volume or value of business generated by consultants for Pfizer. The written consulting agreement should specify that there is no connection between the compensation provided and the prescribing of Pfizer products.

Your objective in entering into a consulting arrangement with an HCP must never be to:

- Establish or improve a relationship with the HCP;
- Gain or improve access to the HCP;
- Reward past prescribing;
- Induce future prescribing;
- Influence formulary decision making; or
- Gain any other improper business advantage.

[Corporate Policy \(CP\) #207: Global Policy on Interactions with Healthcare Professionals \(GPIHP\)](#) governs relationships with HCPs, including interactions with physicians, nurses, pharmacists, and others, who administer, prescribe, purchase, or recommend prescription medicines. The process for fair market value analysis of HCP payments is described in the HCP Engagements SOP and discussed in detail in the US Fair Market Value (FMV) – Consulting and Speaking [SOP](#). The process for conducting meetings and consultancy engagements with individuals who hold employment outside the U.S. is outlined in [My Anti-Corruption Policy and Procedures \(MAPP\)](#). You should consult these SOPs, as applicable, to identify the

specific steps that are necessary to plan and execute a compliant consulting engagement. The [GCO Policy Xchange on GCO on Demand](#) website also contains job aids, guidelines, and other useful documents to help ensure a compliant consulting arrangement.

For R&D colleagues, the HCP engagements process is detailed in [SOP 201: R&D HCP/GO Engagements & Interactions](#) and R&D's Compliance CNTR contains guidance, tools and resources conducting compliant interactions with the external scientific community. The Pfizer **Enterprise Travel & Meetings Americas** team is generally responsible and should always be consulted for managing the logistics for meetings that involve HCP consultants.

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

Key Points to Help Achieve Compliance

All HCP/GO consulting engagements must meet all of the following requirements:

- Further a legitimate business need that has been adequately documented.
- Involve HCPs/GOs who are:
 - Selected based on documented expertise and knowledge that meets that business need;
 - Not selected to gain access or influence prescribing or recommendation of a product, nor to promote off-label use (or make other impermissible claims); and
 - Cleared through the Restricted Party Screening (RPS) process (even if the engagement is occurring solely within the United States);
 - For HCPs/GOs processed through the ENGAGE system, automated RPS occurs in ENGAGE.

Key Points to Help Achieve Compliance

- HCPs/GOs not processed through Engage Plus must be screened through the RPS OnDemand Portal³ by the colleague wishing to engage the consultant (or someone else assigned to do so).
- Not on any applicable internal Pfizer exclusion lists or any lists of HCPs/GOs subject to state disciplinary actions, state licensing suspension or revocation, FDA Warning Letters, Independent Oversight Committee membership, or any international equivalent to the foregoing.
- Be memorialized in a written contract that:
 - Specifies the nature and scope of the services and the amount and basis of payment for those services;
 - Has a term of agreement for at least one year (unless Legal approves a shorter term); and
 - For non-U.S. HCPs and GOs, includes required MAPP terms and conditions.
- Not involve a payment in excess of fair market value; and
- Not involve either of the following, unless required licenses or other authorizations have been obtained, the issuance of which is not guaranteed, and written approval received from an attorney in the [Global Trade Controls Center of Excellence](#) (GTC CoE).
 - Activities in a Restricted Market, organizations or governmental entities from a Restricted Market, or individuals ordinarily resident in a Restricted Market; or
 - The exchange of Technology that is controlled for export (see [CP #206](#) and [gtc.pfizer.com](#)).

Additionally, Pfizer colleagues must ensure that:

- The output/work product of a consulting engagement is collected and retained, and for engagements subject to the HCP Engagements SOP, it is documented how such output/work product was used to aid the business;
- The output/work product is consistent with the terms of the consulting agreement; and
- Where a Business Rationale Form (BRF) is required by the applicable SOP, the engagement was consistent with the relevant BRF (or ensure that a legitimate rationale for any significant differences, as well as any approval thereof, are documented).

³ [RPS OnDemand](#).

Key Points to Help Achieve Compliance

- The GCO **Meetings and Events (M&E)** North America team oversees organization of meetings involving HCP consultants. For additional guidance on engaging an HCP or GO, consult the [HCP Engagements](#) tab on GCO Policy Xchange on GCO on Demand.

Consulting Engagement Controls Overview

Pfizer has developed, implemented, and continued to maintain controls to manage HCP consulting engagements, including:

- **Annual Consultant Needs Assessment:** For engagements subject to the HCP Engagements SOP, on an annual basis, **U.S. business unit** Compliance, Global Product Counsel, and their respective brand teams will develop **Annual Consultant Needs Assessments (ACNAs)** relating to each product in accordance with each brand's operating plan. Generally, an ACNA must be completed for all marketed products and products within 18 months of anticipated approval date. Each ACNA must identify the estimated number of, expenses associated with, and the business rationale for, HCP consultant engagements and activities intended to occur during the year in connection with government-reimbursed products. R&D SOP 201 does not require completion of an ACNA.
- **Business Rationale Form Requirements:** Prior to each engagement under the HCP Engagement SOP (and certain engagements related to FDA-approved Pfizer products under R&D SOP #201), Pfizer must ensure that a **Business Rationale Form (BRF)** is completed describing the justification for retention of a consultant by Pfizer. The BRF must identify the business need for the services of the consultant and must provide specific details including qualifications of the consultant(s) to be engaged, the scope of services to be provided, and the expected work product/information to be generated from the engagement. The relevant approver will review the BRF for consistency with Pfizer policy and with the relevant ACNA if applicable. The team attorney will **ONLY** review BRFs that include at least one US HCP and the project will have any impact on advancing US business directly or indirectly. Explanation for any variance from the ACNA (if applicable) should be documented.
- **Contract Requirements:** Pfizer must execute written agreements with the consultants it engages prior to work beginning. The agreement must describe the scope of work to be performed as well as the consultant fees to be paid. Fees are determined based on a centrally managed rate structure that represents fair market value. The agreement must also describe the compliance obligations of the consultant, including consent to and cooperation with Pfizer's public disclosure of payment to the HCP. The agreement must also obligate the consultant to adhere to any disclosure requirements regarding their relationship with Pfizer, such as requirements of any healthcare institution, medical committee, or

other medical or scientific organization with which the consultants are affiliated. If the consultant is a non-U.S. HCP or Government Official, the [My Anti-Corruption Policy and Procedures \(MAPP\)](#) process must be completed before the contract (with MAPP required clauses for consultant engagements) is executed.

- **Work Product:** Any work product created as a result of a consultant engagement must be collected, retained, and assessed to verify consistency with what the consultant was engaged to provide/do, as set forth in the BRF, if applicable. Other documentation of completion of services may be appropriate. This assessment and verification must be documented in an **Engagement End Document (EED)**.

Requirements for a Bona Fide Consulting Arrangement

The following section provides an overview of the key compliance requirements pertaining to the process for engaging HCP consultants as outlined in the [HCP Engagements SOP or R&D SOP 201](#).

Legitimate Need for Services

Because of the inherent kickback risk that many HCP consulting arrangements pose, a legitimate need for services must always be established and documented. For engagements under the HCP Engagements SOP (and engagements under R&D SOP 201 related to an FDA-approved product), Pfizer colleagues must complete a BRF to document and obtain approval that **a legitimate need** exists for a proposed consultant service. This involves:

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

The relevant team attorney must review each BRF associated with any proposed consulting engagements prior to the retention of consultants. The attorney will review BRFs for consistency with Pfizer policy and with the relevant ACNA, if applicable, and will work with the team to ensure that any variance from the ACNA has been appropriately documented.

Legitimate Need



A Marketing team would like to organize a series of four advisory board meetings with various specialties to gain a better understanding how its pain medication is used in different clinical settings. The team would like to engage 15 HCPs for each meeting and intends to use the information to improve and tailor the promotional message for each specialty. Is this an acceptable initiative?

Legitimate Need



Maybe. It is permissible to engage consultants to gain a better understanding of how a promotional strategy or campaign may be received by HCPs. However, it is important that such initiatives involve the minimum number of HCPs necessary to meet the business objectives of the team. Here, it is not clear whether it is necessary to hold four separate advisory board meetings involving a total number of 60 HCPs. Depending on the nature of the information sought, it may indeed be necessary and appropriate, but it is also possible that a smaller number of meetings and consultants would be able to provide the same information. The Marketing team must provide specific details in the BRF explaining why this approach is necessary.

Consultant Qualifications

It is essential that the **qualifications of a proposed consultant meet the identified business need**. You are prohibited from selecting an HCP because he or she is a “high prescriber” or because you are seeking to influence his or her prescribing or recommendation of Pfizer products, or to gain any other improper business advantage. Though a consultant’s experience with a particular class of drugs may be taken into consideration in determining whether he or she is qualified to provide the requested services, prescribing habits may not be the basis for selection. For engagements subject to the HCP Engagements SOP, requiring a BRF the following must be addressed:

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

For engagements subject to the HCP Engagements SOP, project managers should work with a Pfizer Medical colleague to define the required qualifications and specifications for consultant selection.

Consultant Screening Requirements

Pfizer colleagues must submit a request to screen prospective consultants before proceeding with any engagement or signing a related contract. HCPs/GOs processed through Engage Plus are automatically subjected to applicable screenings.

- **Restricted Party Screening (RPS):** As discussed in [CP #206](#), when HCPs/GOs are subjected to RPS, they are compared to over 70 Restricted Party Lists maintained by various governmental entities around the world. Individuals and entities are placed on such lists for a variety of reasons, including participation in criminal activity and support for such activity. Pfizer is prohibited from any interactions with these Restricted Parties, even if the engagement in question is occurring solely within the United States. Parties appearing on a Restricted Party List may not be engaged as consultants or speakers

for Pfizer. These requirements apply to both institutions and entities, as well as individual HCPs engaging with Pfizer.

- HCPs/GOs not processed through Engage Plus must be screened through [RPS OnDemand](#)⁴, by the colleague wishing to engage the consultant (or someone else assigned to do so).
- A consultant agreement may only be signed after the consultant clears the RPS process.
- **State Discipline and FDA Warning Letter Screening:** Pfizer actively screens its HCP speakers and consultants for disciplinary actions by state medical boards, FDA warning letters, and other misconduct (In rare cases, exceptions may be granted by the BU Chief Counsel or BU Compliance Counsel.)
- **IOC Member List:** Per [Clinical and Medical Controlled Document \(CMCD\) CT22-GSOP-RF08 2.0: Independent Oversight Committees Conflicts of Interest](#), depending on their role, current members of an active **Independent Oversight Committee (IOC)** for a Pfizer trial (including Data Monitoring Committees) may not be engaged in certain financial relationships with Pfizer, including as paid consultants, advisors, or speakers for Pfizer. The IOC Database can be accessed using this link: <http://dmc.pfizer.com/>.
 - For additional information regarding permissible activities of IOC members, please consult [CMCD CT22-GSOP-RF08 2.0: Independent Oversight Committees Conflicts of Interest](#) and [White Guide Chapter 9: Pfizer-Sponsored and Non-Sponsored Clinical Research Including Investigator-Initiated Research Studies \(IIRs\)](#).
- **Minnesota-Licensed Prescribers:** Per Pfizer policy, Minnesota-licensed prescribers may only be engaged as consultants in certain circumstances. For more information see [White Guide Chapter 15: State Laws: HCP and Government Employee Restrictions](#).

Restricted Markets

An engagement cannot involve any of the following, unless required licenses or other authorizations have been obtained, the issuance of which is not guaranteed, and written approval received from an attorney in the [GTC CoE](#):

- Activities in a Restricted Market;
- Organizations or Governmental Entities from a Restricted Market; or
- Individuals ordinarily resident in a Restricted Market.

The list of Restricted Markets is available on gtc.pfizer.com, under the “Restricted Markets” section⁵.

⁴ For information on how to use RPS OnDemand, see the [GTC CoE website](#).

⁵ <http://ecfd13.pfizer.com/sites/GTC/Pages/Restricted-Markets.aspx>.

Export Controlled Technology

Most Pfizer projects do not involve transfers of Technology controlled for export. However, if there will be any exchange of Technology that is controlled for export (see full definition in [CP #206](#)), you must contact the GTC CoE for further guidance prior to proceeding. Export controlled Technology can include information regarding certain viruses, toxins, bacteria, or pathogens; information regarding medical countermeasures to treat nerve agent poisoning; certain military or defense related items, services, or projects; and certain sensitive or sophisticated manufacturing or equipment processing information.

Fair Market Value Compensation


Pfizer may only provide compensation that does not exceed fair market value for consultant services and in a manner that does not account for the volume or value of business that may be generated by the consultant for Pfizer. Generally, colleagues should determine appropriate fees by utilizing the [US Fair Market Value Calculator](#) for U.S. consultants and the “Consultancy/Service Arrangements” tab (subsection “FMV”) of the Country Profiles for non-U.S. HCPs and/or GOs, or by going to the FMV webpage on Pfizer’s GCO Policy Xchange on GCO on Demand. For U.S. consultancies, if the proposed FMV for an HCP exceeds the high end of the system-generated range for a particular tier (e.g., based on the unique and relevant credentials and attributes of that HCP), the responsible colleague for the engagement must receive legal and business approval prior to committing to the higher rate. Note that colleagues should make every effort to ensure consistency in FMV when engaging an HCP (i.e., the rate should be generally consistent for a specific activity regardless of which business or function is engaging a particular HCP). The FMV rate must then be reflected in the written agreement. Pfizer must pay all US and International Consultant fees directly to all consultants/institution i.e., vendors may not make payments to consultants on behalf of Pfizer. (this would not apply to market research that is blinded to Pfizer, where a vendor may pay the HCPs directly).

Zero Fee Engagements





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

Zero Fee Engagements

	<p>Maybe. If an HCP interaction will be merely exploratory to a business relationship and no compensation of any kind will be provided, it probably does not constitute a consultant engagement triggering the controls described in this Chapter (although colleagues should consider whether a confidentiality agreement is appropriate). However, when the activities are such that compensation would normally be provided <i>but for</i> an HCP's request not to be compensated, and/or if Pfizer will cover or reimburse an HCP's travel expenses (e.g., hotel; airfare; taxi), the interaction should be processed as a formal consulting engagement. For further guidance, consult your team attorney.</p>
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Consulting Engagements with Non-HCPs

	<p>Do the HCP Engagements SOP and the requirements in this Chapter apply to interactions and payments to patients or U.S.-based non-healthcare professionals?</p>
	<p>No. But colleagues must understand that the definition of “HCP” in the HCP Engagements SOP is very broad and includes categories of individuals who may influence prescribing behavior without being prescribers themselves. For a list of specialties and categories considered to be HCPs for purposes of these requirements, consult the HCP Consulting: U.S. Fair Market Value SOP. Further, these requirements apply to interactions with any non-U.S. Government Officials.</p>



Written Agreement

Consultants must execute a **written consulting agreement** with Pfizer prior to the services being provided. The requirements below apply specifically to engagements subject to the HCP Engagements SOP, but the requirements for engagements subject to R&D SOP 201 are similar. The written agreement must:

- Include a detailed description of the services that the consultant will provide including the project deliverables or other appropriate milestones;
- Specify the fee and that payment is contingent on full participation in meetings and/or completion of any work product or other deliverables;
- State why the consultant was selected (i.e., why his/her expertise is needed);
- Indicate that the consulting fee was not determined in a manner which accounts for past, present, or future volume or value of business generated by the consultant for Pfizer;

- Specify that only reasonable, documented expenses may be reimbursed;
- Describe the compliance obligations of the consultant;
- Contain the consultant's consent to an agreement to cooperate with Pfizer's disclosure of payments and other items of value provided in connection with the engagement, in accordance with Pfizer policies on HCP payment disclosure (including U.S. HCP Payment Disclosure Policy) and applicable laws;
- Require the consultant to disclose his/her relationship with Pfizer and to adhere to the disclosure requirements of any healthcare institution, medical committee, or other medical or scientific organization with which the consultant is affiliated;
- Contain the consultant's representation that he/she has not been, and is not, subject to government discipline or criminal sanction unknown to Pfizer;
- Include the Standard Anti-Corruption Contract Provisions for Consultancy or Services Arrangements, set forth in [MAPP Appendix 8](#), if a non-U.S. HCP or GO is being engaged; and
- With respect to the RPS and Restricted Market points noted above, the GTC CoE maintains template contract provisions that are recommended for any Consultancy or Services agreements, or contracts. (Contract templates in the Engage Plus system include GTC provisions. The GTC CoE maintains the latest version of the provisions on gtc.pfizer.com, under the [Guidance and Contract Language](#) tab.

HCP Consultant Engagements with Employer Institutions

	<p>An HCP that I wish to engage as a consultant has advised me that her employer-Institution requires that her consulting fees be paid to the Institution, not her. Is this OK?</p>
	<p>Yes. In these cases, the Consulting Agreement should generally be between Pfizer and the Institution (or other employer entity) directly, with the HCP identified in the contract as the Institution employee performing the services. Although Pfizer contracts with and provides payment to the Institution rather than the HCP individually, all of the consulting arrangement compliance principles outlined in this Chapter apply. If the consultant is a U.S.-licensed prescriber, the data Pfizer reports to the government will identify the Institution receiving the payment and the individual HCP associated with the payment. Finally, if you are engaging a non-U.S. HCP/Institution, MAPP/FCPA due diligence requirements will apply. Contact ENGAGE2@pfizer.com, EngageWRD@pfizer.com, and/or FCPAQuestions@pfizer.com, as relevant, if you have questions about a particular arrangement.</p>

Meeting Venue

The venue for any consultant meeting, including a live speaker training meeting, must be conducive to the business purpose of the meeting, commercially reasonable, and not susceptible to characterization by third parties as “resort-like” or “lavish”. If a colleague plans an HCP engagement at a Congress, or as part of a sponsorship of a Congress, that is held at a “resort-like” destination, the Legal approver must be made aware of this location prior to BRF approval in order to discuss the appropriateness and need for the ad board with the team and BU Compliance, as needed. Pfizer colleagues should generally utilize the Enterprise Travel & Meetings Americas team to organize meetings involving HCP consultants.

Output / Deliverables

The Project Manager is responsible for ensuring the retention of any work product generated from the engagements and for completing an **Engagement End Document (EED)** which:

- Describes the information or work product (e.g., advice, slides, meeting minutes, and agendas) collected from or generated by or with the consultants;
- Provides recommendations/incorporation of the information learned or advice obtained from the consultant, if applicable; and
- Where a BRF was required, assesses whether the work product is consistent with what was identified in the BRF and required under the consulting agreement. If there are inconsistencies, they must be noted and explained in the EED.

Reimbursement of Expenses

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

Types of Consulting Arrangements

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

Advisory Board Meeting



Advisory Boards are a specific type of Consultancy or Services Arrangement involving meetings with consultants to obtain advice and feedback on scientific, commercial, and/or healthcare-related issues to help Pfizer better understand the external environment, therapeutic areas, data and use of products (approved or in development), commercial, clinical, and medical asset strategies, payer landscape, or

unmet medical needs. Advisory board meetings may pose risk because they can involve larger numbers of HCPs and potentially entail discussion of off-label information about Pfizer products. (If off-label information is presented at an advisory board meeting, it must bear a direct relationship to the legitimate purpose of the meeting. For additional information, see [White Guide Chapter 8: Non-Promotional and Media Activities](#).) The purpose of an advisory board meeting **must be to gain needed feedback or advice**, and not to provide a forum for product promotion.

Certain minimum standards applicable to the compliant execution of Advisory Board interactions must be addressed when organizing an Advisory Board. These global requirements are set forth in the [Global Advisory Board Guidelines](#) which must be adhered to in addition to local requirements and laws Pfizer colleagues should ensure that advisory board participants clearly understand that they are being retained to provide a service and not to passively receive promotional presentations. An advisory board meeting cannot be designed:

- To reward, influence, or induce the invited consultants to prescribe, recommend, supply, sell, administer, or buy any Pfizer products or to affect the outcome of any clinical trial inappropriately;
- To provide physicians with an opportunity to meet and mingle with their peers;
- To solicit confidential competitive information; or
- To convey product information where Pfizer is not obtaining appropriate advice or information.

Consulting Engagements with Non-HCPs

	<p>A brand team is planning an advisory board meeting to solicit feedback and learn about a disease state related to a pending new indication for the product. Can the Brand team seek assistance from Sales to identify possible advisory board consultants?</p>
	<p>Yes. Sales can be a valuable resource in assisting brand teams with the identification of HCP experts. Sales may suggest possible consultants based on specific criteria provided by the brand team that would meet the needs for the advisory board. Sales Colleagues, however, may not be involved with any communications with HCPs regarding the proposed advisory board, e.g., offering an invitation to participate, and may not participate in the advisory board itself.</p>

If the meeting involves a non-U.S. HCP or GO, Pfizer colleagues must also complete the necessary due diligence in compliance with MAPP.

Live Speaker Training Meeting

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

DL-Speaker-Operations@pfizer.com to verify compliance training completion or to setup a speaker for online compliance training. Paid speaker training activities are treated as consulting arrangements.

When your speaker program initiative requires speakers to be trained, you should consult with your brand RC to determine whether a live training program is appropriate. In many cases, a training method other than a live meeting may be sufficient. If an HCP is compensated for participating in speaker training, the speaker contract must obligate the HCP to speak twice within 12 months about the product on which he or she received speaker training. For more information on speaker recruitment, contracting, and training, see [White Guide Chapter 4: Marketing Programs](#), and [Orange Guide Chapter 9: Speaker Programs for HCPs](#).

Focus Groups and Market Research

Market research initiatives typically involve canvassing randomly selected HCPs (or those selected on the basis of objective criteria) to obtain representative information via a “focus group” meeting or a telephone or online survey. Pfizer conducts market research for a number of purposes, including to help us gain a better understanding of customer needs, to assess how Pfizer and competitor products are perceived and used in clinical practice, and to develop and test promotional messages.

Typically, market research initiatives are conducted in a manner which “blinds” Pfizer and the HCPs from knowing each other’s identities. In order to prevent Pfizer from learning the identity of individual market research respondents and to protect respondent-identifiable information, the final set of respondents is generally a randomly selected or screened subset of a larger sampling universe, and outside vendors are typically utilized to conduct the research. Such “blinded” market research does not constitute a consultant engagement and is specifically excluded from the scope of the [HCP Engagements SOP](#).

To help achieve compliance with Pfizer policies and procedures governing the conduct of market research, Pfizer colleagues should generally execute any market research activities through **Business Analytics**. All market research activities must be conducted in accordance with the [CASRO Code of Standards and Ethics for Survey Research](#). Further, no detailing or other dissemination of promotional information is permitted, except for the purpose of legitimately testing a particular promotional message or strategy.

Preceptorships and Mentorships

A **preceptorship** is a training program for Pfizer colleagues, usually provided and hosted/managed by university or teaching hospitals, which addresses a therapeutic area or the clinical use of one or more Pfizer product(s) in professional practice. Occasionally, a preceptorship may also be conducted by one or more HCPs directly engaged by Pfizer at a Pfizer-organized/managed training event. All of the consulting arrangement compliance principles outlined in this Chapter apply to preceptorship programs regardless of whether Pfizer engages with or pays an institution or an individual HCP.

Preceptorships should not be confused with **mentorship** programs, which are one-on-one observational teaching sessions where a Pfizer colleague (usually a Sales Representative) observes or “shadows” an HCP (usually a physician) at his or her office or institutional practice. No compensation of any kind may be provided to an HCP mentor. Mentorships are not considered consultantships subject to the HCP engagement process; however, a letter agreement describing the purpose of the mentorship and setting forth patient privacy and confidentiality obligations must be executed. For additional information regarding mentorships, please consult the Mentorship Guidelines and Forms available on MyPfizerNet.

Preceptorship institutions and HCP mentors must be selected based on their expertise and qualifications. These programs may not be used as selling opportunities or offered to influence prescribing practices or formulary decisions. For information on the privacy considerations of these activities, see [White Guide Chapter 11: Privacy: Protecting Personal Information](#).

For activities specific to R&D, see R&D's Compliance CNTR and R&D SOP 201.

Retaining Government Employees as Speakers or Consultants

Non-U.S. HCPs and Government Officials

The **Foreign Corrupt Practices Act (FCPA)** is a U.S. law that prohibits corrupt or improper payments to non-U.S. GOs. The FCPA prohibits offering, paying, promising to pay, or authorizing payment or the provision of anything of value to a foreign official with the intent of influencing the official or gaining an improper advantage. The statute broadly covers “anything of value,” which includes cash payments, gifts, meals, and any other item that may have value to the recipient. Further, the definition of “foreign official” is very broad and includes any officer or employee of a non-U.S. government (any department, agency, or instrumentality) or public international organization. Due to public funding of many health systems outside the United States, many non-U.S. individuals employed outside the U.S. could fall within this definition. HCPs working at foreign government-owned hospitals, for example, qualify as government officials under the FCPA. If you intend to engage as a consultant an individual who is employed outside the U.S. or enter into any other interaction in which a payment or other benefit (monetary or non-monetary) may be given to the individual, you must follow all applicable Pfizer procedures as outlined in the [U.S. Regional MAPP SOP](#).

Note also that, in addition to the FCPA, other anti-bribery/anti-corruption laws govern interactions with both U.S. and non-U.S. government officials, including the UK Bribery Act. It is critical that colleagues fully comply with all applicable Pfizer policies and procedures on interactions with government officials.

Non-U.S. Government Official



May I engage an HCP who may be a Government Official in his or her home country to attend an advisory board?

Non-U.S. Government Official



Maybe. Pfizer does not prohibit engaging GOs, but MAPP requires that whenever a non-U.S. HCP or GO is being engaged as a consultant for an ad board, certain due diligence and approvals are required. Further, additional approvals are needed when a GO is in a position where he/she could influence Pfizer's business (called a "potentially-influencing government official" or "PIGO") to ensure there is no appearance of impropriety with respect to the engagement. The due diligence and approvals are initiated in the FCPA/MAPP pre-approval system (Ariba ACM). The FCPA Requirements Project form must be completed in ACM prior to the engagement. The form will help guide you through the correct MAPP process, including the determination of whether a GO is a PIGO and, if so, will route the form for required additional approvals. Remember that any engagement must also comply with local law. Consult the [Country Profile](#) for the HCP's country of employment for local law and restrictions, notify the consultant's employer if required, and use the non-U.S. Consultant Agreement template.

U.S. State and Federal Government Officials

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

Part-time State or Federal Employees



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



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

Retaining Government Employees in Connection with Their Official Duties

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



Retaining Government Employees Outside of Their Official Duties

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



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

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

Part-time State or Federal Employees

	<p>Can a VA employee be a speaker for Pfizer?</p>
	<p>Yes, with appropriate approvals from the VA entity that employs the individual, as long as Pfizer complies with the entity's requirements pertaining to its employees. Every consultant agreement with a government employee must include the representation that he/she has been approved to enter into it by the relevant agency and/or the agency's ethics officer and specifically state whether the employee may accept a fee as well as expense reimbursement.</p>

National Institutes of Health

	<p>Can National Institutes of Health (NIH) employees work for Pfizer as consultants, if they have their employer's permission? May we offer them payment for speaking at a Pfizer event?</p>
	<p>The NIH, as well as most other government agencies, has special conflict of interest rules. Part-time and full-time NIH employees are prohibited from working or consulting for industry, with or without compensation, unless they have been granted <i>prior written approval</i>. Therefore, Pfizer may not directly retain NIH employees as consultants in their personal capacity without written approval from an authorized representative of NIH, and may not compensate NIH employees for teaching, speaking, writing, or editing.</p>

For More Information

- [GCO Policy Xchange on GCO on Demand.](#)
- [HCP Engagements SOP.](#)
- [HCP Consulting: U.S. Fair Market Value SOP.](#)
- [PolicySource:](#)
 - [CP #206: Compliance with Global Trade Control Laws](#)
 - [US-CS-BTE-SOP-01 US Consultant/Speaker Business Travel and Expense \(T&E\)](#)
 - [CP #207: Global Policy on Interactions with Healthcare Professionals \(GPIHP\)](#)
 - [CP #301: Travel, Entertainment and Other Business-Related Expenses](#)
 - [CP #304: Global Meetings and Congresses Policy and Procedure](#)

- My Anti-Corruption Policy and Procedures (MAPP)
- [Orange Guide Chapter 9: Speaker Programs for HCPs.](#)
- [White Guide Chapter 4: Marketing Programs.](#)
- [White Guide Chapter 8: Non-Promotional and Media Activities.](#)
- [White Guide Chapter 9: Pfizer-Sponsored and Non-Sponsored Clinical Research Including Investigator-Initiated Research Studies \(IIRs\).](#)
- [White Guide Chapter 11: Privacy: Protecting Personal Information.](#)
- [White Guide Chapter 15: State Laws: HCP and Government Employee Restrictions.](#)
- [White Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure.](#)
- [CMCD CT 22: Use of Data Monitoring Committees and Conduct of Interim Analysis.](#)
- [SOP 201: R&D HCP/GO Engagements & Interactions.](#)
- [Global Advisory Board Guidelines .](#)
- E-mail Contacts:
 - Refer FCPA questions to FCPAQuestions@pfizer.com
- Refer GTC, RPS, and Restricted Market questions to gtc@pfizer.com



CHAPTER #6 – GOVERNMENT HEALTHCARE PROGRAMS

Chapter**#6****Government Healthcare
Programs**

CONTENTS

Government Healthcare Programs

Introduction	93
Medicare.....	94
Medicare Part D.....	95
Pharmacy and Therapeutic (P&T) Committee Members	97
Medication Therapy Management Programs.....	98
Medicaid	98
Medicaid Drug Rebate Program	99
Medicaid Risk Areas	100
Inaccurate Price or Product Reporting and Concealing Best Price	100
Health Insurance Exchanges	101
Section 340B Pricing Program	101
Federal Supply Schedule	102
Federal Ceiling Price.....	102
Department of Veterans Affairs and the Department of Defense	103
State Pharmaceutical Assistance Programs.....	103
340B AIDS Drug Assistance Programs	104
For More Information.....	104

Chapter #6 Government Healthcare Programs

Introduction

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

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 Pricing 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, failure to provide the government with preferential pricing in certain situations may expose a manufacturer to liability under various federal and state laws. 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.

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

Medicare

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

The original Medicare program had two parts: Part A (Hospital Insurance) and Part B (Supplemental Medical Insurance). **Medicare Part A** helps defray the costs of inpatient care received in a hospital, skilled nursing facility, or hospice. **Medicare Part B** helps pay for medically-necessary healthcare professional services and other outpatient care not covered under Part A. Part B also covers some preventive services such as screening exams and lab tests to detect, prevent, or manage a medical condition. Under the original Medicare program, the government reimburses the provider (e.g., a doctor or an institution) for certain drugs used in certain settings as part of payment for the patient's overall care. Medicare beneficiaries may also enroll in the **Medicare Advantage (MA) Program**, otherwise known as **Medicare Part C**. MA Plans are managed care Medicare plans that generally provide a wider range of services than those covered under the original Medicare program.

In addition, with the changes introduced by the MMA, individuals covered under Medicare are also eligible for outpatient prescription drug coverage under **Medicare Part D**. Operationally, beneficiaries may obtain prescription drug coverage through Part D stand-alone **Prescription Drug Plans (also called PDPs)** or through **Medicare Advantage-Prescription Drug Plans (also called MA-PD plans)** under Part C. Part D enrollees incur cost-sharing obligations (including deductibles and copayments), although many low-income individuals are eligible for subsidies. A Medicare beneficiary who wants prescription drug coverage can choose to enroll in either a stand-alone PDP under Part D (for drug coverage only), or, if the beneficiary wants health and drug coverage, he/she can enroll in a MA-PD plan.

Medicare Part D

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

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

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

- A pharmaceutical manufacturer and a Managed Care Customer have a commercial agreement that provides the Managed Care Customer with an average 10% rebate on all products. The parties enter into negotiations on new commercial and Part D agreements. In exchange for the Managed Care

Customer placing a pharmaceutical manufacturer's products on the new Part D formulary, the manufacturer offers to increase its rebate on the commercial agreement to an average 12.5% rebate. The additional 2.5% rebate is the swap and may be considered an improper reward to the Managed Care Customer for providing the pharmaceutical company with access to the Managed Care Customer's Part D plan. In the government's eyes, this could be a problem, because Medicare beneficiaries or the government would have been cheated out of the additional 2.5% rebate provided on the commercial side.

- A pharmaceutical manufacturer and a Managed Care Customer have no existing contractual relationship and seek to negotiate new commercial and Part D rebate agreements. During the negotiations, the parties reference and compare the terms of both agreements. Since the agreements were negotiated at the same time, any concessions made by the Managed Care Customer to accept lower rebates on the Part D agreement could be construed to have occurred in order to improperly compensate the pharmaceutical company for providing the Managed Care Customer with greater rebates on its commercial plans. Additionally, even if the rebate rates were equivalent under both contracts, the fact that there were commingling and the comparison of terms might prompt the government to scrutinize any concessions made to identify whether the commercial deal was made at the expense of Medicare Part D.

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

Contract Negotiations



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

Contract Negotiations



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

Pharmacy and Therapeutic (P&T) Committee Members

Many healthcare organizations and PBMs, including Managed Care Customers administering Part D drug plans, maintain lists of preferred drugs (commonly referred to as **formularies**) that healthcare professionals within that organization may prescribe, or which are eligible for reimbursement by the organization. Decisions about which pharmaceutical products are included on a formulary are determined by that organization's **Pharmacy and Therapeutics (P&T) Committee**. P&T Committees typically make formulary decisions based upon assessments of safety, efficacy, tolerability, and increasingly, cost-effectiveness. Those organizations with P&T Committees frequently make decisions regarding the drugs that are covered under Medicare Part D, Medicaid, or other government healthcare programs.

P&T Committee members are charged with an important responsibility and therefore are expected to avoid both actual and perceived conflicts of interest when making formulary decisions. It is Pfizer policy not to engage in any activity that could be construed as improperly influencing the independent judgment of a P&T Committee member. In fact, consistent with the PhRMA Code on Interactions with Healthcare Professionals, any HCPs engaged by Pfizer as speakers or consultants who also serve as members of a P&T Committee must disclose to the Committee the existence and nature of their relationship with Pfizer. This requirement should generally extend for at least two years beyond the termination of any speaker or consulting arrangement.



It is important that Pfizer colleagues not give P&T Committee members anything that might be considered "special treatment." In addition, Pfizer colleagues must take special care not to link any financial transaction (other than disclosed rebate or discount arrangements) to Part D formulary decisions or Part D formulary placement of a Pfizer product. For additional information on interactions with P&T Committee Members, see [Orange Guide Chapter 7: P & T Committee Interactions](#) addressing Sales Colleagues' promotional P&T committee interactions and the [Green Guide: Governance for External Medical Activities](#), addressing **Field Medical Director (FMD)** activities.

Medication Therapy Management Programs

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

Currently, Part D sponsors have the flexibility to develop and implement a MTMP that best serves the needs of their specific patient populations. Pfizer customers often seek help in developing a MTMP. Since MTMPs are mandated by law, any substantial assistance provided by Pfizer in this area could be construed as remuneration or a subsidy of that customer's business expenses, which would constitute a violation of the Anti-Kickback Statute. Therefore, Pfizer may not provide any substantial assistance in the structuring of a Part D sponsor's MTMP. In addition, Pfizer may not provide any substantial resources to, or work with, a Part D sponsor for the purpose of helping such a customer fulfill its MTMP obligations. For additional information on permissible and impermissible activities with respect to MTMPs, consult the Pricing & Access Legal team.

Managed Care Customer Resources

	May Pfizer provide approved patient care materials in order to help satisfy a Pfizer customer's MTMP obligations?
	No. Pfizer may not provide Pfizer materials (including Pfizer quality programs and quality care pyramids) with the intent that a customer uses them to satisfy its MTMP requirements. Pfizer may not assist in the structuring of MTMPs or encourage the use of Pfizer materials in MTMPs. For additional information regarding MTMPs, consult the Pricing & Access Legal team.

Medicaid

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

Medicaid Drug Rebate Program

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

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

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

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

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

Generally, if Pfizer provides anything of monetary value to its customers as part of price negotiations, it must be reflected in Pfizer's reported price points. When submitting government price reports to the government, Pfizer must therefore take into consideration all cash discounts, free goods contingent upon a purchase requirement, volume discounts, and rebates (other than rebates under the Medicaid Drug Rebate Program itself). In addition, free or reduced-price services, grants, other price concessions, or other benefits offered to induce a sale may also be considered pricing terms.

The following transactions are excluded from the Best Price calculation:

- Sales at "nominal prices" (defined as prices less than 10% of AMP) if made to "covered entities" under Section 340B of the Public Health Service Act (see discussion below), intermediate care facilities for the mentally handicapped, and certain state-owned or operated nursing facilities;

- Prices paid by Medicare Part D Plans;
- Prices charged to the Indian Health Service, the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and entities entitled to discounts which include federally-qualified and migrant health centers and certain high-indigent care hospitals;
- Prices charged under the Federal Supply Schedule of the United States General Services Administration and qualifying single award contract price of any federal agency;
- Prices negotiated from drug manufacturers for covered drugs under a qualifying discount card program; and
- Any prices used under a qualified state pharmaceutical assistance program.

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

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

Medicaid Risk Areas

Inaccurate Price or Product Reporting and Concealing Best Price

The government has become increasingly focused on manufacturers' pricing and price reporting to ensure that its programs are receiving the greatest benefit for taxpayer-funded healthcare dollars. Therefore, the government expects companies to provide complete and accurate sales and discount data when reporting AMP and Best Price. The government also expects companies to accurately identify and report the required product and package size information. Misclassification or incorrect product information reported to the government may cause inaccurate rebate payments to states and may also subject a manufacturer to penalties. Under no circumstances may Pfizer conceal information to avoid paying higher Medicaid rebates. Indeed, reporting false or inaccurate information to the government could lead to significant liability under the federal **False Claims Act (FCA)**. In addition, inaccurate or incomplete reporting could be used to prove criminal liability under the False Claims Act and/or a violation of the Medicaid Drug Rebate Agreement, respectively. Significantly, liability under any of these statutes could subject Pfizer to exclusion from federal healthcare programs.

Health Insurance Exchanges

In 2010, the **PPACA** went into effect and seeks to expand coverage, control healthcare costs, and improve healthcare delivery in part by: (1) requiring most U.S. citizens to have health insurance; (2) creating state-based health insurance exchanges where individuals can purchase coverage; and (3) providing premium and cost-sharing credits to individuals/families with income between 133-400% of the federal poverty level who purchase insurance on the exchanges.

The state-based exchanges created by the PPACA, called **Health Insurance Exchanges (HIEs or Exchanges)** are intended to be a marketplace where individuals can compare health insurance benefit programs and costs and buy insurance. The PPACA requires that health insurance plans provide a minimum package of services in 10 categories called **Essential Health Benefits (EHB)**, including prescription drug coverage. Individuals who purchase insurance through an Exchange may be eligible for premium credits and cost-sharing subsidies depending on their income. The premium credits offset an individual's premium payments so that they do not exceed a certain percentage of their income (e.g., an individual whose income is 133-150% of the Federal Poverty Limit may receive credits so that their premium payments won't exceed 4% of their income). Cost-sharing subsidies are intended to reduce the amounts individuals will have to pay for out-of-pocket costs.

Because Pfizer products may be covered under a plan purchased on an Exchange and by an individual eligible for premium credits and costs-sharing subsidies, kickback risks may be heightened. For information on permissible and impermissible activities with respect to HIEs, consult the Pricing & Access Legal team.

Section 340B Pricing Program

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

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

Section 340B pricing discounts are calculated using the Medicaid rebate formula and notably are excluded from Best Price calculations. These discounts are deducted from the manufacturer's selling price at time of purchase by an eligible covered entity. Any subsequent price reductions necessitated by Medicaid pricing data restatements are paid as rebates. To determine these discounts, each quarter Pfizer calculates the **Section 340B Ceiling Price** (the statutorily defined maximum price that can be charged to Covered Entities) for every covered drug marketed by Pfizer using the same pricing data submitted to CMS for the Medicaid Rebate Program. For additional information on Section 340B and Pfizer's pricing policy, consult the Pricing & Access Legal team.

Federal Supply Schedule

The **Federal Supply Schedule (FSS)** program provides federal agencies with a simplified process of acquiring almost everything the federal government uses, including pharmaceutical products, at a discounted price.

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

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

Federal Ceiling Price

The Big Four federal agencies have the right to purchase their pharmaceutical drugs from the FSS like every other federal agency. Under the Veterans Healthcare Act of 1992, however, manufacturers must also make covered outpatient drugs available to the Big Four at a statutorily discounted price, known as the **Federal Ceiling Price**, which is at a minimum 24% below the **Non-Federal Average Manufacturer Price (non-FAMP)**. Non-FAMP is conceptually similar to the Medicaid AMP but is calculated based on prices paid by a different class of customers. (AMP is based on prices paid by U.S. wholesalers for drugs to be distributed to the retail pharmacy class of trade, but non-FAMP is the average of actual prices paid by U.S. wholesalers to the manufacturer for drugs to be distributed to non-federal purchasers generally.)

Manufacturers must report their non-FAMP on a quarterly basis. As with Best Price, in calculating the non-FAMP, a manufacturer must take into consideration any eligible cash discount or similar price reduction to

eligible customers during the reporting period. “Nominal” prices and prices paid by the federal government are categorically excluded from non-FAMP calculations. The government also requires an additional discount if the Federal Ceiling Price increases faster than inflation.

Department of Veterans Affairs and the Department of Defense

In addition to purchasing prescription drugs from FSS or from the manufacturer at the Federal Ceiling Price, the VA and DoD may negotiate lower prices through competitively bid arrangements.

Blanket Purchase Agreements: Blanket Purchase Agreements (BPAs) are awarded under an existing FSS contract and per regulations issued by GSA, BPAs must be competed. DoD uses BPAs to obtain sub-FSS pricing for its Military Treatment Facilities and Mail Order Pharmacy in exchange for favorable placement of drugs on the DoD Uniform Formulary. DoD BPAs are competed as part of the Uniform Formulary review process and each manufacturer with drugs under review has an opportunity to submit a BPA offer. To facilitate and standardize BPA offers, DoD issues various formulary scenarios or “condition sets” for manufacturers to bid on. BPAs are awarded to the companies whose products are selected for formulary placement consistent with the condition set.

In recent years, the VA has limited its use of BPAs, because the VA’s former process for awarding BPAs did not comply with the requirement that BPAs be competed.

FSS Temporary Price Reductions: Manufacturers that wish to voluntarily offer FSS purchasers a more favorable price can do so through a voluntary temporary price reduction (TPR) to the FSS contract. TPRs are put in place through the FSS modification process. Manufacturers can control which FSS agencies are able to access the TPR and how long it will be in place.

National Contracts: Another mechanism for the VA or DoD to obtain lower pricing is through a National Contract. The agencies seek competitive bids from manufacturers for products that have multiple generics on the market and award the National Contract to the manufacturer that offers the lowest price. Because a National Contract is a requirements contract, the agencies that have access to the contract will buy the product only from the National Contract holder (unless a particular patient is unable to tolerate that product).

State Pharmaceutical Assistance Programs

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

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

340B AIDS Drug Assistance Programs

AIDS Drug Assistance Programs (ADAPs) are state-operated programs, federally funded through the Ryan White HIV/AIDS Treatment Modernization Act, intended to help HIV positive patients have access to HIV treatments. Notably, ADAPs are covered entities under the 340B Drug Pricing Program and, thus, are able to receive 340B pricing on covered outpatient drugs. There are 57 jurisdictions that operate ADAPs, including Puerto Rico, the U.S. Virgin Islands, and other associated territories. Each individual state or territory decides which medications will be covered and how they will be distributed, as well as the clinical and income eligibility for participation in the programs. Reimbursement models include the following:

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

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

For More Information

- [Orange Guide Chapter 7: P&T Committee Interactions](#)
- [Green Guide: Governance for External Medical Activities](#)
- <http://www.pfizerxpathways.com>
- Refer any other questions to your team attorney or the Pricing & Access Legal team.



CHAPTER #7 – SUPPORT OF EXTERNAL ORGANIZATIONS

Chapter**#7****Support of External Organizations**

CONTENTS

Support of External Organizations

Introduction	107
Key Points to Ensure Compliance	108
Sponsorships and Charitable Contributions: All Divisions	111
General	111
Sponsorships and Charitable Contributions: WRDM and GPD	111
Sponsorships and Charitable Contributions: BUs, CBO, WMS, and Corporate Affairs	111
Sponsorships	112
Charitable Contributions	114
Collaborations	120
Overview	120
Collaborations – Tangible Benefit and Disclosure of Pfizer Involvement.....	121
Awards, Scholarships, and Fellowships.....	121
Overview	121
Non-Financial Support	123
Personal Volunteering	123
Regular Membership and Board Membership.....	123
For More Information.....	124

Chapter #7 Support of External Organizations

Introduction

Pfizer is often asked to provide funding or other support to external organizations including for-profit and not-for-profit entities. Pfizer provides external funding through 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 Open Payments and State Laws. Included in scope for reporting are any payments or transfers of value that are made directly or indirectly to a Covered Recipient.

“Covered Recipient” Defined

A Covered Recipient under Open Payments means any U.S. licensed physician, dentist, podiatrist, optometrist, chiropractor, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist and anesthesiologist assistant, certified nurse-midwife or teaching hospital as defined under section 6002 of the U.S. Affordable Care Act and section 6111 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (“SUPPORT”) 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 Covered Recipient required for disclosure using the [Sunshine Data Template](#).

The Centers for Medicare and Medicaid Services (CMS) discloses the data publicly on [Open Payments](#). CMS discloses calendar year data on June 30th of the following year. Please refer to **Orange Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure** for more information on our disclosure obligations under Open Payments.

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, 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.
- Funding to external organizations by U.S.-based colleagues in WRDM (excluding Worldwide Medical & Safety (WMS)) and 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 Research Collaborations \(RCs\)](#).
- 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)
Non-Healthcare Charitable Contribution		Yes*	Yes	Yes	
Healthcare Charitable Contribution					Yes
Policy Focused Healthcare Charitable Contribution			Yes		
Special Event			Yes		
Sponsorship	Yes, but DBM and above only	Yes	Yes	Yes	Yes
Collaboration	Yes, but DBM and above only	Yes	Yes	Yes	Yes
Fellowship				Yes**	
Independent Charity Patient Assistance Programs			Only certain Colleagues within Global Health & Social Impact (legacy Corporate Responsibility)		

* 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 make a verbal or written commitment until the funding request is fully approved.
- 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.

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 the [R&D Compliance CNTR](#).

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 [External Funding SOP](#), “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"> • 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). • Distribution of branded materials or dissemination of information on specific products. • Promotional placement of product logos on a podium or in literature aimed at HCPs or patients. • Opportunity to promote Pfizer products (e.g., via branded materials or a booth at an exhibition). • Opportunity to promote Pfizer's programs or services (e.g., Pfizer RxPathways). • Providing or selecting a speaker (including for a policy topic). • Opportunity to promote Pfizer unbranded programs (such as smoking cessation which may have related branded or unbranded materials). • 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. • Opportunity for a Pfizer colleague to speak at a meeting regarding Pfizer products or unbranded programs. • Opportunity for Pfizer to provide input for the agenda to a meeting or participate in a workshop in a pipeline disease state. 	<ul style="list-style-type: none"> • Placement of a Pfizer corporate logo by itself on a podium, in literature, on social media, or on a purchased table at an event. • Honorable mentions and announcement of thanks, written or verbal. • Ability of Pfizer colleagues to welcome attendees. • Playing a video that is on Pfizer's public website. • Tickets to an event. • Recognition in conference brochure/program (such as listing as Gold Sponsor).

* 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) in Ariba

Evaluate Substantive Nature of Funding Request

	<p>Can a colleague in a BU, WMS, CBO, or Corporate Affairs, fund a sponsorship as long as the tangible benefit criteria is met?</p>
	<p>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.</p>

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 in Ariba. However, if a U.S. Sales Colleague funds a sponsorship that provides for a package of various benefits (i.e., in addition to the exhibit and display space) then the External Funding SOP should be followed.

Before submitting any requests using the FRF, 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 designated reviewers aligned to each BU/Division/Function, unless otherwise noted. **Colleagues must never make a verbal or written commitment until the funding request is fully approved.** Contact 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 Key Account Management & 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 in Ariba. All such requests are subject to review and approval by designated reviewers aligned to each BU/Division/Function.

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 other programs provided by 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 microsite: pfizer.com/healthcarecharitables. 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. Organizations 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 in Ariba. All such requests are subject to review and approval by designated reviewers aligned to each BU/Division/Function.

"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 in Ariba. All such requests are subject to review and approval by designated reviewers aligned to each BU/Division/Function.
- **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 outside the U.S.)	Yes (except for Exhibit and Displays)	Yes
Pfizer must receive a “tangible benefit”	Yes	No
Payment can be made to an individual HCP or private practice group	No	No
Tickets or invitations received as a result can be offered to Healthcare Professionals	No	No
Agreement documenting terms and conditions of Pfizer funding	Yes (agreement must clearly indicate the “tangible benefit”)	Yes



Information on Pfizer’s External Funding 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?
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Information on Pfizer's External Funding SOP

	<p>Funding requests must be initiated in Ariba under the Create menu, select “Funding Request Project”. Additional resources are also available at PolicyXchange under the Funding Requests tab. Policy Xchange also includes a funding request “wizard” and other tools that can help colleagues determine whether a proposed funding activity is permissible to support. Colleagues can direct any questions about the process to USFundingRequest@Pfizer.com.</p>
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Purchase of a single ticket to a Gala/Fundraiser

	<p>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?</p>
	<p>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.</p>


Funding Request from For-Profit Organizations

	<p>Does the External Funding SOP apply to funding requests from for-profit organizations?</p>
	<p>No. These requests are evaluated under similar standards but are not covered by the External Funding SOP. However, colleagues should submit the funding request using the Funding Request Form (FRF) in Ariba with a note clearly indicating the organization is for-profit for the reviewer's attention.</p>



Sales-Funded Exhibit and Display Requests

	<p>Are Exhibit and Display Fees made payable to not-for-profit organizations covered by the External Funding SOP?</p>
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Sales-Funded Exhibit and Display Requests

	<p>Sales-funded Exhibits and Displays are subject to a different SOP – ED SOP2-01 available on Policy Xchange under the Funding Requests tab which is separate from the External Funding SOP. Sales colleagues should submit Exhibit and Display requests in Ariba using the Funding Request Form (FRF) which will be routed to the aligned program activity coordinator for review and follow the applicable policies (available in Policy Xchange under the “Funding Requests” tab). However, if an Exhibit and Display request is part of a larger promotional sponsorship package that includes other tangible benefits (in addition to an exhibit and display space), then the External Funding SOP should be followed.</p>
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Appropriate Pfizer Foundation Referrals

	<p>Can a customer’s request for a charitable contribution be forwarded to the Pfizer Foundation for consideration?</p>
	<p>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.</p>

Funding Virtual Activities

	<p>During the coronavirus pandemic, activities may be converted from live (or in-person) to virtual. How is funding support for virtual activities impacted?</p>
	<p>The tangible benefit requirements remain in effect when supporting sponsorships for virtual activities. While some uncertainty as to virtual attendance is understandable given the novelty of these virtual activities, it is the responsibility of colleagues to ensure that for any such virtual activity there is a realistic expectation of a legitimate, appropriate, and business-oriented benefit to the proprietary interests, business, or public policy goals of Pfizer or its products, services, or programs. More importantly, colleagues should also consider after each virtual event how valuable the event was in terms of 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), including consideration of the number of attendees and that the anticipated opportunities actually materialized consistent with the basis of approval by Pfizer. For sponsorships already approved/paid that result in significantly revised</p>

tangible benefits due to cancellation/postponement, please refer to [Guidance for Activities Cancelled/Postponed due to COVID-19](#). Colleagues can direct any questions about the process to USFundingRequest@Pfizer.com.

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 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. 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, which are subject to formal review and approval by designated reviewers aligned to each BU/Division/Function.

- 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 [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 supports 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 designated reviewers aligned to each BU/Division/Function.
- **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
 - 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-supported 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, individuals who already have positions at the requesting organization are not prohibited from consideration as long as the pool of candidates is wide-ranging. 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.

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 colleagues to be active in the community in which they 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, colleagues should inform their 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 Global Health & Social Impact (legacy Corporate Responsibility) prior to making a financial commitment. In addition:

1. Make appropriate disclosures to the 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 Policy Xchange under “Funding Requests”.
- [The External Funding SOP](#) 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.
- For other general information and training materials regarding Funding Requests, consult the [Funding Requests tab](#) on Policy Xchange.
- For questions regarding (non-policy-focused) healthcare charitable contributions, e-mail healthcharitables@Pfizer.com or visit www.pfizer.com/healthcharitables.
- R&D colleagues must refer to [R&D's Compliance CNTR](#) for guidance and support.
- Please refer to White Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure for more information on our funding disclosure obligations under Open Payments and State Laws.
- For more information on the Pfizer Foundation, please 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 #803 – Contributions to Independent Charity Patient Assistance Programs](#).
- Refer other questions to your Legal support.



CHAPTER #8 – NON-PROMOTIONAL AND MEDIA ACTIVITIES

CONTENTS

Non-Promotional and Media Activities

Introduction	127
Service-Based Relationships	129
Bona Fide Consulting Engagements	129
Speaker Programs	130
Non-Promotional Communications	130
Scientific Exchange	131
Third Party Scientific Meetings	132
Transactional Communications	133
Responding to Unsolicited Requests for Medical Information	134
Specified Roles with Respect to Non-Promotional Communications	134
Pfizer Medical Information Department	134
External Promotional Speakers	134
Field Medical Therapeutic Area Experts and Similar Field-Based Medical Colleagues	134
Field Based Outcomes & Analytics (FMO&A) Colleagues and Similar Field-Based Medical Colleagues	135
Other Pfizer Medical Colleagues	135
Press Releases and Other Media Communications	136
Disclosures of “Material” Developments	136
Corporate Press Releases	138
Press Releases relating to new clinical study results	138
Promotional Press Releases	139
Product-Specific Press Kits and Other Media Materials	139
Contact Information & Disclaimer	140
Non-Promotional External Speaking Engagements and Publications	140
Interviews and Other Requests for Information	141
For More Information	141

Chapter #8 Non-Promotional and Media Activities

Introduction

In the United States, the **Food and Drug Administration (FDA)** regulates all advertising and promotional labeling that Pfizer disseminates for its products. For more information on Pfizer policy regarding the development, review, and approval of advertising and promotional labeling, see White Guide Chapter 2: Advertising and Promotional Materials. The FDA does recognize, however, that certain activities and the provision of information about current research and scientific data may be neither advertising nor promotional labeling. Thus, manufacturers may distribute certain information, and make some communications, without being subject to FDA rules. Such non-promotional activities can generally be characterized as either service-based relationships or non-promotional communications.

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

Key Points to Ensure Compliance

- Non-promotional communications are those which are not designed or intended to promote the use of a Pfizer product in order to impact prescribing, purchase, or recommendation. They must be: truthful, accurate, and not misleading; supported by relevant scientific data (including any relevant safety data) where applicable, and complete (i.e., not "cherry-picked"); narrowly tailored to the topic being discussed; and void of any promotional claims or promotional context.
- Within a service-based relationship, both on-label and unapproved uses for an approved product as well as unapproved products may be presented or discussed with an HCP during his or her performance of a service for Pfizer so long as any off-label information is relevant and narrowly tailored to the specific bona fide purpose of the service arrangement. All applicable policies, procedures, and approval processes for engaging HCPs for services must be followed.

Key Points to Ensure Compliance

- Transactional communications are those that are generally administrative or "business to business" in nature, do not involve a clinical discussion and do not contain any promotional claims.
- Scientific exchange is a type of medical communication, defined as "the communication of medical information in a non-promotional manner and may include unapproved information." Scientific exchange is generally regarded by Pfizer as an infrequent activity in which **authorized Medical colleagues** engage and which requires approval by the BU Medical Asset Lead, BU Chief Counsel, and the Medical Governance Committee.
- All Pfizer colleagues (including Medical colleagues engaged in scientific exchange) are prohibited from making any claims of safety or efficacy about an unapproved product (e.g., a pipeline product) or about an unapproved use for an approved product.
- Pfizer policy only permits certain Pfizer Medical colleagues to respond to unsolicited requests for medical information about unapproved products or uses. All other colleagues must refer unsolicited medical requests to Pfizer's Medical Information Department (1-800-438-1985) or www.pfizermedinfo.com.
- All press releases must be coordinated with and issued by Pfizer Global Media Relations (1-212-573-1226). A press release discussing an unapproved product or use or other information that may be considered inconsistent with product labeling must be non-promotional in tone and must comply with the principles of scientific exchange. It may not state that an unapproved product (or an unapproved use of an approved product) is "safe" or "effective."
- Material nonpublic information (i.e., information that could reasonably be expected to impact the Company's stock price) must be communicated only in a press release, a filing with the U.S. Securities and Exchange Commission, and/or a webcast presentation to which the public has been invited in advance, and/or another method reasonably designed to provide broad dissemination (as confirmed with Pfizer Legal).
- All media inquiries must be directed to Pfizer Global Media Relations (1-212-573-1226) and all inquiries from investors and investment analysts must be directed to Pfizer Investor Relations (1-212-573-2668).

Service-Based Relationships



Pfizer engages HCPs and others (such as consumers and advocates) to perform services necessary for the operation of Pfizer business. Generally, such service-based relationships are performed under a service/consultant agreement, and any compensation provided to the engaged individual in return for services performed must be at fair market value. At times, an individual may be willing to provide services to Pfizer without compensation. Regardless, in all service-based relationships, Pfizer must have a legitimate, good-faith business need for the services being performed and an agreement in place.

When HCPs are engaged to provide bona fide services, communications directly related to the service-based relationship are considered non-promotional. Although service-based relationships must never be used as a pretext for communicating information that would otherwise be impermissible to disseminate, information about unapproved products or indications may be shared so long as it is relevant and narrowly tailored to the specific bona fide purpose of the service arrangement. Unapproved information may also be discussed prior to the service-based relationship for the purpose of proposing a service-based relationship; however, any such information must be limited to that which is essential to enable a decision on whether to enter into the service arrangement and must not be a pretext for a discussion that would otherwise be impermissible. A non-disclosure agreement may be required before any such communication. Consult your team attorney before sharing any potentially sensitive information without a non-disclosure agreement in place.

Bona Fide Consulting Engagements

Consulting engagements are one type of service-based relationship. For instance, Pfizer may engage HCPs, consumers, advocates, and formulary decision makers to serve as consultants in their individual capacity, as well as to serve on advisory boards with other consultants. All applicable policies, procedures, and approval processes for engaging consultants must be followed. For more information, see White Guide Chapter 5: HCP and Government Official Consulting Engagements.

Bona Fide Consulting Engagement

	<p>Pfizer is planning to pursue a new indication for an oncology product. The clinical team lead for the product would like to engage a consultant to assist with clinical trial design, which would involve discussion of unapproved uses for the product. Is this permissible?</p>
	<p>Yes. In order to obtain services in connection with clinical trial strategy for a new indication, the clinical team would have to discuss unapproved uses for the product. Of course, the interaction must always be scientific and objective in tone and substance and follow relevant Pfizer guidelines.</p>

Speaker Programs

Although speaker programs involve a Pfizer service-based relationship with a speaker, speaker programs are promotional activities because they are intended to influence the prescribing of the HCPs who attend the programs. To ensure compliance, all speakers must be trained and contractually agree to abide by FDA regulations and Pfizer policies governing promotion. These policies require that all Pfizer promotional speakers use RC-approved materials and provide information consistent with product labeling. Remember that it is not permissible to engage a particular HCP as a speaker in order to influence his or her prescribing.

In strictly limited circumstances, Pfizer permits speakers to respond to unsolicited questions from the audience requesting specific information outside of product labeling. The speaker may respond briefly to the specific question but must note that the use/information under discussion is unapproved and that he or she is answering the question based upon his or her own knowledge or experience and that their response may not represent the view of Pfizer. For more information, see White Guide Chapter 4: Marketing Programs and Orange Guide Chapter 9: Speaker Programs for HCPs.

Non-Promotional Communications

The FDA regulates promotional labeling – including both printed and oral statements designed or intended to promote the use of a Pfizer product in order to impact prescribing – regardless of whether the promotional statement is made by a Sales or Marketing colleague or someone from another function. All promotional statements must be consistent with a product's approved labeling and Global Commercial Content: [Review and Approval Procedure – U.S. Addendum](#). In contrast, non-promotional communications are those that are not designed or intended to promote the use of a Pfizer product in order to impact prescribing.

Non-promotional communications outside of service-based relationships are generally divided into several distinct categories:

- Responses to unsolicited medical requests from HCPs or other customers;
- Proactive communication of clinical or scientific information that relate to approved Pfizer products and indications, the therapeutic areas or categories to which such products belong or other scientific topics relevant to the healthcare community to particular HCPs/customers (See [MA01-WI-USA01 1.0 Medical Review Committee 15-Feb-2021](#) for review and approval process);
- Limited category of proactive external communications initiated by authorized Medical colleagues which relate to unapproved Pfizer products, indications, or information inconsistent with approved product labeling (called “Scientific Exchange”)
- Transactional Communications.

Each category has specific rules that govern its appropriate use, but in general, non-promotional communications must be:

- Truthful, accurate, and not misleading;
- Supported by relevant scientific data where applicable, including any relevant safety data, and complete (i.e., not “cherry-picked”);
- Narrowly tailored to the purpose and/or topic being discussed; and
- Void of any promotional claims or promotional context.

Scientific Exchange

In limited circumstances, Pfizer may proactively provide scientific and medical information about unapproved products or uses, or information inconsistent with an approved product’s labeling under the principle of “**scientific exchange**.” Scientific exchange includes the proactive communication by Medical colleagues of medical information in a non-promotional manner. Whether a communication will be considered non-promotional depends on the **content** of the communication as well as the **context** in which the information is presented. Given the infrequent nature of Scientific Exchange, any proposed medical communication of this type must first be approved by the BU Medical product/asset lead and BU Chief Legal Counsel, in consultation with Medical Affairs Governance.

Key factors that BU Medical, BU Chief Legal Counsel, and Medical Governance Committee will consider when evaluating a proposal for Scientific Exchange include the following:

- Whether the data proposed to be communicated is novel and/or urgently important to particular HCPs/customers. Providing previously disclosed information that is no longer new or is already known within the medical community is more likely to be viewed as promotional, while providing new, robust, important scientific information that is not widely known in the medical community is more likely to be viewed as non-promotional;
 - Often such data will include new safety information;
- Proposed frequency, duration, and reach of the medical communication;
 - Frequency and duration should be limited and HCPs/customers receiving the information should be narrowly selected on a need to know basis;
- Proposed execution of the communication. Non-promotional communications must not be promotional in tone (i.e., they must be devoid of brand logos and colors, promotional slogans, and other content promoting a Pfizer product). *Claims* about the safety or efficacy of an unapproved product or for an unapproved indication are likely to be considered promotional and are not permitted to be proactively delivered under the guise of scientific exchange.

In terms of context:

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

Scientific exchange is generally regarded by Pfizer as an infrequent activity in which authorized Medical colleagues engage. Scientific exchange must be approved by the BU Medical Asset Lead, BU Chief Counsel, and Medical Governance Committee.

All Pfizer colleagues (including Medical colleagues engaged in scientific exchange) are prohibited from making claims of safety or efficacy about an unapproved product (e.g., a pipeline product) or about an unapproved indication for an approved product.

Even within the context of scientific exchange, all information disseminated must be truthful, accurate, and non-misleading. Similarly, any communications, including those under scientific exchange, that are viewed by the government as concerted activity to promote unapproved use of a company's product, and/or concerted activity intended to result in improper claims for government reimbursement, could lead to civil or criminal prosecution under the federal **False Claims Act (FCA)**.

Third Party Scientific Meetings

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

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

	More likely to be viewed as	
Content / Context	Promotional	Non-promotional
Type of Presentation	Company-sponsored satellite symposia	Peer-reviewed podium or poster presentation in bona fide scientific session of a medical congress
Originality of Content	Previously disclosed information that is no longer new or is already known within the medical community	New, important scientific information that is not widely known in the medical community

Content / Context	More likely to be viewed as	
	Promotional	Non-promotional
Peer Review	Information has not undergone formal peer review	Information has undergone formal peer review
Location of Activity	Commercial booth	Medical Information booth separated from any commercial space or activity
Speaker	An individual with no direct involvement in the research being presented	A Medical colleague or investigator with direct involvement in the research being presented
Role of Sales and Marketing	Sales or Marketing involvement	No involvement by Sales or Marketing

Since no one factor is determinative, the totality of the circumstances must be considered when assessing whether a particular presentation or activity constitutes legitimate scientific exchange or other non-promotional communication not subject to promotional standards. For more information please consult your team attorney.

Transactional Communications

Transactional communications are those that are generally administrative or “business to business” in nature, do not involve a clinical discussion and do not contain any promotional claims. Examples of transactional communications are:

- Communications with customers that contain only a factual statement of matters such as product price, availability, formulary status, coding, etc. and do not contain any clinical information;
- Administrative communications with consumers or HCP customers regarding copay, patient assistance or similar approved programs, that contain no promotional claims (such as letters enclosing reimbursement checks; letters confirming eligibility or denial in copay programs; websites that only administer reimbursement or copay programs with no promotional claims; etc.); and
- Communications to “C-suite” or similar level customers that are not intended to promote product use or formulary placement but have separate business purposes such as a potential business collaboration or joint initiative with a customer.

Any disease state or product related information contained within these Transactional Communications should be non-promotional in content and tone and should be the minimum necessary to meet the non-promotional purpose of the communication.

Responding to Unsolicited Requests for Medical Information

To help ensure that responses to unsolicited questions seeking unapproved information are considered non-promotional communications, Pfizer policy permits only certain Pfizer Medical colleagues to respond to such requests for information. For these colleagues, the provision of off-label information in response to a question is appropriate so long as the question is unsolicited, and the response is:

- Truthful, accurate, balanced, and not misleading;
- Supported by relevant scientific data, including any safety data, and complete (i.e., not “cherry-picked”);
- Narrowly tailored to answer the question asked;
- Void of any promotional claims; and
- Documented in accordance with relevant Pfizer policy (e.g., the Green Guide, MI01 GSOP).

For more information on whether Medical colleagues not identified below are permitted to respond to a request for unapproved medical information, please consult your team attorney.

Specified Roles with Respect to Non-Promotional Communications

Pfizer Medical Information Department

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

External Promotional Speakers

HCPs retained as promotional speakers cannot solicit unapproved questions or initiate unapproved discussions of our products with other HCPs at Pfizer speaker programs. If a promotional speaker is asked an unsolicited question regarding unapproved information by an audience member, however, he or she may *briefly* respond to the specific question. Speakers must note that the use/information under discussion is unapproved, that he/she is answering the question based upon his/her own knowledge or experience, and that his/her views may not represent the views of Pfizer. A promotional speaker retained by Pfizer is “speaking for Pfizer” when he or she presents, and failure to adhere to these guidelines could expose Pfizer (and the speaker) to the risk of prosecution and penalties.

Field Medical Therapeutic Area Experts and Similar Field-Based Medical Colleagues

Field Medical Therapeutic Area Expert (FMTA) provide approved (through the Medical Review Committee process [EMC01 – LSOP 3.0 Medical Review Committee](#)), non-promotional medical and

scientific information to HCPs regarding the safe and appropriate use of Pfizer medicines for approved indications. FMDs may also provide support for Pfizer-sponsored research activities (e.g., facilitation of research site selection and study placement) and interact, where appropriate, with Investigator-Sponsored Research investigators. Please consult the Green Guide: Governance for External Medical Activities, for policy on responding to requests for unapproved information and other non-promotional activities. The Green Guide is applicable to **FMTA, Outcomes & Analytics (FMO&A)**, and other field-based Medical colleagues in the United States, as well as **U.S. Business Unit (BU) Medical Affairs** colleagues, when interacting with HCPs.

Field Based Outcomes & Analytics (FMO&A) Colleagues and Similar Field-Based Medical Colleagues



Field Based Outcomes & Analytics (FMO&A) is a group within U.S. Medical Affairs that primarily works with organized customers such as payers (including formulary and P&T committees), Integrated Delivery Networks, medical groups, and colleges of pharmacy. In general, MOS responsibilities include: (a) demonstrating the pharmacoeconomic value of Pfizer's in-line products; (b) collaborating with customers to advance the quality of patient care in areas of interest to Pfizer; (c) working with customers on outcomes research to identify provider or patient knowledge gaps and areas for quality improvement interventions; and (d) providing Pfizer brand teams with customer perspectives to enable the development of appropriate customer-focused tools and medical communications to support patient access to medicines. The MOS group may respond to unsolicited requests for: on-label data; pharmacoeconomic information related to an approved indication, whether or not included in product labeling; and information consistent with the product label and approved by a **Medical Review Committee (MRC)**. MOS are not permitted to respond to unsolicited requests for unapproved data.

All unsolicited requests received by MOS for unapproved data, including those seeking information on the general safety or efficacy of Pfizer products, must be referred to Pfizer's Medical Information Department. The MOS group and other similar field-based medical groups must adhere to the Green Guide.

Other Pfizer Medical Colleagues

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

Unsolicited Request for Medical Information

	A physician contacts Pfizer seeking information regarding the unapproved use of the Pfizer product. Can the Pfizer Medical colleague who supports the product provide this information?
	Yes. It is permissible for the Medical colleague to provide the requested information as long as the information provided is: (1) truthful, accurate, and not misleading; (2) supported by the relevant scientific data, including any safety data; (3) narrowly tailored to answer the question asked; and (4) void of any promotional claims.

Press Releases and Other Media Communications

Press releases provide timely updates on an array of topics, such as new business alliances, significant regulatory decisions, major recalls or safety issues, financial performance, and significant clinical trial results. They are typically disseminated over a paid news distribution service (e.g., *BusinessWire*) and to print, broadcast, and online news sources, as well as posted on www.Pfizer.com. Pfizer Global Media Relations oversees all communications intended for release to the media, whether written, verbal, or electronic (including press releases, video news releases, submissions for newspapers, and media FAQ documents). For guidance regarding dissemination of press releases and other information via corporate social media channel(s), please see the [Pfizer Twitter Guidelines](#) and [CP #407: Social Media Policy](#).

Disclosures of “Material” Developments

Because Pfizer is a publicly traded company, Pfizer generally seeks to inform the investment community of **“material” developments** (i.e., developments that could reasonably be expected to impact the Company’s stock price). Press releases help Pfizer to accomplish this goal. Our press releases must provide balanced, accurate, complete, and non-misleading information. Failure to do so can trigger lawsuits. For example, investors might seek damages based on a claim that they were not provided adequate information about events that negatively impacted the Company’s stock price. Pfizer Global Media Relations will consult with Corporate Governance to determine if a disclaimer is required regarding forward looking information (see “Contact Information & Disclaimer” below).

Material nonpublic information may not be disclosed selectively – meaning it may not be disclosed in nonpublic conversations, meetings, or written materials or other means – to financial market participants. Such information may be disclosed only for legitimate business reasons on a need-to-know basis internally to Pfizer colleagues or to engaged consultants or advisors who are bound by an obligation to maintain confidentiality. At the time of public disclosure, such information must be disclosed to the entire investment community in a press release, a filing with the **U.S. Securities and Exchange Commission (SEC)**, a webcast presentation to which the public has been invited in advance, and/or another method reasonably

designed to provide broad dissemination (as confirmed with Pfizer Legal). Only information that has been previously disclosed publicly may be discussed in nonpublic settings, such as in meetings or calls with investors or investment analysts. For more information, see [CP #604: Treatment of Material Nonpublic Information](#).

Corporate Governance, in consultation with investor relations/media (as well as, if appropriate, certain internal stakeholders) will make an assessment as to whether a press release is material (i.e., whether the press release discloses developments/information that could reasonably be expected to impact the Company's stock price). A determination will also be made regarding whether a blackout notice (which may restrict trading of Pfizer securities, or securities of a third-party, by certain colleagues) should be sent to, and/or preclearance procedures imposed upon, those colleagues "in the know" prior to public disclosure of the development. Individuals that are "in the know" should not trade in Pfizer securities prior to the determination of whether the information included in the press release is material and whether a blackout notice is required. Whether or not a blackout notice is imposed, pursuant to CP 604, colleagues must not trade in Pfizer securities while aware of material nonpublic information relating to the Company or trade in the securities of any other company while aware of material nonpublic information relating to that company which was obtained in the course of their employment with Pfizer.

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

- Press releases disclosing "material" developments are typically non-promotional and must be approved by Pfizer Global Media Relations in consultation with Finance, Investor Relations, Corporate Governance, as well as the Legal, Regulatory, and Medical colleagues responsible for the product/therapeutic area, if applicable.

If you receive an inquiry from investors or investment analysts, you must refer them to Pfizer Investor Relations (1-212-573-2668). Any inquiry from the media should be forwarded to Pfizer Global Media Relations (1-212-573-1226).



Following is additional information regarding Corporate, New Data, and Promotional press releases, each of which must be assessed for materiality, blackout notice, etc. in accordance with the procedures set forth above.

Corporate Press Releases

Pfizer typically announces new business alliances, significant regulatory decisions, major recalls or safety communications, and information regarding financial performance, among other things, via “Corporate” press releases. A Corporate press release may not contradict product labeling or promote an unapproved use. Similarly, it should not claim that a product is “safe.” If an unapproved use is discussed, it must be described as investigational in the press release.

- Corporate press releases must be approved by Pfizer Global Media Relations in consultation with Investor Relations, Corporate Governance, as well as the Legal, Regulatory, and Medical colleagues responsible for the product/therapeutic area.

Pre-approval Communications / Press Releases

	<p>Is it permissible to issue a press release to the investment community claiming that a new study demonstrates that a product (or a new use) that has not yet been FDA-approved is safe and effective?</p>
	<p>No. Press releases that provide details about unapproved products or uses must be objectively factual and should avoid the use of promotional adjectives or conclusory comments about safety or efficacy (as the regulators have not yet made determinations about those issues). They should also describe such uses as “investigational.”</p>

Press Releases relating to new clinical study results

Press releases announcing new clinical trial results must describe the size of the study, the study design, and the primary endpoints. If a decision is made to include results of secondary endpoints, all of the secondary endpoints must be included. Furthermore, if the new data release contains disclosure of Phase 3, Phase 3B and certain Phase 4 study results subject to Clinical and Medical Controlled Document (CMCD) CT20-POL: Public Disclosure of Pfizer Clinical Study Data and Authorship, the requirements of that policy should be met. For more information, see [CMCD CT20-POL: Public Disclosure of Pfizer Clinical Study Data and Authorship](#).

If Pfizer decides to disseminate previously released study data on a subsequent occasion via a press release, then it would generally be considered a “promotional” press release, which is discussed in more detail below. Similarly, if promotional language or tone is used, then the press release needs to be treated as a promotional press release.

- “New data” press releases are initiated by Global Media Relations and must be approved by the Product Counsel in consultation with Clinical Development Legal; Regulatory, and Medical colleagues

responsible for the product/therapeutic area in consultation with Investor Relations and Corporate Governance.

Promotional Press Releases

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

Risk information typically includes contraindications, warnings, precautions, adverse events, and other material information. Unless the press release is targeted to media outlets that primarily reach scientific or professional audiences, a consumer-friendly version of safety information should be included. In addition, the FDA-approved full prescribing information should be supplied with all press releases involving marketed products (paper copies should include a copy of the approved prescribing information and electronic copies should reference the location of the prescribing information on <https://www.pfizer.com>). A promotional press release may not contradict FDA-approved labeling or promote an unapproved use. In addition, the FDA views promotional product-related press releases as subject to submission at time of first use. Thus, such press releases must be reviewed and approved by the relevant **Review Committee (RC)** and submitted to the FDA's **Office of Prescription Drug Promotion (OPDP)** or **Advertising and Promotional Labeling Branch (APLB)** (for biologics, including vaccines) for filing on or before **date of first use (DOFU)**, prior to dissemination.

- Promotional press releases must be approved by the Product Review Committee (Medical, Regulatory, Legal, and Marketing) and Pfizer Global Media Relations in consultation with Investor Relations and Corporate Governance.



Product-Specific Press Kits and Other Media Materials

Product-specific "press kits" are subject to the same FDA regulatory requirements as written promotional materials. Thus, a press kit must meet promotional standards (e.g., not misleading, consistent with product labeling, and including appropriate safety information) and must be RC-approved.

For components within the press kit that may be distributed further, the appropriate balance must be included within those components. A press kit must also contain a copy of the full **Prescribing Information** for any Pfizer product that is referenced in the press release.

As with press kits, other media materials, such as audio/video news releases, are generally regarded as promotional labeling and therefore must meet promotional standards and be RC approved. For more information on such standards and the review and approval process for promotional materials please refer to Global Commercial Content: [Review and Approval Procedure – U.S. Addendum](#) and White Guide Chapter 2: Advertising and Promotional Materials002E

Post-approval Communications

	Do we need to submit for internal review a press release that highlights newly published clinical trial data for an approved Pfizer product?
	Yes. Any release that discusses data about an approved product or unapproved product must be approved by Legal, Medical, and Regulatory, as well as Pfizer Global Media Relations in consultation with Investor Relations and Corporate Governance.

Contact Information & Disclaimer

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

If a press release could be seen as including any “forward-looking” information (e.g., information that describes or suggests future events or results), it should include a disclosure notice. Colleagues should work with their legal representative and contact the Corporate Governance team as early as possible in order to confirm whether information may be considered forward-looking and to work together to draft and approve an appropriate disclosure notice, as needed. The press release’s disclosure language will be customized to the information included in the press release.

Non-Promotional External Speaking Engagements and Publications

Pfizer colleagues may participate in external non-promotional speaking engagements and contribute to articles and publications relevant to their areas of expertise. As representatives of Pfizer, colleagues must, however, ensure that any Company information disclosed in presentation materials, handouts, Q&A sessions, articles, etc., is truthful, accurate, complete, timely, and not proprietary or otherwise confidential. Further, such external communications should generally be consistent with Pfizer’s publicly stated position on related issues.

When invited to speak at a third-party sponsored meeting, seminar, workshop, conference, etc., or to author a document for publication, you must obtain the approval of your manager. Your manager must determine whether it is appropriate for you to participate and should consult Legal, if necessary. (If you are unclear whether the content of your proposed activity is likely to be perceived as promotional, you should consult your team attorney for further guidance).

Colleagues approved to participate in external speaking engagements are not required to obtain prior review and approval of their presentation materials (including pre-read materials, PowerPoint presentations, handouts, etc.) unless requested by the approving manager, but must be sure not to disclose any confidential information or material non-public information and to include appropriate disclaimers in

their presentations (including that you are an employee of Pfizer and that views expressed by you may not represent the views of Pfizer).

If you have any uncertainty regarding what information may be considered confidential or material (or if the nature of the engagement involves discussion related to Pfizer or Pfizer products) you should consult with your manager or Legal, as appropriate. If you are asserting any personal opinions in a talk or speaking engagement, you must clarify with the audience that the opinions expressed are yours and not necessarily those of Pfizer. If the press, other media, and/or analysts or investors are reasonably likely to be present at a third-party sponsored event, you must contact Pfizer Global Media Relations and Pfizer Investor Relations (as applicable) well in advance of the event to ensure effective preparation.

Interviews and Other Requests for Information

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

- If you receive any type of inquiry or request for information from the media (including verbal or telephone, written or electronic requests): direct the inquiry or request to Pfizer Global Media Relations (1-212-573-1226). Unless specifically directed by a member of Pfizer Global Media Relations, you may not answer any questions or supply any information directly to the media or conduct interviews with the media. For more information, see [CP #409: Relations with the News Media](#).
- If you receive any type of inquiry from investors or investment analysts: direct the inquiry to Pfizer Investor Relations (1-212-573-2668).

If you receive any type of inquiry or request for information from any federal, state, or local government entity: **promptly** seek guidance from the Legal Division before responding.

For More Information

- Refer any questions to your Regulatory Affairs or Legal team colleague, Pfizer Global Media Relations & Digital Communications (1-212-573-1226), or Pfizer Investor Relations (1-212-573-2668).
- [Green Guide Green Guide – Governance for External Medical Activities](#)
- [MA01-WI-USA01 1.0 Medical Review Committee 15-Feb-2021](#)
- [CMCD GNT-01 Independent Medical Grants](#).
- Orange Guide Chapter 9: Speaker Programs for HCPs.
- White Guide Chapter 2: Advertising and Promotional Materials.
- White Guide Chapter 4: Marketing Programs.

- White Guide Chapter 5: HCP and Government Official Consulting Engagements.
- [CMCD CT20-POL: Public Disclosure of Pfizer Clinical Study Data and Authorship.](#)
- [CP #407: Social Media Policy.](#)
- [CP #409: Relations with the News Media.](#)
- [CP #604: Treatment of Material Nonpublic Information.](#)
- [Pfizer Twitter Guidelines.](#)
- Requests for medical information should be directed to Global Medical Information at 1-800-438-1985 or www.pfizermedinfo.com.



CHAPTER #9 – PFIZER-SPONSORED RESEARCH AND CLINICAL RESEARCH COLLABORATIONS (CRCs)

Chapter**#9****Pfizer-Sponsored Research and Clinical
Research Collaborations**

CONTENTS

Pfizer-Sponsored Research and Clinical Research Collaborations (CRCs)

Introduction	146
Healthcare Law Compliance Issues.....	147
Pfizer-Sponsored Clinical Studies.....	148
Regulatory and Ethical Framework	148
IND Requirements.....	148
IDE Requirements.....	148
Privacy Rules	148
Good Clinical Practice.....	149
Interactions with HCPs and Government Employees.....	149
Additional Requirements	149
Scientific Validity and Value to Pfizer	150
Selection of Investigators	150
Study Design, Conduct, and Monitoring.....	152
Managing Study Conduct Quality Issues	152
Compensating Investigators	153
Investigator Meetings	154
Public Disclosure and Access to Study Data	155
Expanded Access.....	157
Clinical Research Collaborations	157
General Requirements	157
CRC Support	158
Evaluation of Potential CRCs	159
Scientific Review	159
Monitoring, Auditing, Tracking and Data Collection by Pfizer	159
Collaborators Roles and Responsibilities	159
Regulatory and Ethical Obligations	159

Regulatory Requirements.....	160
Protocol, Informed Consent and other Study Document Development	160
Study Monitoring	161
Document Reviews and Site Visits	161
Regulatory Inspections and Audits	161
Reporting of Safety Data	161
Investigational Drug Supply	161
Study Budget	162
Governance.....	162
Confidentiality Agreement	162
CRC Agreement	162
Joint Study Team Meetings.....	162
Study Deliverables	163
Study Results.....	163
Clinical Study Report (CSR)	163
Study Data	163
Publications	164
Primary Submission.....	164
Publication Quality	164
Pre-publication Review by Pfizer.....	164
Redaction of Confidential Information	165
Authorship Standards	165
Disclosure of Support	165
Secondary Publications	165
For More Information.....	166

Chapter #9: Pfizer-Sponsored Research and Clinical Research Collaborations (CRCs)

Introduction

Pfizer engages scientists, **Healthcare Professionals (HCPs)**, academic and other research institutions, for-profit co-development partners, as well as government agencies to conduct **research and development projects and studies**. These include *in vitro* experiments (discovery), *in vivo* studies (preclinical animal), human clinical studies, and consultancies and services related to these areas. This research can generate important information about Pfizer products as well as valuable medical and scientific information that can lead to improvements in clinical care, the development of new treatments, and better delivery of healthcare to patients.

Pfizer-sponsored clinical studies are frequently a key part of the development of medicinal products and devices. Pfizer-Sponsored clinical studies are designed, conducted, and overseen by Pfizer or on behalf of Pfizer. When Pfizer is the sponsor, it is generally responsible for the regulatory obligations applicable in the geographies where these studies are conducted. Pfizer-sponsored studies may be intended to support a new product, a significant change in the labeling of a product, a new indication, a proposed advertising claim, or post-marketing commitments. The company may engage the services of **Contract Research Organizations (CROs)** or other service providers to assist in execution of some or all elements of clinical trial conduct including study design, start-up, study management, data monitoring, data analysis, and reporting. There are various types of Pfizer-sponsored clinical trials, which are covered by different SOPs, [CMCD CT02-GSOP Protocol Development for Interventional Studies](#), [CMCD CT24-GSOP Non-Interventional Studies](#) and [CMCD CT45-GSOP Interventional Studies With Minimal Risk](#). Contact the **Business Process Owners (BPOs)** for information about these SOPs.

Clinical Research Collaborations or CRCs are engagements under which Pfizer collaborates with an external party to perform a clinical study and/or other clinical research activities. CRCs allow Pfizer to partner with investigators and organizations (**Collaborators**) to generate innovative research of potential scientific value to patients, physicians and the greater scientific community. Collaborators may be academic institutions, research networks, cooperative groups, government agencies or other entities. Pfizer may provide Collaborator with one or more types of support, such as funding, product(s), device(s), equipment or other types of support such as in-kind services like publication writing support, **Pharmacokinetic (PK)** analysis, etc. In addition, Pfizer can contribute to the development of the protocol, **Informed Consent Documents (ICDs)**, **Statistical Analysis Plan (SAP)**, and other relevant study documents. In certain CRCs, Pfizer will want to obtain access to and/or request data to be transferred to Pfizer.

CRCs facilitated and managed by the Research Collaboration Center of Excellence (COE and/or R-CRC team (part of GPD), that is part of the Global Medical Grants group, are subject to the requirements of

CMCD CT44-GSOP: Registrational Clinical Research Collaborations, see [link](#). For more information, please contact the BPO for CT44 or a member of the Clinical Development Legal team.

This Chapter is relevant to all Pfizer colleagues who have responsibility for Pfizer-sponsored clinical studies and CRCs. Non-compliance with policies applicable to those activities 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

- The decision to engage an HCP as a clinical investigator in a Pfizer-sponsored study or in a CRC study, must be made by Pfizer colleagues in a Medical, Clinical, or R&D function (i.e., not Commercial). Commercial colleagues may not attempt to influence a decision to engage the services of an HCP as a clinical investigator, or to collaborate in a CRC.
- Funding or other support for medical research must never be provided to:
 - Establish or improve Pfizer's relationship with an HCP or health care organization;
 - Gain or improve access to an HCP;
 - Reward past prescribing practices or influence or induce future prescribing practices; or
 - Reward a past formulary decision or influence a future formulary decision.
- Research sponsored or supported by Pfizer must:
 - Have genuine scientific and/or medical value;
 - Involve investigators or institutions selected on the basis of criteria relevant to the research;
 - Involve compensation that reflects "fair market value" for the services provided; and
 - Be conducted in compliance with recognized scientific and ethical standards, as well as applicable laws and regulations.
- Pfizer colleagues must follow all Pfizer policies and procedures in establishing and administering Pfizer-sponsored studies and in the support of CRCs.

Healthcare Law Compliance Issues

Payments to HCPs may violate certain international, federal, and/or state anti-kickback statutes if such payments are offered or made to reward or influence the recipient's prescribing or formulary practices or to establish, maintain, or improve Pfizer's relationship with an HCP or formulary decision maker. In addition, both the [Pharmaceutical Research and Manufacturers of America \(PhRMA\) Code on Interactions with Healthcare Professionals](#) and the [Department of Health and Human Services Office of Inspector General \(OIG\) Compliance Program Guidance for Pharmaceutical Manufacturers](#) forbid the use of "token" consulting

arrangements. An example of a “token” consulting arrangement would be one involving payment to an investigator to encourage the use of a Pfizer product or to reward an investigator for previous use of a Pfizer product, rather than to address a genuine scientific issue or obtain meaningful clinical information.

If a clinical study involves the performance of bona fide research in return for fair market value compensation and conforms to the ethical requirements for clinical studies, the study should pass scrutiny under the various healthcare laws; Pfizer policies and procedures, including global [Clinical and Medical Controlled Documents \(CMCDs\)](#); regulatory requirements; ethical standards; and Pfizer-endorsed industry guidelines.

Pfizer-Sponsored Clinical Studies

Regulatory and Ethical Framework

IND Requirements

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

In certain instances, Pfizer may choose to conduct studies at clinical trial sites outside of the U.S. under an IND application to facilitate acceptance of the results of those studies by the FDA. Those studies would then be subject to FDA regulations. In addition, all non-U.S. studies must comply with applicable local laws, regulations, guidelines, and ethical codes.

IDE Requirements

Clinical studies of investigational devices in the United States, unless exempt, must be conducted under an approved **Investigational Device Exemption (IDE)** to support a **Premarket Approval (PMA)** application or a premarket notification 510(k) submission to the FDA. Clinical studies are most often conducted to collect safety and effectiveness data to support a PMA, as few 510(k)s require clinical data to support the application. Investigational use also may include clinical evaluation of modifications or new intended uses of legally marketed devices.

Privacy Rules

Global and U.S. data privacy rules require investigators to protect the confidentiality of any identifiable health information about a study participant that they obtain in connection with the study and to secure

appropriate informed consents from study participants before disclosing such information to Pfizer. The **Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)** also impacts the conduct of Pfizer-sponsored clinical studies in the United States. While HIPAA is not directly applicable to Pfizer in its role as study sponsor, it applies to most of Pfizer's contracted U.S. investigators with respect to their use and disclosure of Protected Health Information collected in studies. Pfizer personnel must always ensure that appropriate measures are taken to protect any study participant information that they access or review in accordance with [Corporate Policy \(CP\) #404: Protecting the Privacy of Personal Information](#). For a more detailed discussion of Protected Health Information, please see [White Guide Chapter 11: Privacy: Protecting Personal Information](#).

Good Clinical Practice

All Pfizer supported studies must be conducted in accordance with the principles of recognized international ethical and data integrity standards, including the [International Council on Harmonization Good Clinical Practice \(ICH GCP\) guidelines](#) and applicable regulatory standards. [CMCD CT19-POL: Global Standards for Interventional Studies](#) describes Pfizer clinical study standards that are applicable worldwide, including in those countries that do not have established laws or practices for protection of human subjects.

Interactions with HCPs and Government Employees

All interactions with HCPs in connection with Pfizer supported studies must comply with [CP #207: Global Policy on Interactions with Healthcare Professionals \(GPIHP\)](#). Pfizer is also committed to compliance with relevant industry standards, including [PhRMA's Principles for Conduct of Clinical Trials and Communication of Clinical Trial Results](#). In addition, all interactions with government officials or persons likely to interact with government officials in Pfizer supported studies must comply with [My Anti-Corruption Policies and Procedures \(MAPP\)](#). See [White Guide Chapter 5: HCP and Government Official Consulting Engagements](#), for additional information on interactions with government officials. In addition there are useful materials available at the R&D's Compliance CNTR <http://ecfd13.pfizer.com/sites/wrdcompliance/Pages/Home.aspx>) and on [GCO Policy Xchange on GCO on Demand](#), such as the [U.S. Healthcare Professional Payment Disclosure, State Law and Physician Payment Sunshine Act Reporting SOP](#).

Additional Requirements

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

In placebo-controlled treatment studies, Pfizer policy also requires that the medical care provided to the control cohort is medically and ethically appropriate. Placebo-controlled studies are appropriate only in

certain limited circumstances (e.g., when use of a placebo does not present undue risk to the health or well-being of the study participants), and in all cases the IRB or IEC must review and approve the appropriateness of the proposed treatment for the control group. Where applicable, Pfizer-sponsored clinical study teams also coordinate the provision of study drug to study participants after the study concludes (i.e. post-study access) in accordance with local laws and regulations. Applicable regulatory and ethical requirements and industry standards for Pfizer-sponsored clinical studies are reflected in the [CMCD Policies and SOPs on Clinical Trials](#).

Scientific Validity and Value to Pfizer

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

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

Selection of Investigators

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



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

The roles and responsibilities of Pfizer clinical investigators in a Pfizer-sponsored study are documented in a **Clinical Study Agreement** between Pfizer and/or Pfizer’s CRO and the investigator or his or her institution. The Clinical Study Agreement also memorializes the investigator’s commitment to conduct the



study in accordance with an approved protocol, comply with all regulatory obligations, report to Pfizer any adverse experiences that occur over the course of the study, and secure study participant informed consent.

Pfizer policies and procedures relating to selection of investigators and financial disclosures are described in [CMCD INV02-GSOP: Investigational Site Selection Preparation and Initiation](#), [CMCD INV04-GSOP: Investigational Site Management and Monitoring](#), CMCD INV02-INV04-WI-GL02: Managing Investigational Site Documents, and [CMCD REG32-WI-GL03: Preparation of Financial Disclosure Information for U.S. FDA Submissions](#).

Conflict of Interest

	<p>Why does Pfizer need to ask investigators and sub-investigators to disclose financial interests they, their spouses and/or their dependent children have in Pfizer?</p>
	<p>Per FDA regulation, when we submit a marketing application to FDA for approval of a drug, device or biologic, we will need either to certify to the absence of certain financial interests and arrangements of clinical investigators and sub-investigators that could affect the reliability of data submitted to FDA, or disclose those financial interests and arrangements to the agency and identify steps taken to minimize the potential for bias. If an applicant does not include certification and/or disclosure with its application or does not certify that it was unable to obtain the information despite exercising due diligence, the agency may refuse to file the application.</p>

Data Monitoring Committee Members

	<p>May a member of a Data Monitoring Committee (DMC) for a Pfizer-sponsored study be engaged as an investigator for another Pfizer study? May a DMC member be engaged for other services, such as consulting or speaking for Pfizer?</p>
	<p>Members of a DMC or other Independent Oversight Committee (IOC) for Pfizer sponsored studies relating to a particular product are not permitted to serve (concurrently or within the prior 12 months) as an investigator on a study relating to the same product. They are permitted, however, to serve as an IOC member for one product and simultaneously be an investigator for a different product. With limited exceptions, individuals may not contract with Pfizer in any other capacity (e.g., on an advisory board, as a speaker, or as a consultant) while serving as an IOC member for a Pfizer study. Furthermore, a former or current DMC member may not author a publication about that study, even if the study has been completed and the DMC disbanded. For further details, see CMCD CT22-GSOP: Independent Oversight</p>

[Committees](#), and [White Guide Chapter 5: HCP and Government Official Consulting Engagements](#)



Study Design, Conduct, and Monitoring

Pfizer-sponsored studies are conducted according to a general study plan and clinical protocol developed and documented by Pfizer. Pfizer [CMCD Policies and SOPs on Clinical Trials](#) identify Pfizer requirements for the preparation of clinical protocols, as well as the requirements for securing IRB or IEC approval, informed consent, study participant recruitment, participation and compensation criteria, data collection and privacy, and study documentation and monitoring practices, including adverse event monitoring and reporting.

Managing Study Conduct Quality Issues

All Pfizer colleagues and parties with whom Pfizer contracts in support of clinical trial activities must report within 1 business day, to the appropriate Pfizer Quality Assurance group any suspected **Quality Events (QEs)**. QEs are nonconformities to applicable policy, procedure, protocol or **Good Practices Quality Guidelines and Regulations (GxP)**. Examples of QEs are those that involve the safety or rights of participants, or non-compliance with accepted ethical research norms that is likely to impact the integrity of the study data, such as significant departures from the clinical protocol or falsification of research records. It is Pfizer policy to investigate promptly any suspected quality issue related to a clinical study. Pfizer will take appropriate action to investigate the quality issue, remedy it, when possible, and prevent future recurrence. Pfizer's requirements and procedures for reporting and handling QEs are described in [CMCD QMS01-GSOP: Reporting and Management of Quality Events](#).

Safety Information & Adverse Event Monitoring – Pfizer-Sponsored Studies

	<p>Are Pfizer study teams obligated to report safety information from Pfizer-sponsored studies? Can Pfizer choose what type of information it reports to regulatory authorities?</p>
	<p>Study sponsors cannot choose what safety information they report to regulatory authorities. As a study sponsor, Pfizer is required to record and evaluate all safety information received from any source and to provide expedited reports to regulatory authorities of adverse events that are both serious and unexpected. Pfizer study teams must immediately notify all investigators, IRBs, and IECs, as well as the relevant regulatory authorities of significant unanticipated problems such as new safety information, in accordance with CMCD AEM01-POL: Adverse Event Monitoring (AEM) System. If significant safety information is discovered after study participants have agreed to be involved in the study, the study participants must be provided this new</p>

information, regardless of whether it may affect their willingness to continue to be involved in the study.



Compensating Investigators

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

Requirements relating to investigator compensation are set out in [CMCD CT18-POL: Compensation to Investigators](#), and include the following:

- Compensation must be linked to specific protocol-related services or associated activities (e.g., booking or reimbursement of reasonable travel, lodging, and meal expenses associated with attendance at investigator meetings). Investigators cannot be paid for the development of the primary publication (abstract, poster, presentation or manuscript) related to the study).
- The basis of compensation must be documented in a study budget that serves as an attachment to the Clinical Study Agreement;
- Compensation must be reasonable when compared to compensation for similar clinical studies sponsored by the pharmaceutical/biotechnology industry in the country where the study is conducted; and
- Study participants should be informed, as part of the informed consent process, that Pfizer is providing compensation to the investigator or institution for involvement in the study.
- Under no circumstances may financial compensation to investigators in Pfizer-sponsored studies:
 - Be tied to the outcome of the study;
 - Include Pfizer stock or stock options;
 - Include payments to HCPs outside the study for referring potential study participants;
 - Include special incentives such as enrollment bonuses, awards, or gift certificates designed to reward the achievement of participant enrollment goals within a specified time period; or
 - Include any other type of additional incentives or rewards, except those prospectively identified in the Clinical Study Agreement or approved by the IRB or IEC.

Investigator Compensation

	<p>If enrollment is lagging in a sponsored study, can Pfizer offer investigators increased compensation or gifts to help expedite enrollment? For example, can we pay investigators an extra \$700 per enrolled study participant or give them an iPad if a certain enrollment figure is reached?</p>
	<p>While Pfizer may compensate investigators with fair market value payments for their participation in a clinical study, offering investigators increased per-participant incentives to accelerate enrollment is not permitted. Investigator compensation must be linked to bona fide services. If enrollment is difficult, Pfizer can make arrangements to cover the cost of additional advertising, staff time, or bona fide recruitment efforts by the investigator or others. These additional payments will need to be made to an investigator's institution or clinical trial office, rather than to an individual investigator or his or her staff. If a study team has questions about whether a particular type of additional compensation is acceptable, the team should consult the relevant attorney supporting the asset on the Clinical Development Legal team.</p>

Investigator Meetings

Pfizer routinely invites investigators and key research staff working on Pfizer-sponsored studies to study-related meetings. Such meetings are usually held at the launch of a study and, as needed, intermittently as the study progresses. These investigator meetings provide information about the drug and study protocol, as well as opportunities for training and other activities designed to increase the consistency and quality of study conduct. Any Reimbursement to investigators and staff for travel to investigator meetings and associated expenses must comply with [CP #301: Travel, Entertainment and Other Business Related Expenses](#). The venue of investigator meetings should be conducive to the business purpose of the meeting, convenient for the participants, and not “resort-like” or “lavish.” International investigator meetings must comply with Pfizer’s [MAPP](#). The Meetings & Events Team within Global Commercial Operations is typically responsible for organizing such investigator meetings. Financial Support



In a Pfizer-sponsored study, Pfizer covers the cost of the **investigational aspects** of the study. This includes any treatments, procedures, or tests that are required by the protocol and that the study participant would not have received had he or she not participated in the study. In studies involving the use of a Pfizer product as the study drug, Pfizer generally provides or covers the cost for all study drugs. In the United States, the value of the study drug may be captured for reporting under the Physician Payments Sunshine Act.

Some studies also include certain protocol-required **Standard of Care (SOC)** services. SOC services are medically necessary treatments, procedures, or tests that would be administered to the patient even if

he/she had not enrolled in the study, consistent with good medical practice. Under certain circumstances, the costs of SOC services are not required to be covered by the study sponsor. However, Pfizer generally will not charge study participants for the costs of a Pfizer drug used in a Pfizer-sponsored study, even if the use of that drug is standard of care. For studies conducted in the United States, the determination of whether SOC costs may be charged to the study participant/insurer is governed by [CMCD CT48-WI-GL01 Development of Per Subject Cost](#) and [CMCD INV02-INV04-CT24-WI-GL01 Clinical Study Agreements and Site Investigator Payments](#). For studies conducted outside the United States, this determination requires consultation with local Legal and Regulatory.

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

Participant Compensation

	<p>May Pfizer compensate research participants for their time and any reasonable expenses incurred during their participation in a sponsored clinical study? Can any payment be made contingent upon the completion of the study?</p>
	<p>Pfizer is committed to compensating research participants fairly. Study participants should not have to bear unduly burdensome costs as a result of their participation in a Pfizer-sponsored study but should also not be offered compensation that could be seen as excessive and, therefore, undermine the principle of voluntary informed consent. Pfizer may offer a reasonable payment to research participants so long as the payment has been reviewed and approved by an IRB or IEC prior to the commencement of the clinical study. Payments must also be based on consistent criteria and must not be contingent on completion of the study. For more information please see CMCD CT17-POL, Compensation to Research Subjects.</p>

Public Disclosure and Access to Study Data

Pfizer believes that it is important for researchers, trial participants, regulators, and others acting in the best interest of patients to have access to clinical trial information to advance medical understanding and progress. It is also important that this access works in ways that protect patient privacy, preserve regulatory authority, and maintain incentives for those who generate data to conduct new research. Pfizer publicly shares results from its clinical trials, whether the results are neutral, negative or positive.

Pfizer recognizes that there are public health benefits associated with making clinical study information widely available to HCPs and study participants through clinical study registries and results databases. On [ClinicalTrials.gov](https://clinicaltrials.gov), Pfizer prospectively registers Pfizer-sponsored interventional studies in human subjects that evaluate the safety and/or efficacy of a product, as well as Pfizer-sponsored non-interventional studies (regardless of study design or data source) in which the safety and/or efficacy of a Pfizer product will be assessed. [ClinicalTrials.gov](https://clinicaltrials.gov) is a publicly-available study registry provided as a service by the United States National Institutes of Health. **Pfizer posts results of studies on ClinicalTrials.gov (and on [EudraCT](https://eudraCT.europa.eu/), a publicly-available portal managed by the European Medicines Agency) within the timeframes specified in [CMCD CT28-GSOP: Public Disclosure of Pfizer-Sponsored Studies](#).**

Pfizer is committed to compliance with all federal and state requirements regarding access to clinical study information and results. In addition, all investigators who participate in the conduct of a single or multi-site clinical study are entitled to review relevant statistical tables, figures, and reports for the entire study at a designated Pfizer facility or other mutually-agreeable location.

Pfizer also voluntarily complies with [PhRMA's Principles for Conduct of Clinical Trials and Communication of Clinical Trial Results](#) and encourages the publication of the results of its sponsored studies whether or not the results are favorable to the Pfizer product. Under those principles and Pfizer policy, study results must be reported in an objective, accurate, balanced, and complete manner and must discuss study strengths and limitations. Reports must also disclose Pfizer's financial support. Pfizer reserves the right to review, prospectively, any proposed publication or other disclosure of the results of a Pfizer-sponsored study to prevent inadvertent disclosure of Pfizer proprietary information, and may request a delay in publication, if necessary, to protect intellectual property rights. Publications from Pfizer-sponsored interventional clinical studies, Registrational CRCs and certain Research Collaborations are in scope for PUB01-GSOP *Pfizer Scientific Publications*.

Pfizer applies the authorship criteria established by the **International Committee of Medical Journal Editors (ICMJE)**, which ensures that only those individuals who deserve authorship credit based on their contributions to a publication are identified as authors. Individuals, who contribute to the publication in other roles, including technical writers, should be appropriately acknowledged, and sources of financial support for the study should be disclosed. Pfizer's policy on the public disclosure of information, access to data, and publications related to Pfizer-sponsored studies is outlined in [CMCD CT20-POL: Public Disclosure of Pfizer Clinical Study Data and Authorship](#), [CMCD CT28-GSOP: Public Disclosure of Pfizer-Sponsored Studies](#), and [PUB01-GSOP Pfizer Scientific Publications](#). Authorship of publications, including

the standards for acknowledgment as an “author” or “contributor,” is also discussed more fully in [White Guide Chapter 17: Publications](#).

Expanded Access

Pfizer is sometimes asked to provide an investigational product that has not yet received regulatory approval to treat a seriously ill patient who has exhausted approved treatment options and is ineligible to participate in any ongoing clinical study. Such requests should be submitted to Pfizer’s external online portal, [PfizerCAREs.com](#). [CMCD CT16-GSOP: Expanded Access Programs](#) identifies the criteria that must be met for Pfizer to consider a “Expanded Access” request. Expanded Access requests are reviewed by our medical experts inside the company, and we strive to respond within 5 business days. Some of the criteria include that the investigational product is being investigated under an appropriate regulatory authorization and there is meaningful human clinical data to support the determination that the potential benefits to the patient outweigh the risks. Non-clinical factors, such as the identity of the patient or the requestor, must not play a determinative role in the consideration of a compassionate access request. The relevant study team is responsible for evaluating expanded access requests, and the clinical lead will make the final determination. See [CT16-GSOP](#) for more information, and e-mail PfizerCAREs@pfizer.com with any questions.

Clinical Research Collaborations

General Requirements

CRCs can be initiated either by Pfizer (i.e., Pfizer approaches an external party to propose a collaboration), or by the external (i.e., external party approaches Pfizer to propose a collaboration). If confidential information will be shared during the initial discussions with the collaborator, a **Confidentiality Disclosure Agreement (CDA)** must be executed prior to such discussion.

It is important to understand the similarities and differences between a CRC and **Investigator Sponsored Research (ISR)** (also known as **investigator-initiated research (IIR)** or an investigator-sponsored trial). Similar to an ISR, a Collaborator is responsible for carrying out the research in accordance with the study protocol and, unless country-specific laws require otherwise, acting as the regulatory sponsor of the study. Pfizer’s contribution may include funding, product(s), device(s), equipment or other forms of support such as in-kind services like publication writing support, **Pharmacokinetic (PK)** analysis, etc. However, unlike an ISR in the CRC context, Pfizer can contribute to protocol design and statistical plan, reviews and approves the study protocol and any informed consent documents prior to submission to the **Institutional Review Board (IRB)/Independent Ethics Committee (IEC)**, has study oversight capabilities and may access patient-level data to facilitate its own research, development, commercialization and other activities. For example, Pfizer may use the data to support an application to a regulatory authority or to fulfill a regulatory commitment.

CRCs must only be used for medical or clinical research that is scientifically sound, supports Pfizer strategy, and is compliant with relevant regulations.

All industry standards, local laws, regulations, and professional standards appropriate to a country or region also apply to CRCs. In the event that those standards are more stringent than those described in this SOP, the more restrictive standard applies.

It is important to engage the CRC group as early as possible to determine feasibility & resource needs across the enterprise prior to engaging fully with a potential collaborator.

If a CRC is an option for clinical development of an asset, then it is important to have proactive communications with key internal stakeholders and partner lines regarding expectations concerning the process, timelines and roles and responsibilities. It is also important to consider integrating CRC into asset planning (i.e., life-cycle, operating plan) discussions.

- The Principal Investigator (PI) as well as the regulatory sponsor of record for the research must be determined and documented and collectively are considered the “Collaborator”. CRCs must have a protocol that outlines the details of the research activities being conducted. There should be a clear rationale for selecting a collaborator (e.g., an external partner like an Academic Research Organization) that is based upon their medical and clinical research expertise (e.g., therapeutic area knowledge and experience, efficient clinical trial execution, global filing capabilities) and is confirmed through the diligence process.
- There are several important questions that should be discussed early on with the potential collaborator(s) in order to assess their ability and willingness to engage in certain aspects of the collaboration as applicable such as (but not limited to):
 - Pfizer review and contribution to protocol, Informed consent documents, statistical analysis plan, monitoring plan, data capture elements or tools, data analysis, publications etc.)
 - Pfizer access to and/or a copy of the raw data, tables and listings, samples, regulatory documentation etc.
 - Pfizer review of systems, trainings and processes
 - Auditing, monitoring and termination rights

CRC Support

Pfizer may provide a Collaborator with one or more types of support, such as funding, product(s), device(s), equipment or other types of support such as in-kind services like publication writing support, Pharmacokinetic (PK) analysis, etc. In addition, Pfizer can contribute to the development of the protocol, Informed Consent Documents (ICDs), Statistical Analysis Plan (SAP), and other relevant study documents.

Evaluation of Potential CRCs

Pfizer's evaluation of a proposed CRC is based on scientific merit, strategic fit and the Collaborator's qualifications and ability to perform the study. All proposed CRCs undergo scientific review and a standard due diligence review, each described below.

Scientific Review

Scientific review of proposed CRCs is carried out by Pfizer representatives with medical, clinical and statistical expertise. Decisions are based on the scientific merit and quality of the proposed research, technical feasibility and strategic alignment of the research with Pfizer projects.

Due diligence review is a thorough, cross-functional process designed to evaluate CRCs from a risk-mitigation perspective, as well as to assist in the development of the collaboration framework. Reviewers include representatives from Pfizer's functional lines such as Quality Assurance, Clinical Informatics, Clinical Operations, Medicinal Sciences, Pharmacovigilance, Regulatory, Legal and other subject matter experts as needed. In order to facilitate Pfizer due diligence activities and understand the collaborators research facility(ies) and capabilities, Pfizer requests the collaborator to complete questions around feasibility, site process and procedures, systems and training procedures

Monitoring, Auditing, Tracking and Data Collection by Pfizer

Pfizer and its representatives may review Collaborator's study conduct and monitoring practices and general procedures to verify data quality and integrity. Collaborator has the obligation to cooperate with such activities and ensure reasonable access. If Pfizer notifies Collaborator of any concerns, Collaborator must promptly take appropriate steps to ensure the integrity of the study data.

Collaborators Roles and Responsibilities

Unless the parties otherwise agree, the Collaborator may conduct the research using its own system, policies and procedures. The **Trial Master File (TMF)** resides with the collaborator.

Regulatory and Ethical Obligations

A Collaborator acts as the research sponsor and must ensure that the study is conducted in accordance with the protocol, all applicable laws and regulations, and good practice quality guidelines such as, **Good Clinical Practices and Good Laboratory Practices (collectively, GxPs)**. As sponsor, a Collaborator assumes all regulatory responsibilities, including ensuring approval and oversight of the study by an IRB/IEC, obtaining necessary regulatory approvals (e.g., submitting and holding the clinical trial authorization or obtaining an **investigational new drug (IND)** application), and all reporting obligations to the appropriate regulatory authorities.

Unless an exemption applies, all applicable CRC studies must be reviewed and approved by a qualified **Institutional Review Board (IRB)** or **Independent Ethics Committee (IEC)** to help ensure the protection of the rights and welfare of study participants. Pfizer requires the provision of IRB/IEC approval and renewal letters. Continuation of support by Pfizer requires timely submission of a copy of IRB/IEC renewal documentation subsequent to the original IRB/IEC approval (as required per local regulations).

Regulatory Requirements

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

For studies conducted in the European Union, conduct under a **clinical trial application (CTA)** is required, a copy of the submission letter to the CTA, must be provided to Pfizer in English. If Pfizer will provide packaged and labeled Pfizer product, then Pfizer must receive a copy of the approved CTA, with Section 4.2 (IMPD or Letter of Access from Pfizer) and Section D (in its entirety) must be translated in English, before Pfizer can provide Qualified Person release of product. For more information regarding CTAs, please consult <http://eudract.emea.europa.eu/document.html>.

Collaborator confirms study registration on applicable registries such as [ClinicalTrials.gov](#) or www.clinicaltrialsregister.eu.

Protocol, Informed Consent and other Study Document Development

Collaborator and Pfizer can jointly develop study documents including but not limited to the Protocol, SAP, ICDs, and data capture forms as agreed to. It is important that Pfizer have the opportunity to review and approve all study documents prior to submission to regulatory and/or ethic committees and must receive the final IRB/IEC approved protocol and informed consent documents. It is also important to engage Pfizer when considering any amendments to such documents as continuation of support by Pfizer for a CRC study will be contingent on Pfizer's review and acceptance of these changes.

For studies with sites in the **European Union (EU)** where drug support is being requested, the final study protocol must be signed by the principal investigator and is required for **Qualified Person (QP)** release of drug supplies.

Study Monitoring

Collaborator monitors the study in accordance with GxPs and all applicable law and provides Pfizer with access to information relating to study deviations, including any significant GxP protocol compliance issues. Collaborator and Pfizer agree to a monitoring plan prior to study commencement.

Document Reviews and Site Visits

Upon reasonable notice and during regular business hours, Collaborator shall permit Pfizer personnel and representatives access to study premises, facilities, systems and processes including **Standard Operating Procedures (SOPs)** and study records, as well as investigators and other research staff.

Regulatory Inspections and Audits

To satisfy its duties as study sponsor, Collaborator may conduct quality oversight reviews and audits of the facilities, services, systems and processes of third parties, such as labs, who are involved in study execution. Collaborator provides Pfizer, at Pfizer's request, with copies of all findings from such reviews.

Reporting of Safety Data

As study sponsor, the Collaborator reports required safety information (such as **serious adverse events (SAEs)**) to the appropriate regulatory authorities and to the IRBs/IECs. Pfizer also requires the provision of certain safety information as outlined in the Contracts and *Safety Reporting Reference Manual for IIR or Clinical Research Collaboration Studies* provided to the Collaborator prior to study commencement. Collaborator and all investigators and other study staff must understand and fully comply with the adverse event reporting requirements.

Investigational Drug Supply

The Collaborator ensures that each study site has appropriate procedures, training and controls in place to receive, store, dispense and destroy or return the investigational Pfizer product as required for the proposed study. Any investigational drug product provided by Pfizer for an approved study must only be used in accordance with the approved protocol.

Collaborator maintains a record of any investigational drug product that was received, dispensed, returned or destroyed throughout the duration of the study. Unless otherwise instructed by Pfizer, Collaborator arranges for the destruction of any expired or unused investigational drug product in accordance with all applicable laws and regulations and institutional policies.

Study Budget

Detailed budgets should be provided as soon as possible during protocol development and are subject to review and fair market value evaluation. Pfizer provides Collaborator with a budget template to ensure that all study-related expenses have been appropriately itemized and included.

Pfizer does not pay or reimburse Collaborator for (i) services not performed, or services performed that are not in compliance with the CRC Agreement; (ii) Standard of Care services; or (iii) any attorneys' fees incurred by Collaborator in the negotiation of the CRC Agreement or any related agreement. "Standard of Care" means any medically necessary treatments, procedures or tests administered in a manner that is consistent with current medical practice and that would be expected to be performed on or provided to a subject even if the subject were not participating in the study.

Pfizer Inc. complies with state, federal and voluntary ethics code reporting requirements worldwide (e.g., Open Payments f/k/a Sunshine Act; EFPIA Code). This includes the reporting of payments and drug supply costs provided to Collaborator and any investigators by Pfizer in support of collaborative studies.

Governance

Confidentiality Agreement

Prior to engaging in CRC discussions, confidential information may be exchanged. Therefore, it is generally necessary to enter into a confidentiality agreement with Collaborators to ensure that any confidential information is protected. Each Collaborator ensures that its employees, agents and subcontractors are aware of Collaborator's confidentiality obligations, and that they are able to abide by the same restrictions in carrying out study-related activities.

CRC Agreement

The CRC Agreement outlines each party's roles and responsibilities, as well as expectations regarding study conduct, milestones and deliverables, publications, intellectual property, term/termination, safety/pharmacovigilance, confidentiality and other provisions. Study-related activities do not commence until a CRC Agreement is signed by all parties.

Joint Study Team Meetings

It is important for the Collaborator's study personnel and Pfizer colleagues to keep the lines of communication open as to the status of study activities from the beginning. Pfizer and the Collaborator will determine the appropriate meeting format and frequency to communicate study progress which address (among other things) the progress of research activities, reported patient outcomes/clinical activity, safety updates, projected publication dates, and projected and completed milestones.

Study Deliverables

Study Results

Pfizer requires the provision of study results at the conclusion in accordance with the agreed statistical analysis plan for this study. Collaborator will provide to Pfizer the study results in the form of a written, succinct summary of key study results, whether such study results arise from interim analyses or final analysis.

Clinical Study Report (CSR)

In some cases, Pfizer may also require the provision of a CSR. The final study report should reflect the results of the study as a whole. The CSR will be organized in a mutually agreeable manner and should include at a minimum, the information identified below. Collaborator should provide Pfizer with an opportunity to review and comment on the CSR, including but without limitation the proposed list of tables, and Collaborator will incorporate any comments reasonably requested by Pfizer.

The CSR should address:

- Ethics;
- Investigators and study administration;
- Study objectives;
- Investigational plan;
- Study subjects;
- Efficacy evaluation;
- Safety evaluation; and
- Discussion and overall conclusions; supportive tables, figures and graphs.

Study Data

In certain CRCs, Pfizer will want to obtain access to and/or request data to be transferred to Pfizer. To ensure that study data are collected in a way that facilitates analysis and use by both Parties, Collaborator will provide Pfizer an opportunity to review and comment in advance on the case report forms on which study data will be recorded. Pfizer and Collaborator will discuss the use of a mutually agreeable electronic transmission method that is demonstrated to be compatible with uploading to the targeted Pfizer database and that protects the security and integrity of the data.

Publications

Pfizer supports the exercise of academic freedom and encourages the Collaborator(s) to publish the study results, whether or not they are favorable to Pfizer or any Pfizer product. It is encouraged that both the Collaborator and Pfizer discuss publication plans, including but not limited to, the targeted Congress or journal, publication type, proposed publication title, proposed authors and writing support. When selecting a peer-reviewed journal, it is recommended the authors choose one which offers Open Access publishing.

All registrational CRC publications and certain RC publications must comply with PUB01-GSOP and [PUB01-GSOP-RF04 Clinical Research Publications Checklist](#).

Primary Submission

Unless the Collaborator and Pfizer decide there is a reason a Publication is not needed, the Collaborator is responsible for ensuring submission of one or more manuscripts reporting study results for the primary endpoint(s) to a peer-reviewed medical or scientific journal and congresses (e.g. manuscripts, abstracts, posters, and presentations) within 18 months of the last subject last visit or the primary completion date, whichever is earlier.

Publication Quality

Publications should not be based on preliminary or interim data analyses, unless (i) such analysis(es) was specified in the study's SAP prior to commencement of the study and approved by both Collaborator and Pfizer, and (ii) a contemporaneous copy of the relevant interim data has been archived. Publications should only be based on applicable data quality standards as agreed between the Parties in writing and will be generated from data that meet data quality standards consistent with Pfizer-provided guidance.

Pre-publication Review by Pfizer

Neither Collaborator nor Principal Investigator will submit a Publication without providing Pfizer at least 30 days to review and comment on the proposed Publication and any data that supports it. Collaborator will provide Pfizer with any study data that supports the Primary Publication, or any interim Publication at least 30 days in advance of any public disclosure (including disclosure to journals, scientific congresses, etc.). Pfizer shall provide its comments with respect to such Publication within 30 days of its receipt of such written copy. The review period may be extended upon the request of Pfizer for an additional period of 45 days in the event that Pfizer wishes to prepare and file any patent applications relating to any of the Confidential Information or Inventions. Collaborator is responsible for ensuring that the Principal Investigator consider Pfizer's comments on any such proposed Publication in good faith, including a recommendation not to publish if the data or proposed Publication does not satisfy the standards set forth in the Pfizer policies or standard operating procedures.

Redaction of Confidential Information

Collaborator will, and will ensure that the authors, on request, remove any confidential information that has not previously been publicly disclosed from the Publication before disclosure to third parties and submission to a journal. If Collaborator deems disclosure of such confidential information necessary for appropriate scientific presentation or understanding of the study results, Collaborator will initiate discussions with Pfizer regarding this issue.

Authorship Standards

For all Publications, Collaborator will ensure all authors comply with standard academic practice and the International Committee of Medical Journal Editors (ICMJE) authorship guidelines and with any additional professional, published standards of the journal or professional society where they seek to publish their study findings. Pfizer personnel may be included as appropriate authors for primary and secondary publications if they qualify under ICMJE guidelines.

Disclosure of Support

In any Publication, authors will disclose Pfizer support (and support by any other external entity) of the study. Collaborator will also adhere to any journal guidelines for disclosing industry support and conflicts of interest in a Publication.

Secondary Publications

Both Parties have the right to publish or present any aspect of the study results, after the Primary Publication of the study results as a whole. Secondary Publications will acknowledge Collaborator's sponsorship and Pfizer's support of the study and any participating sites. Secondary Publications will be submitted to the other Party for review and comment 30 days before any public disclosure. Each Party is responsible for ensuring it considers the other Party's comments on any such proposed Publication in good faith, including a recommendation not to publish if the data or proposed Publication does not satisfy the standards set forth in Pfizer's policies or standard operating procedures.

Safety Information & Adverse Event Monitoring – Clinical Research Collaborations

Are Pfizer study teams obligated to report safety information from CRCs? Can the CRC sponsor choose what type of information to report to regulatory authorities?

Safety Information & Adverse Event Monitoring – Clinical Research Collaborations

CRC sponsors cannot choose what safety information they report to regulatory authorities. The CRC, sponsor/investigator is required to record and evaluate all safety information received from any source and provide expedited reports to regulatory authorities of adverse events that are both serious and unexpected. However if a Pfizer colleague becomes aware of an adverse event, Pfizer must also report it in accordance with [CMCD AEM01-POL: Adverse Event Monitoring \(AEM\) System](#). For CRCs, all investigators, IRBs and IECs, as well as the relevant regulatory authorities, should be immediately informed of significant unanticipated problems such as new safety information. If significant safety information is discovered after study participants have agreed to be involved in the study, the study participants must be provided this new information, regardless of whether it may affect their willingness to continue to be involved in the study.

For More Information

- [My Anti-Corruption Policy and Procedures \(MAPP\)](#)
- [CP #207: Global Policy on Interactions With Healthcare Professionals \(GPIHP\)](#)
- [CP #301: Travel, Entertainment and Other Business Related Expenses](#)
- [CP #404: Protecting the Privacy of Personal Information](#)
- [PUB01-GSOP Pfizer Scientific Publications](#)
- [PUB01-GSOP-RF04 Clinical Research Publications Checklist](#)
- [PhRMA's Principles for Conduct of Clinical Trials and Communication of Clinical Trial Results](#)
- Consult the following Clinical and Medical Controlled Documents (CMCD) Policies and SOPs
 - [CMCD AEM01-POL: Adverse Event Monitoring \(AEM\) System](#)
 - [CMCD CT19-POL: Global Standards for Interventional Clinical Studies](#)
 - [CMCD CT20-POL: Public Disclosure of Pfizer Clinical Study Data and Authorship](#)
 - [CMCD CT22-GSOP: Independent Oversight Committees](#)
 - [CMCD CT28-GSOP: Public Disclosure of Pfizer-Sponsored Studies](#)
 - [CMCD PUB01-GSOP Pfizer Scientific Publications](#)
 - [CMCD CT44-GSOP: Registrational Clinical Research Collaborations](#)

- [RC01-GSOP Research Collaborations](#)
- [CMCD GNT01-GSOP: Independent Medical Grants](#)
- [CMCD INV02-GSOP: Investigational Site Selection Preparation and Initiation](#)
- [CMCD INV04-GSOP: Investigational Site Management and Monitoring](#)
- [CMCD INV02-INV04-CT24-WI-GL01 Clinical Study Agreement and Investigator Site Payments](#)
- [CMCD QMS01-GSOP: Reporting and Management of Quality Events](#)
- [Orange Guide Chapter 6: Clinical Research and Clinical Research Collaborations](#)
- [White Guide Chapter 2: Advertising and Promotional Materials](#)
- [White Guide Chapter 5: HCP and Government Official Consulting Engagements](#)
- [White Guide Chapter 11: Privacy: Protecting Personal Information](#)
- [White Guide Chapter 17: Publications](#)



**CHAPTER #10 – THE PFIZER
PATIENT ASSISTANCE PROGRAM
(PAP) AND DONATIONS TO
INDEPENDENT CHARITABLE
PATIENT ASSISTANCE PROGRAMS
(ICPAPS)**

Chapter

#10

**The Pfizer Patient Assistance Program
(PAP) and Donations to Independent Charity
Patient Assistance Programs (ICPAPs)**

CONTENTS

The Pfizer Patient Assistance Program (PAP) and Donations to Independent Charity Patient Assistance Programs (ICPAPs)

Introduction	170
Donations to Independent Charity Patient Assistance Programs (ICPAPs)	170
Patient Support Hubs and Pfizer RxPathways	171
Core Compliance Principles.....	171
Key Points to Ensure Compliance	172
Pfizer Patient Assistance Program (PAP)	173
The Pfizer Patient Assistance Program (i.e., Free Drug Program)	174
Medicare Part D Patients and the Pfizer Patient Assistance Program.....	176
Institutional Patient Assistance Program (IPAP)	177
Compliance Core Principles – Pfizer PAP	178
PAP Guidance for Pfizer Non-Field Colleagues.....	178
Interactions and Communications with Pfizer PAP/IPAP Vendors	180
External Communications Regarding Pfizer Foundation PAP/IPAP	180
Independent Charity Patient Assistance Programs (ICPAPs)	181
ICPAP Guidance for Pfizer Non-Field Colleagues.....	182
Pfizer RxPathways® and Product-Specific Patient Support Hubs	183
For More Information.....	185

Chapter #10 The Pfizer Patient Assistance Program (PAP) and Donations to Independent Charitable Patient Assistance Programs (ICPAPS)

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 eligible patients access the medicines they need through a number of programs.

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**), which includes 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 product-specific or therapeutic-area specific **Patient Support Hubs (Hubs)** and Pfizer RxPathways, through which patients may access the Pfizer PAP as well as certain other patient support programs/services (e.g., copay cards, discount cash pay cards, prior authorization assistance, benefits verification) that help eligible patients in the United States, Puerto Rico, Guam (where applicable), and the U.S. Virgin Islands access the Pfizer medications prescribed by their HCPs. See White Guide Chapter 19 for information regarding these programs.

As part of its commitment to improving patient access to medicines, Pfizer established a charitable internal free drug program that provides commercially-available Products⁶ to nearly 300 **Federally Qualified Health Centers (FQHC)**, free clinics and disproportionate share hospitals. Through this initiative, Pfizer donates applicable 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. Pfizer operates the PAP, which includes the IPAP, on behalf of the **Pfizer Patient Assistance Foundation (PPAF)**, a Pfizer non-profit 501(c)(3) private operating foundation. Information regarding Pfizer's policies related to the PAP, including the IPAP, is provided in 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 (ICPAPs)

In addition to the programs described above, 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

⁶ Product availability varies by institution.

medicines by assisting such patients with their out-of-pocket copay obligations. ICPAPs may establish disease state funds that provide financial assistance with copay obligations associated with treatment for specific disease states, including 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](#).

Patient Support Hubs and Pfizer RxPathways

Patients may access the Pfizer PAP, information regarding other financial assistance options (which may include 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.

Core Compliance Principles

The Pfizer PAP (including IPAP), donations to ICPAPs, and other patient support programs⁷ play an important role in assisting patients with accessing medically necessary products after they are prescribed by their HCPs. However, operation of these programs implicate several federal and state laws and other regulatory guidance, 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 Products (or to other prescribed medicines as well in the case of ICPAP donations) and are not 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 Product 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, Pricing & Access Legal Team reviews and provides guidance regarding the programs and activities covered in this Chapter, including PAP, donations to ICPAPs,

⁷ These programs include copay cards, discount cash pay cards, and the Pfizer Savings Program.



RxPathways and Hub activities in the United States, Puerto Rico, Guam (where applicable), and the U.S. Virgin Islands. In addition, Pricing & Access Legal must review and approve the inclusion, removal and exclusion of Products from the Pfizer PAP and IPAP. The ICPAP Review Committee (RC) must approve all donations to ICPAPs.

NOTE: Third-party vendors acting on Pfizer's behalf in administering the Hubs, PAP, and IPAP must certify/warrant compliance with applicable state and federal healthcare laws and regulations and Pfizer policies and procedures.

Consult Pricing & Access Legal for additional information on Pfizer's PAP, IPAP, and interactions with ICPAPs, and your team attorney 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; (ii) interacting with ICPAPs, to the extent appropriate; (iii) discussing patient support programs and resources with HCP customers
- **Pfizer PAP:**
- On behalf of PPAF, a non-profit 501(c)(3) private operating foundation, the Global Health & Social Impact team and other authorized Pfizer colleagues operate the Pfizer PAP with its 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.
 - 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 providers, practitioners, 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.

Key Points to Ensure Compliance

- ICPAPs (See *also* Corporate Policy and Procedure #803):
 - Global Health & Social Impact (with ICPAP Review Committee oversight) is solely responsible for ICPAP donations and related activities and, with limited exceptions, Global Health & Social Impact must not share information related to ICPAP donations with other Pfizer colleagues.
 - Colleagues outside of Global Health & Social Impact team must not:
 - Discuss patient need, business interests, or funding decisions related to donations to ICPAPs for copay assistance with Global Health & Social Impact for the purpose of influencing donations; or
 - Seek to influence, or be involved in, any communications between the Global Health & Social Impact team and the ICPAPs related to donations for copay assistance.
 - Pfizer colleagues must not discuss with HCPs or patients:
 - Specific ICPAPs;
 - The availability of funding in relevant disease states; or
 - That ICPAPs can overcome copay barriers.
- **Patient Support Programs Offered through Hubs or 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 Product.
 - Pfizer colleagues must not state or suggest that patient support programs provide independent value to any HCP or reduce economic or administrative burdens for an HCP (or related practice or office staff).
- Patients and HCPs may visit the Pfizer RxPathways website (PfizerRxPathways.com), the PAP Connect website (PfizerPAPConnect.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 your team attorney.

Pfizer Patient Assistance Program (PAP)

The Pfizer PAP is 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. PPAF operates consistent with its certificate of incorporation and bylaws. Pfizer Colleagues elected to PPAF's Board of Directors and

Rev. 12/21

Page 173 of 381



Pfizer's Global Health & Social Impact team, some of whom serve as officers of PPAF, have primary responsibility for managing the Pfizer PAP operations on behalf PPAF, with support from certain other functions (e.g., Legal, Compliance, Privacy, Global Procurement, Finance, Pfizer Global Supply).

Pfizer's Global Health & Social Impact, on behalf of PPAF, is responsible for the day-to-day operations of the Pfizer PAP, including establishing patient and institution eligibility criteria and determining Product inclusion, exclusion, and removal criteria. Global Health & Social Impact must complete a PAP Program Approval for Pricing & Access Legal review and approval of product inclusion, exclusion, or removal from the PAP.

All Pfizer Colleagues that conduct business related to the Pfizer PAP 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 up to 12 months (as long as they remain eligible). Eligible underinsured patients, which 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.

Covered Products: A large number of 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 website.

In general, a majority of Pfizer Products are available through the Pfizer PAP, EXCEPT the following:

- Products that are typically administered in an inpatient hospital setting (the Pfizer PAP is for outpatients only);
- Products that are classified as opioids; and
- Products 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), except as available by medical exception.

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 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 must also 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.
- 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 or consent to electronic income verification
- Patients must live in the United States, U.S. Virgin Islands, Guam (when applicable), 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 copay cards (for commercially insured patients only), Medicaid, Medicare Part D Extra Help, or ICPAP support, before they can be enrolled in the Pfizer PAP.
- Other eligibility criteria may apply and will be included in the program-specific business rules.

Referring Patients to the Pfizer PAP



You are a Sales representative and one of your HCP customers tells you that he has Xeljanz patients who are uninsured. He asks you whether Pfizer can provide these patients with financial assistance to cover their out-of-pocket costs for Xeljanz. Xeljanz 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?

Referring Patients to the Pfizer PAP



Yes, you may inform the HCP that he can refer patients to the Pfizer RxPathways website 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.



OIG has stated that manufacturers may provide free medications to Medicare Part D beneficiaries so long as several safeguards are met (see list below), including that manufacturers provide such free medications entirely outside the patients' Part D benefits. This means that if a Part D beneficiary receives free Product through a PAP no claims for payment can be filed with the Part D plan associated with such Product. 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 following requirements:

- Notification to Part D plans that the Product is being provided to a Part D beneficiary outside the Part D benefit;
- Provision of free Product for the whole Part D coverage year or the portion of the year remaining after the beneficiary received patient assistance;
- Provision of free Product even if the beneficiary's use of the drug is periodic;
- Maintenance of accurate and timely records to verify the provision of the free Product outside the Part D benefit;
- Award free Product based on reasonable, uniform, and consistent measures of financial need and without regard to providers, practitioners, or suppliers; and

- Compliance with any applicable guidance issued by the Centers for Medicare and Medicaid Services.

Pfizer Patient Assistance Program and Medicare Part D

	<p>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?</p>
	<p>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. The patient must sign the PAP Application/Program Enrollment Form indicating 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 directly notify Part D plan sponsors when their members are enrolled in the PAP.</p>

Institutional Patient Assistance Program (IPAP)

Overview of Program: The IPAP provides select Products to eligible, financially needy, uninsured patients through nearly 300 federally-qualified community health centers, disproportionate share hospitals, free clinics, and state pharmacy programs.⁸ 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.

Covered Products: At present, many Pfizer Products are available for free through the IPAP. For a complete list of Products available, visit PfizerRxPathways.com.

Eligibility Requirements: To qualify to receive Product for free through the IPAP, patients must:

- Receive their care at one of the nearly 300 institutions that participate 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.

⁸ Product availability varies by institution and eligibility.

Compliance Core Principles – Pfizer PAP

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 consistent with its charitable purposes and without undue influence from Pfizer Commercial Colleagues.

PAP Guidance for Pfizer Non-Field Colleagues

Pfizer's Global Health & Social Impact team is responsible for administering the Pfizer PAP on behalf of PPAF a non-profit 501(c)(3) private operating foundation. Except as described below or in the PAP/IPAP SOP, or as otherwise approved in advance by Pricing & Access Legal, Pfizer Colleagues must not be involved in the development, operation, or management of the Pfizer PAP.

- **Budget** – The Pfizer PAP budget is a component of the Global Health & Social Impact budget within the Corporate Affairs budget and, consistent with Company procedures related to budget approval, is approved by the Pfizer Executive Leadership Team. Brand teams indirectly fund the Pfizer PAP operations through permanent budget transfers to Global Health Partnerships & Social Impact and/or GH&SI charges, as needed, to a quarterly topside adjusting entry to the Pfizer Biopharmaceuticals Group. As part of this process, relevant Commercial Colleagues may communicate with Global Health & Social Impact Colleagues to understand Global Health & Social Impact's requests for budget transfers. As part of these communications, Global Health & Social Impact team may provide relevant Pfizer PAP data (e.g., PAP utilization or forecasting data, and information about expected administrative costs).
- **Operations** – Except for Pfizer Colleagues acting on behalf of or in service of PPAF, or appropriately involved in establishing and approving the Pfizer PAP budget in accordance with the PAP/IPAP SOP, Pfizer Colleagues may not be involved in the management or operations of the Pfizer PAP. Further, Pfizer Colleagues must not seek to influence Global Health & Social Impact's management or operation



of the Pfizer PAP, including but not limited to decisions regarding whether to include a Product in the Pfizer PAP, the patient or institutional eligibility criteria, and other program terms and conditions.

Commercial Colleagues may provide to Global Health & Social Impact information about the timing of new Product launches and Product acquisitions and may request that GH&SI consider adding any such new Product to the Pfizer PAP. In addition, at the request of Global Health & Social Impact team, relevant Pfizer Colleagues (including Commercial Colleagues) may provide information about Products, relevant diseases, and patient populations to allow Global Health & Social Impact team to develop the PAP budget and establish patient need.

- **PAP Data** – Pfizer Colleagues may request reports containing Pfizer PAP data from Global Health & Social Impact team. Global Health & Social Impact team must consult with Pricing & Access Legal prior to distributing any new report type/data to anyone not working on behalf of PPAF. Consult your team attorney for review and approval of Pfizer PAP data reports from co-promote partners. 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 data and reports to drive commercial objectives (e.g., to increase product utilization and any related strategy). All data requests that have been approved must be used only for the stated purpose and the data is only available to the recipients identified in the formal request. Any deviations including additional data, audience, or purpose must be requested from GH&SI and approved by Pricing & Access Legal.
 - Pfizer Colleagues *must never conduct Return on Investment (ROI) analyses on the provision of free drug through the Pfizer PAP, attempt to correlate Pfizer's donations to ICPAPs with Pfizer PAP utilization, or use PAP data to conduct any analysis prohibited by the [Corporate Policy and Procedure #803 Contributions to ICPAPs or any other Pfizer policy](#).*
 - Pfizer Colleagues should contact Legal and Compliance with any questions on the appropriate use of PAP/IPAP data and reports.
- **Patient Data** – Pfizer Colleagues and vendors who must access patient data to perform services related to administration of the Pfizer PAP must keep such data confidential and must ensure that they do not provide such data to any other person who should not have access to it, consistent with all data privacy requirements described in White Guide Chapter 11: Privacy: Protecting Personal Information. Other than those Pfizer Colleagues who must receive patient data to administer the Pfizer PAP or address individual patient cases within the scope of their roles, no Pfizer employee or contractor may receive identifiable data from PAP vendors related to the Pfizer PAP. IPAP institutions must not provide individually identifiable data, including personal health information, to the IPAP vendor, PPAF, a non-profit 501(c)(3) private operating foundation, or Pfizer, except as may be required for program auditing purposes.

- Use of Patient and HCP Personal and Contract Information – Patients and their prescribing HCPs must be notified in writing and acknowledge how patient and HCP information may be used when a patient applies for the Pfizer PAP. Patient and HCP contact information gathered through the PAP application and enrollment process may not be used to promote or market other Pfizer programs or Products. Patients and HCPs must not be required to enroll in any other program or opt-in to receive Pfizer marketing materials as a condition of enrolling in the Pfizer PAP. If information regarding such patients or HCPs is gathered through other means (e.g., Hub or PfizerPro enrollment), Pfizer may use that information for purposes consistent with other Pfizer policies and SOPs.

Interactions and Communications with Pfizer PAP/IPAP Vendors

- Other than Pfizer Colleagues authorized to act on behalf or in service of PPAF, a non-profit 501(c)(3) private operating foundation, and field reimbursement colleagues (e.g. FRMs, FAS and PACs) within the approved scope of their roles, Pfizer Colleagues must not communicate with the vendors that administer the Pfizer PAP and IPAP for any reason.
 - This prohibition does not prevent the SAS CoE and other appropriate Colleagues from communicating with Hub vendors who also administer the Pfizer PAP regarding other patient support programs or activities. Pfizer Colleagues should refer all questions or concerns regarding vendors' operation of the Pfizer PAP and IPAP to Global Health & Social Impact team.

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.

In general, all external communications should comply with the following guidelines:

- 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, Commercial Colleagues, contractors, and third-party vendors must not promote the availability of the Pfizer PAP or IPAP for any off-label use of a Product.
- Pfizer Colleagues, contractors, and third-party vendors must not describe the Pfizer PAP and IPAP as a way to fill gaps in Product coverage (e.g., Medicare Part D donut hole).
- Pfizer Colleagues, contractors, and third-party vendors 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.



- Pfizer Colleagues, contractors, and third-party vendors (other than those contracted to administer the Pfizer PAP and IPAP) must not fill out or submit PAP applications on behalf of patients or HCPs.
- All marketing materials that reference the Pfizer PAP and/or IPAP must be approved through all applicable Pfizer materials review processes.

A Note about Field Commercial Colleagues: The above guidance also applies to all Field Commercial Colleagues. Therefore, it is particularly important to keep in mind the rules surrounding external communications when creating marketing materials that reference the Pfizer PAP and IPAP. For additional guidance on creating marketing materials, see White Guide Chapter 4: Marketing Programs.

Independent Charity Patient Assistance Programs (ICPAPs)

In addition to the Pfizer free drug programs described above, Pfizer also may make charitable contributions to ICPAPs through its Global Health & Social Impact team. 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 copay, deductible, and/or premium obligations for prescriptions (collectively, “copay assistance”). ICPAPs may focus financial assistance on costs associated with treatment for specific disease states, and generally have disease-state funds that provide copay 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 before they can be enrolled in the Pfizer PAP, including for example, ICPAP support.

OIG has issued guidance permitting ICPAPs to provide copay 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 Non-Field Colleagues

All Pfizer Non-Field Colleagues must understand and operate according to the following standards in relation to ICPAPs:

- **Communications with ICPAPs.** Only the Global Health & Social Impact team (including Legal and Compliance Colleagues advising Global Health & Social Impact) may communicate with, and receive information and data from, ICPAPs regarding donations to ICPAPs for copayment assistance.
- **Data from Other Third Parties.** Hubs, Pfizer RxPathways, and specialty pharmacies may assist patients with searching for available ICPAP funding. Data received from these third parties (whether incorporated into a Pfizer business report or otherwise) must be limited in frequency (i.e., not more than monthly), may be shared internally only as necessary, and the nature and type of report that will be shared must be approved by Legal prior to distribution. Under no circumstances should Pfizer **obtain information about: (1) other donors or other donations made to the ICPAP except for general information on total donations received or funding available; or (2) use the data to correlate the amount or frequency of Pfizer's donations to ICPAPs with the ICPAP's support of patients prescribed Pfizer Products. Subject to the one exception listed below, data received from third parties must not be: (1) disaggregated and/or patient-specific; or (2) whether or not in the aggregate, related to the identity or amount of subsidized drugs.**
- **Exception:** Vendors may provide certain patient-specific or disaggregated information to Pfizer Colleagues responsible for administering the Pfizer PAP (e.g., Global & Health Social Impact or SAS CoE Colleagues) or engaged in reimbursement support (e.g., Field Reimbursement Managers) in the event such information is critical to the Colleagues' job responsibilities with respect to operating the Pfizer PAP or assisting patients access their medicines. Other Pfizer Colleagues must not seek to obtain or be provided with such information.
- **Independence of ICPAPs.** Pfizer Colleagues, including the Global Health & Social Impact team, must not exert or attempt to exert any direct or indirect control over an ICPAP or the entity operating the ICPAP regarding establishing new disease state funds, the scope of a new or proposed disease state fund, the modification of a disease state fund, or criteria for determining eligibility of patients who qualify for assistance.

- **Information Related to ICPAPs.** The Global Health & Social Impact team must not share information related to donations to ICPAPs *for copay assistance* with any other Pfizer Colleagues, except as specifically provided in [Corporate Policy and Procedure # 803 Contributions to Independent Charity Patient Assistance Programs](#).
- **ROI Analysis.** Pfizer Colleagues are prohibited from undertaking any “Return on Investment” analysis or other analysis that seeks to correlate a past or future donation to ICPAPs to the number of subsidized prescriptions for Pfizer Products including, for example, to determine the amount to donate to ICPAPs.
- **Undue Influence.** The Global Health & Social Impact team has sole responsibility for determining the allocation of the approved budget for donations to ICPAPs, subject to review and approval by the ICPAP Review Committee. Pfizer Colleagues are prohibited from discussing patient need, business interests, or funding decisions related to donations to ICPAPs for copay assistance with Global Health & Social Impact team for purposes of influencing donations decisions.
- **Co-Promote Agreements.** If Pfizer collaborates with a third party in the marketing or promotion of a drug, it will be responsible, through Global Health & Social Impact team, for making its own decisions regarding the provision of donations to ICPAPs for copay assistance in accordance with Pfizer’s policies and procedures and co-promote partners will make their own donations separately. Pfizer must not provide any funding or reimbursement to its co-promote partners for donations to ICPAPs for copay assistance and must not share information about its donations with its co-promote partners. Pfizer Colleagues with responsibility for co-promote partnerships should consult [Corporate Policy and Procedure # 803](#) and Legal.

Pfizer RxPathways® and Product-Specific 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, prior authorizations and appeals support, drug delivery and administration assistance, copay support, financial assistance for eligible patients, 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, copay and savings offers, free trial programs, and other resources. Pfizer RxPathways is run by the Global Health & Social Impact 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 & Social Impact 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 & Social Impact team is responsible for Reimbursement Support and the



Pfizer Patient Assistance Program services, while Pfizer brand teams or the SAS CoE oversee most Copay and Free Trial Programs).

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 Product. RxPathways and the Hubs are intended to support patient access to independently-prescribed Pfizer Products 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 Pricing & Access 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.

Pfizer Colleagues must not promote Pfizer's Hub activities as a reason to prescribe a Pfizer Product. Pfizer Hub programs are not a means to reduce economic or administrative burdens for HCPs and staff, and . Pfizer Colleagues must 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 Review Committee-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 and Field Access Counselors) should refer all inquiries from their HCP customers regarding the status of a particular patient case to the applicable Field Reimbursement Manager or Field Access Counselor through the appropriate channel or refer the HCP or office staff to RxPathways or the applicable Hub.

In addition, Pfizer Colleagues, other than Field Reimbursement Managers, Field Access Counselors, Patient Access Coordinators within the approved scope of their roles, should not contact RxPathways or any Hub directly to discuss patient cases or receive any data from RxPathways or any Hub without previous direction approved by the Pricing & Access Legal Team.



For More Information

- For more information about Pfizer RxPathways, the Pfizer PAP and IPAP, or other patient support programs, please contact The Pfizer RxPathways Team at PfizerRxPathways@pfizer.com.
- For more information about Hub programs, please see the Standard Operating Procedure for Patient and Reimbursement Support Hubs including, for example, guidance to govern the initiation, management, and execution of Hubs / Hub activities
- For RC-approved FAQs and Talking Points, visit [MyPfieldNet](#).
- If you have additional questions about the information covered in this Chapter, please contact your team attorney.



CHAPTER #11 – PRIVACY: PROTECTING PERSONAL INFORMATION

Chapter**#11****Privacy: Protecting Personal Information**

CONTENTS

Privacy: Protecting Personal Information

Introduction	189
Governing Laws and Pfizer Policies	189
The Legal Landscape.....	193
Health Insurance Portability and Accountability Act of 1996 (HIPAA).....	193
Pfizer is Not a Covered Entity under HIPAA	193
Pfizer is Generally Not a Business Associate under HIPAA.....	193
HIPAA is Still Relevant for Pfizer	194
State Medical Information Privacy Laws	194
Federal and State Privacy and Security Laws.....	194
Federal and State Breach Notification Laws	195
Laws Protecting the Personal Information of Children	196
Requirements for Transparency, Notice, and Consent	196
Pfizer's Policies Relating to Privacy and Personal Information	197
Notice and Consent	197
Aggregated, Anonymized or De-identified Data	197
Avoiding Exposure to Protected Health Information.....	198
Adverse Event Reporting.....	198
Vendor Obligations	198
Activities That May Result in the Use and Disclosure of Personal Information	199
Marketing Initiatives and Other Communications.....	199
Pfizer-Sponsored Third-Party Communications	199
Digital Marketing Initiatives	200
Pfizer's Patient Programs	200
Working with HCPs.....	201
Mentorships and Preceptorships	202
Consumer Health Fairs or Screenings	203
Patient Information and Clinical Trials.....	204



Other Privacy Issues	205
Healthcare Professional Prescriber Data	205
Handling Personal Information of Healthcare Professionals and Other.....	206
Pfizer Policy on Your Responsibility for Safeguarding Personal Information	207
For More Information.....	208

Chapter #11 Privacy: Protecting Personal Information

Introduction

This Chapter highlights key Pfizer policies regarding the protection of Personal Information (defined below). Activities that involve collection or access to Personal Information include health screenings, surveys, clinical research, and mentorships as well as Personal Information in your possession—such as on your computer.

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

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 Personal Information is shared with others.

Personal information (PI) includes any information that alone or in combination with other data identifies, links or relates to, or can be used to identify or link to a person or household, such as name or initials, address, phone number, e-mail address, preferences, unique online identifiers or IP addresses. **Sensitive Personal Information (SPI)** is a subset of Personal Information that is generally considered to include more sensitive 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

The United States does not have a comprehensive data protection law. Instead there are a number of sectoral data protection and security laws at the federal level. There are also many state data protection and security laws, mainly focused on data breaches. California has recently enacted a new privacy law called the **California Consumer Privacy Act (CCPA)** which applies to all California Residents and is the closest resemblance to a comprehensive privacy law in the United States. Many other countries around the world have enacted more stringent protections on the use, access, or transfer of Personal Information and Sensitive Personal Information. The **European Union (EU)** is widely regarded as having some of the most robust privacy protections for individuals in the world. In 2018 the EU privacy law called the **General Data Protection Regulator (GDPR)** went into effect granting EU residents the most comprehensive privacy protections to date. GDPR requires a number of actions by a company including; prompt review of individual rights claims such as the "right to be forgotten", companies to maintain reasonable security protections of personal data, inventories of personal data processing activities, specific contracts with

service providers, adequate protections for transfers of personal data outside the EU, 72 hour data breach reporting, appointment of a Data Protection Officer and other requirements. Other countries with some form of a comprehensive or more robust privacy law(s) include; Argentina, Australia, Brazil, Canada, Colombia, Israel, Japan, Mexico, Peru, Singapore, South Korea, and Uruguay.

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](#).

During the global pandemic resulting from COVID19 many new processes were implemented to facilitate telecommuting, telemedicine and other measures in order to ensure social distancing and help prevent spreading of the deadly virus. Please be mindful and consider the ways in which uses of personal data may have been impacted by the pandemic. Many of these new processes involved sharing of personal data while people worked remotely. If you have a new practice that needs review related to COVID19 please consult your team attorney. It is unclear what will happen with these new processes once the pandemic is over.

Key Points to Ensure Compliance

- [Corporate Policy \(CP\) #404: Protecting the Privacy of Personal Information](#) requires all Pfizer colleagues and contractors to protect Personal Information collected or used by or on behalf of Pfizer. Before you initially collect any Personal Information (directly or via any third-party service providers), your team attorney must be consulted and approve any collection, use, sharing or storage of personal information.
- Access to Personal Information, including Sensitive Personal Information, should be limited to individuals who need to know the information in order to perform their job duties.
- All Service Providers that process Personal Information must have appropriate contractual privacy and security terms and conditions in place between with Pfizer.
- Sensitive Personal Information should only be processed when it is necessary for an authorized business purpose. If Pfizer or its business partner or service provider will be processing Sensitive Personal Information, consult your team attorney and make them aware of this fact. Pfizer colleagues and contractors must ensure that such information is received in compliance with applicable.
- If you become aware that Pfizer, a business partner, or service provider has processed Sensitive Personal Information or more extensive Personal Information than intended, expected, or necessary for the business purpose, immediately notify your team attorney and report per [CP #411: Information Incident Response Policy](#). All Pfizer-sponsored third-party communications to patients, **healthcare professionals (HCPs)**, and other customers must be approved by the appropriate Pfizer **Review Committee (RC)**, which will consider issues of privacy and consent as part of its review process.
- Do not sign a document that is called a “Business Associate Agreement” or otherwise relates to “Business Associate” status without receiving explicit written approval to do so by your team attorney or the GPO.
- When using Personal Information to identify and communicate with current and potential Pfizer customers (HCPs, patients or other consumers) it is important to work with your team attorney, the GPO, and **Digital Channel Enablement (DCE)** to ensure compliance with applicable legal requirements and Pfizer policies and procedures.
- When setting up a mentorship or preceptorship, Pfizer colleagues must inform physicians serving as mentors or preceptors that they are required to obtain their patients’ written authorization before Pfizer colleagues may be allowed to observe any consultation, examination, and/or treatment of any patient
- Personal Information should generally only be processed in a manner that is transparent and within the reasonable expectations of the individual, whose information is being processed.

Key Points to Ensure Compliance

- 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.
- Pfizer colleagues should not engage health fair attendees in discussions regarding a specific patient's health.
- Always disclose that you are a Pfizer employee or representative 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.
- Safeguard the confidentiality of prescriber data as you would any other Personal Information. As a general rule, prescriber data should be used only for internal business purposes and not in interactions with Pfizer's customers, including the HCPs themselves.
 - Only share an HCP's prescriber data with Pfizer personnel and properly contracted and on-boarded vendors who are assisting with your initiative. Consult your team attorney before sharing HCP prescriber data with anyone outside of Pfizer.
- HCPs are permitted to disclose Protected Health Information (defined below) about patients to persons "subject to FDA jurisdiction" for activities related to the quality, safety, or effectiveness of an FDA-regulated product or activity for which the person has responsibility. (see [CP #903: Your Responsibility to Report Information about Safety, Quality, or Performance of Pfizer Products](#)).
- Any suspected breach of the security of Personal Information, including Sensitive Personal Information, must be immediately reported as an "Incident". Pfizer colleagues should avoid using the term "breach" when reporting a potential incident involving Personal Information. Do not use the word "breach" in e-mail 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 to the Global Security Operations Center at 1-212-733-7900 or GSOCwatchroom@pfizer.com pursuant to [CP #411: Information Incident Response Policy](#). You should also notify your team attorney.

The Legal Landscape

Please be mindful that the overall global trend is towards more privacy laws and greater protection for individuals of their personal information. Privacy laws are evolving on an ongoing basis. Understanding how and what personal information moves from one place to the next is of utmost importance. Generally speaking, organizations must provide individuals with transparency of their data processing activities and limit use of personal information for the purpose in which it was originally collected. International data transfers typically require additional contractual provisions to be implemented in addition to the Master Services Agreement. Data transfers from the European Union to countries such as the United States require specific agreements such as the EU Model Clauses and are subject to some of the most robust data protection laws.

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The **Health Insurance Portability and Accountability Act of 1996**, as amended by the **Health Information Technology for Economic and Clinical Health Act (HITECH Act)** and their implementing regulations, (**collectively, HIPAA**), imposes strict limitations on the use and disclosure of **Protected Health Information (PHI)** by “Covered Entities” and their “Business Associates,” as defined below.

Pfizer is Not a Covered Entity under HIPAA

Under HIPAA, the term “**Covered Entity**” includes HCPs that engage in electronic transactions for which a standard has been adopted under HIPAA, as well as health plans and healthcare clearinghouses. HIPAA requires Covered Entities to take certain reasonable steps to protect the privacy and security of PHI. To accomplish this, HCPs and other Covered Entities must maintain appropriate administrative, technical, and physical safeguards to protect PHI. Pfizer’s employee group health plan is deemed a Covered Entity under HIPAA. **However, Pfizer itself is not a Covered Entity under HIPAA.**

Pfizer is Generally Not a Business Associate under HIPAA

In addition to protecting PHI in the hands of a Covered Entity, HIPAA also protects PHI created, received, maintained, or transmitted by a Covered Entity’s “**Business Associate**.” A Business Associate is a person or entity that creates, receives, maintains, or transmits PHI for certain functions, activities, or services it conducts for or on behalf of a Covered Entity. Under HIPAA, Covered Entities are obligated to enter into a written contract called a **Business Associate Agreement** with a Business Associate before any PHI is disclosed to the Business Associate. Business Associates are required to comply with a variety of requirements under HIPAA and Business Associate Agreements, including safeguarding PHI, limiting the use and disclosure of PHI in connection with the functions performed or services it provides, and requiring notifications of breaches (i.e., impermissible uses or disclosures) of PHI. In the vast majority of situations, Pfizer does not perform work on behalf of an HCP or other Covered Entity and does not function as a Business Associate. It is unlikely that a situation will arise in which Pfizer will act as a Business Associate.

Business Associates are required to enter in a Business Associate Agreement (BAA) when they perform Business Associate functions for a Covered Entity. **No Pfizer colleague or contractor may enter into a Business Associate Agreement without the express written consent of the team attorney or the GPO.**

For more information about Business Associate Agreements, see the section on Working with HCPs within this Chapter.

HIPAA is Still Relevant for Pfizer

Although Pfizer is generally not a Covered Entity or Business Associate, HIPAA is still relevant for Pfizer. There are several HIPAA requirements with important implications for pharmaceutical manufacturer sales and marketing activities, such as manufacturer-sponsored third-party communications, disease management and health outcomes activities, and manufacturer-sponsored online health tracking tools. Please consult your team attorney and/or the [GPO](#) for advice on whether HIPAA may have implications for any proposed business arrangement or program involving health information (even if Pfizer is not receiving such information), such as point-of-sale marketing communications at the pharmacy or marketing communications distributed by a health plan or plan benefits administrator.

State Medical Information Privacy Laws

Nearly every state has its own laws protecting the privacy of health or medical information. Some of these state laws may be more stringent than HIPAA in certain respects. For example, California's medical privacy law is more restrictive than HIPAA in terms of permissible uses and disclosures of medical information and, unlike HIPAA, allows class action lawsuits for significant damages for the negligent release of confidential medical information regulated by law.

HIPAA does not preempt (override) state privacy laws that do not conflict with HIPAA standards, or state privacy laws that are more stringent than HIPAA standards. Furthermore, these state laws sometimes regulate entities that are not subject to HIPAA. Therefore, Pfizer should take steps to ensure compliance with both HIPAA and state laws in connection with Pfizer programs or initiatives, even if Pfizer is not directly subject to the laws itself.

Federal and State Privacy and Security Laws

Federal Law.

In the United States, the **Federal Trade Commission (FTC)** has operated as a “de facto” privacy regulator. Section 5 of the FTC Act prohibits “unfair and deceptive acts or practices in or affecting commerce”. “Deceptive” practices are defined as involving a material representation, omission or practice that is likely to mislead a consumer acting reasonably in the circumstances. This could be a company stating in their privacy policy that they do one thing with regard to personal information and in practice they do not,

including, for example, the statement “we encrypt all sensitive data” when in fact not all sensitive data is encrypted. An act or practice is “unfair” if it causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition. This has been interpreted as companies that process personal information must implement a reasonable information security program and related practices to appropriately protect personal information. Many Companies have faced significant enforcement actions, related costs and public perception implications along with fines for failing to comply with Section 5 of the FTC Act.

State Laws.

In addition to federal laws, some states have their own data protection laws. For example,

The **California** Consumer Privacy Act of 2018 (CCPA) is a sweeping new law that introduces a host of privacy rights for California residents and creates robust obligations for many businesses that collect personal information about California consumers. For example, businesses will need to consider implementing processes and procedures to authenticate and respond to verifiable consumer requests. The CCPA also sets forth certain provisions businesses should include in their contracts with service providers and other privacy requirements under this new law.

Massachusetts has implemented information security requirements applicable to certain types of Personal Information (e.g., social security number, driver’s license number, and financial account information) about Massachusetts residents. These requirements include encryption of portable devices, e-mail, and back-up tapes that contain such classes of Personal Information. Since information related to Massachusetts residents could be intermingled with data relating to residents of other states, this law has effectively imposed information security requirements beyond its borders.

Federal and State Breach Notification Laws

HITECH added new breach notification requirements under HIPAA for Covered Entities and Business Associates related to “unsecured” health information. If PHI is acquired, accessed, used, or disclosed in a manner not permitted by the HIPAA Privacy Rule or in a manner that compromises the security or privacy of the PHI, the HIPAA Breach Notification Rule requires notification to affected individuals, the **U.S. Department of Health & Human Services (HHS)**, and in some cases, the media.

In addition to the federal requirements, every state has its own breach notification law. State breach notification laws require that, under certain circumstances, the individuals whose data has been compromised (unauthorized access or disclosure) be notified of the breach and/or that state government officials be notified. These laws do not contain uniform requirements from one state to the next. The growing trend is expanding the types of matters which are defined as a reportable breach. Many state laws include health data as a trigger for notification. Consequently, managing even a relatively small breach (e.g., a lost laptop containing Personal Information) can be complex, time-consuming, and costly. Some

notification periods under these breach notification laws are very short. Therefore, it is critical that any suspected breach be reported immediately to Pfizer's Global Security Operations Center (GSOC) (1-212-733-7900 or GSOCwatchroom@pfizer.com) pursuant to [CP #411: Information Incident Response Policy](#). 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>).

Laws Protecting the Personal Information of Children

The federal **Children's Online Privacy Protection Act (COPPA)** prohibits the collection, use or disclosure of a broad range of Personal Information collected online from children younger than 13 without the verifiable consent of a parent or guardian and is enforced by the **U.S. Federal Trade Commission (FTC)**. Most Pfizer programs and services do not target children. If your program does intend to target children, or could be perceived to appeal to children (e.g., use of cartoons or games), please consult your team attorney and/or the GPO.

Under at least one state law, Pfizer may not sell the Personal Information of minors without depending on age, either parental opt-in consent or consent of the minor. Such state laws may define "Sales" is very broadly defined 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.

Requirements for Transparency, Notice, and Consent

There is a strong trend toward transparency, notice, and opt-in consent with respect to the collection and use of Personal Information. There also is an expansion of what is defined as "personal information" as technologies and privacy awareness expand. In many cases personal information can now include IP addresses, device identifiers and anything that could reasonably identify an individual. No longer is the definition of personal information limited to "name plus" such as full name plus your social security number. The types of harms or injuries are no longer just financial injuries such as having your credit card number stolen but now often include remedial injuries such as disclosure of racial identity, sexual orientation, political affiliation and more depending on the location.

As privacy laws are constantly evolving with greater and greater protections and rights for individuals, Pfizer colleagues and contractors should consult their team attorney before engaging in any activity that that contemplates the collection, use, sharing or storing of personal information of any kind, whether that individual is an HCP, a patient, or another type of consumer. Special attention should be paid to initiatives that involve collection by Pfizer or third-party vendors of patient cell phone numbers, text messaging, email addresses, DOB, diagnosis or treatment information and dates.

Pfizer's Policies Relating to Privacy and Personal Information

Pfizer respects the privacy of individuals, including patients, caregivers, and HCPs. Pfizer's has enacted appropriate safeguards designed to protect Personal Information it processes of all kinds.

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

Notice and Consent

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

- Communicating directly to patients through approved Pfizer-sponsored third-party communications;
- Engaging in a mentorship or preceptorship involving patient contact;
- Collecting Personal Information as part of an approved survey, screening tool, or other similar activity;
- Collecting Personal Information from HCPs in connection with enrollment in marketing programs;
- Collecting Personal Information from consumers in connection with coupon/copay programs, Internet websites, and other consumer offerings;
- Collecting Personal Information in connection with patient assistance programs;
- Collecting Personal Information in the course of recruiting patients as speakers or to provide testimonials; and
- Analyzing HCP prescriber information in connection with sales and marketing activities.

To be compliant with law and Pfizer policy, it is critical that the appropriate disclosures and, in some cases, an affirmative consent be in place prior to accessing, collecting, or using Personal Information. Before your team collects any Personal Information or designs any program which could result in Personal Information being directly or inadvertently disclosed to Pfizer, you must first consult your team attorney to confirm that any required notice and consent have been provided and/or obtained. To the extent you are using a third-party service provider to assist with your program, consult the relevant Legal colleague who may consult with the GPO to determine whether appropriate contractual terms are in place.

Aggregated, Anonymized or De-identified Data

It is sometimes permissible for Pfizer to obtain previously personally identifiable information from an HCP or health plan administrator without an individual's consent if the information has been **aggregated or**

anonymized. “**Aggregated**” data is information about multiple individuals that is compiled and does not allow for the re-identification of any one individual. “**Anonymized**” data is data that cannot be identified as belonging to any specific individual and usually involves removing certain key identifiers (including the individual’s name, many elements of the individual’s address, telephone number, date of birth, patient ID, and social security number), which either alone or in combination, could link the information with a specific individual. The standard for “anonymizing” data varies between countries. Therefore, always consult your team attorney before assuming information has been properly “anonymized” Who may reach out to GPO.

Avoiding Exposure to Protected Health Information

Pfizer colleagues must avoid situations in which they may be exposed to PHI without an individual’s consent. With certain exceptions, HCPs are not permitted to use or disclose an individual’s PHI unless the individual has authorized the use or disclosure in writing in advance. In the event an HCP or other person inadvertently or intentionally exposes you to the PHI of others, you should not document or reproduce the information in any media or form. You must also strictly maintain the confidentiality of the information in accordance with Pfizer’s policy of safeguarding the privacy of all patient-related data, and consult your team attorney to determine whether any additional steps should be taken.

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,” such as Pfizer, 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](#).

Vendor Obligations

All Pfizer vendors who will have access to Personal Information of or on behalf of Pfizer must follow our policy of safeguarding Personal Information and the Pfizer colleague must ensure contractual terms are in place with the vendor to protect personal information. To this end, Pfizer has a **Privacy Exhibit** and the **Third Party Security Requirements** that may be included as part of contracts with such vendors following consultation with Procurement and/or the GPO. If Personal Information is processed by the Service Provider, the Privacy Exhibit is required. To qualify as a service provider to Pfizer, vendor contracts need certain language to be included under; otherwise disclosures of Personal Information to the vendor may constitute sales, of which a consumer may opt-out. Please note that in addition to the contractual requirements, any vendors that will have access to or process Personal Information on behalf of Pfizer may be required to complete and pass appropriate Pfizer vendor vetting processes managed by BT Audit and

Assessment. For more information about Pfizer's **Vendor Compliance Assessment Service (VCAS)** please visit: <http://ecfd13.pfizer.com/sites/BTCompliance>.

Activities That May Result in the Use and Disclosure of Personal Information

When using Personal Information to communicate with current or potential Pfizer customers (HCPs or consumers) for promotional purposes, it is important to work with **Digital Channel Enablement (DCE)** to ensure compliance with applicable legal requirements as well as Pfizer policies and procedures.

Marketing Initiatives and Other Communications

Pfizer-Sponsored Third-Party Communications

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

Under certain limited circumstances, PHI may be used by HCPs such as pharmacists to tailor communications for treatment of the individual. 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 MCOs and retail pharmacies sending Pfizer-approved disease management, educational materials, or medication compliance mailings to inform or remind patients of the schedule to fill or refill a prescription for a chronic medication. When considering such arrangements, you must consult with your team attorney, who may consult with the GPO as appropriate, to determine compliance with applicable privacy laws and regulations and appropriate contractual terms.

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

A key reason to enter into the service agreement is to ensure the protection of patient privacy as well as compliance with applicable laws and Pfizer policy. Pfizer should not receive any patient names, addresses, or other Sensitive Personal Information. All materials sent to patients must be approved by the appropriate Review Committee, which will consider issues of patient privacy and patient consent as part of its review process. The RC may consult with the GPO on such issues as appropriate.

Digital Marketing Initiatives

Pfizer must implement reasonable measures designed to protect Personal Information collected and transmitted via the Internet. Additionally, laws and other guidance restrict the use of Personal Information for interest-based advertising (sometimes called “online behavioral advertising”).

Pfizer teams proposing to conduct web-based marketing and promotional activities (e.g., advertising, websites, Facebook pages, etc.) that use or collect Personal Information should consult their team attorney or the GPO to determine whether such activities raise privacy concerns. In addition, any externally-facing Internet application (such as a website, mobile device application, or Facebook page) must undergo and pass **Vulnerability and Threat Management Testing**, which may be accessed at <http://websecurity.pfizer.com>. For more information about Pfizer policies on Internet promotion, see [White Guide Chapter 2: Advertising and Promotional Materials](#).

Pfizer's Patient Programs

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

Pfizer has a standardized **Privacy and Consent Policy** for all U.S.-based consumer activities that involve the collection and use of consumers' Personal Information by any channel, including hard copy or online forms, business reply cards, telephone and fax. To obtain the Privacy and Consent Policy and related requirements, see the [Privacy and Consent Policy section under the Patient & Physician Marketing Group tab in GCO Policy Xchange on GCO on Demand](#). These activities include, but are not limited to, disease management program enrollment forms, coupons and rebate offers, and sweepstakes offers. The guidelines apply only when the consumer provides Personal Information, such as name and address or e-mail address. 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; any such programs or offers require review by the Global Privacy Office. Whenever a Pfizer program requires a consumer to provide such information, the program must also include a simple, timely mechanism (e.g., a toll-free telephone number or a mailing address) that allows participating individuals to promptly discontinue or “opt-out” of the program. Before engaging in any loyalty or rewards, or other incentive programs, you must consult with your team attorney. It is also especially important to work with your team attorney and the GPO to ensure that all programs contain appropriate privacy language in both the program terms as well as the opt-out because requirements vary depending upon the communication channel used. The Privacy and Consent Policy must also be communicated to, and followed by, any vendors preparing materials on behalf of Pfizer. Therefore, it is important that Pfizer teams considering programs that would collect Personal Information consult the DCE team to determine whether appropriate authorizations and guidelines

are in place. In addition, **it is important to work through DCE supported processes and vendors to ensure compliance with “Do Not Contact” lists and appropriate management of data.**

Working with HCPs

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



HCPs may incorrectly request that you sign a **Business Associate Agreement**. As noted above, Pfizer generally does not function as a Business Associate, and therefore signing such an agreement is prohibited absent the express written approval of your team attorney or the GPO. The protections HCPs seek can more appropriately be provided through a confidentiality agreement. A confidentiality agreement commits you and Pfizer to treat the Personal Information you may have access to with care and safeguard its confidentiality. To address this need and provide an alternative to a Business Associate Agreement, Pfizer has developed two Pfizer template forms, either of which you are permitted to offer to the HCP as assurance of your intent to keep Personal Information confidential:

1. The **Privacy Pledge** can be signed and provided to HCPs or customers who might have general concerns about Pfizer’s position on HIPAA as it relates to its representatives.
2. The **Patient Health Information Confidentiality Agreement** can be signed and provided to an HCP or institution that would like a specific agreement to cover situations where a Pfizer representative might inadvertently come into contact with patient health information.



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

A copy of the Privacy Pledge and Patient Health Information Confidentiality Agreement can be downloaded from [MyPfieldNet](#) under the “Compliance” tab.

Business Associate Agreements

	What should I do if a physician insists that I sign a Business Associate Agreement before I enter a patient clinic? Can I sign the Business Associate Agreement?
	No. You must not sign a Business Associate Agreement, even if required by an HCP in order to be allowed access to a facility. Colleagues are able to sign the Pfizer Privacy Pledge or Patient Health Information Confidentiality Agreement using the templates found on MyPfieldNet. Providing a copy of one of these documents with your signature is typically enough to satisfy the HCP's concerns about patient privacy. If the HCP continues to insist on a Business Associate Agreement, please promptly contact your team attorney for assistance.

Signing Customer Confidentiality Agreements

	If an HCP insists that I sign a facility's Confidentiality Agreement, even after I sign and show him or her Pfizer's Privacy Pledge and Patient Health Information Confidentiality Agreement, can I sign the version the HCP wants me to sign?
	Maybe. While it is advised that you rely on one of the Pfizer templates, in certain instances a confidentiality agreement provided by a customer may be acceptable to sign. However, you should never do so unless your team attorney has first reviewed and approved the agreement.

Mentorships and Preceptorships

A **mentorship** allows a Pfizer colleague to observe or “shadow” an HCP (usually a physician) at his or her office or institutional practice. A **preceptorship**, on the other hand, is a training presentation by an HCP to a team or group of Pfizer colleagues about a particular therapeutic area or the clinical use of one or more Pfizer products in professional practice.

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

When setting up a mentorship or preceptorship, Pfizer colleagues must ensure that physicians serving as mentors or preceptors know they must obtain their patient's written authorization before Pfizer colleagues may be allowed to observe any consultation, examination, and/or treatment. You may offer Pfizer's [sample Patient Authorization Form](#) (available on MyPfieldNet) to an HCP; however, they are not required to use

the Pfizer form. This form includes language required by HIPAA and may not be altered without the advance approval of your team attorney or the GPO. The requesting HCP should maintain the signed Patient Authorization Form as part of the patient's record and provide a copy of the form to the patient. You should not retain a copy of a signed Patient Authorization Form.

For more information on these activities, see [White Guide Chapter 5: HCP and Government Official Consulting Engagements](#) and the Mentorship Guidelines and Forms available on MyPfizerNet.

Patient Consents Regarding Mentorships and Preceptorships





	<p>Does a patient have to sign an authorization form before a Pfizer Sales Colleague can observe an examination or treatment as part of a mentorship or preceptorship, or is oral permission sufficient?</p>
	<p>It is the HCP's responsibility to secure appropriate patient authorization in a mentorship or preceptorship. Pfizer has developed a form authorization for the HCP to use in the event there is no existing authorization. Under HIPAA, with limited exceptions, a patient must authorize in writing the disclosure of his or her PHI. Oral permission is generally not acceptable under HIPAA or Pfizer guidelines. It is also important to remember that once proper authorization is obtained from the patient, the Pfizer colleague participating in the mentorship or preceptorship must identify himself or herself as an employee or contractor of Pfizer, as the case may be. A name badge identifying the colleague as a Pfizer employee must be worn at all times when interacting with a patient.</p>

Chart Reviews

	<p>Is it permissible to conduct chart reviews as part of our collaborative studies/programs with customers?</p>
	<p>No. Pfizer colleagues should never conduct a chart review.</p>



Consumer Health Fairs or Screenings

Consumer health fairs and screenings may raise patient privacy concerns because Personal Information is often communicated in the presence of Sales Colleagues or other Pfizer colleagues at the health fair. Pfizer colleagues should not engage health fair attendees in discussions regarding a specific patient's health. These discussions should occur between the patient and an appropriate HCP. Should a patient attempt to



initiate such a discussion, the Pfizer colleague should make clear that he or she is not an HCP and is not providing medical advice, and should redirect the patient to an HCP at the fair or state that the patient should discuss the matter with his or her physician.

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

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

	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 practice medicine or provide clinical advice to patients in the course of their work for Pfizer.

Patient Assistance Programs and Protected Health Information

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



Patient Information and Clinical Trials

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

Teams involved with Pfizer-sponsored and investigator-initiated studies are responsible for securing appropriate consent for the use of patient information obtained from clinical trials.

In accordance with [Clinical and Medical Controlled Document \(CMCD\) INV04-GSOP: Clinical Site Management and Monitoring](#), clinical study team members must always protect the confidential nature of the Personal Information that they review. If Personal Information is copied or referenced in monitoring reports, appropriate written authorizations must generally be obtained from patients. Although Pfizer is not directly covered by HIPAA, it is subject to other laws which protect the confidentiality of subjects' Personal Information.

Use of Data from Clinical Studies

	May Pfizer use records from its sponsored clinical studies for marketing purposes?
	<p>No. The use of medical records is strictly regulated. Pfizer's policy is that Personal Information in clinical study records may never be used for marketing purposes. Prior to patient enrollment in a clinical study, investigators are required to explain to patients what health information will be collected, how that information will be used, and to whom and for what purposes it may be disclosed. In general, study participant medical data is generated or received and maintained by the clinical study investigator during the course of the study. Pfizer does receive a report of study-related data; however, the clinical investigator "key-codes" the data by replacing the identities of the participants with unique codes. Pfizer does not receive the keys to these codes, nor does the Company receive the names or other contact information of study participants except in very limited circumstances, such as when necessary to report adverse events.</p>

Other Privacy Issues

Healthcare Professional Prescriber Data

From time to time, Pfizer uses prescriber data to facilitate effective marketing communications with HCPs. Prescriber data serves a variety of purposes, including the tracking of Pfizer-product adverse events and the ability to focus marketing initiatives on HCPs who would most likely benefit from information about a particular Pfizer product. 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 are 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. When developing reports

that contain HCP prescriber data, colleagues should remove any extraneous data prior to distributing the report, if possible. In the event that removing extraneous data is not possible, you must provide instructions to recipients that in reviewing the report, that they must filter for HCPs that are on their TCLs or within their territory or area of responsibility prior to reviewing the data.

Pfizer respects the confidentiality of this data and the wishes of any HCP who asks that his or her prescriber data not be made available to Pfizer Sales Colleagues. Pfizer also has designated the **Global Information Stewardship Lead** in Global Business Analytics as the internal contact to respond to inquiries regarding Pfizer's policy on the use of prescriber data. Given that this area of law is quickly evolving, Pfizer colleagues must consult with their team attorney or the GPO before engaging in an activity that involves the use or disclosure of prescriber data for marketing or promotional purposes. Under many privacy laws business contact information still amounts to what is defined as personal information.

Handling Personal Information of Healthcare Professionals and Other

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

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

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

Pfizer Policy on Your Responsibility for Safeguarding Personal Information

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

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

Pfizer's Handling Sensitive Information (HSI) Guidelines – Procedures for Handling PI and SPI for Colleagues and Contractors provides important guidance about appropriate information handling and security procedures, which include, but are not limited to:

- Encrypting your computer and using only encrypted USB flash drives;
- Properly destroying media or paper containing Personal Information;
- Promptly reporting lost or stolen Pfizer equipment, Personal Information, and other potential data incidents to Pfizer's **Global Security Operations Center (GSOC)** (1-212-733-7900 or GSOC_watchroom@pfizer.com) pursuant to [CP #411: Information Incident Response Policy](#) and to the local IT Service Desk (The worldwide list of contact telephone numbers is available online at <http://ITSupport.pfizer.com>); and
- Never using unencrypted e-mail to transfer Personal Information outside of the Pfizer network.

If you have additional questions about appropriate information handling and security procedures, you should consult the Handling Sensitive Information Guidelines or speak with your team attorney or the GPO.

For More Information

- [CP #403: Acceptable Use of Information Systems](#)
- [CP #404: Protecting the Privacy of Personal Information](#)
- [CP #405: Records and Information Management Policy and Procedure](#)
- [CP #411: Information Incident Response Policy](#)
- Handling Sensitive Information (HSI) Guidelines – Procedures for Handling PI and SPI for Colleagues and Contractors, see [link](#)
- [Clinical and Medical Controlled Document \(CMCD\) INV04-GSOP: Clinical Site Management and Monitoring](#)
- Refer any questions to the Enterprise Multi-Channel Marketing team, your team attorney, or the Global Privacy Office (privacy.officer@pfizer.com)



CHAPTER #12 – PROMOTIONAL INTERACTIONS WITH CONSUMERS

Chapter**#12****Promotional Interactions with Consumers**

CONTENTS

Promotional Interactions with Consumers

Introduction	211
Meals, Educational Items, and Items of Value to Consumers	212
Meals	212
Educational Items and Items of Value	212
Exhibits and Displays	213
Consumer Speaker Programs.....	213
Health Fairs and Public Screenings.....	214
Screenings Offered to Employees of a Single Employer	214
Screenings Offered to the Public at Large	215
Additional Guidelines for All Screenings	215
Product Support Programs.....	217
Disease Management Programs	217
Unbranded Communications	217
Branded Communications.....	218
Medication Compliance Programs.....	218
External Employees as Consumers.....	219
For More Information.....	220

Chapter #12 Promotional Interactions with Consumers

Introduction

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

The FDA has established stringent requirements regarding direct-to-consumer communications. Also, PhRMA has adopted its [Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines](#) to provide guidance to Pfizer and other member companies on ways to ensure that DTC communications provide accurate, accessible, and useful information to patients and consumers. Pfizer has committed to follow this guidance and has adopted its own [Guidance for the Implementation of the Updated PhRMA DTC Principles](#). For more information on the development of consumer-directed promotional materials, see [White Guide Chapter 2: Advertising and Promotional Materials](#).

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

Key Compliance Points

- Pfizer colleagues may provide occasional meals of minimal value to consumers (\$50 or less per person, including tax and tip). However, meals may never be provided to solicit business or in a manner that might suggest that the recipient is being bribed or improperly influenced.
- As with speaker programs for HCPs, Pfizer is responsible for the conduct of speakers and the content of presentations at speaker programs for consumers. The program and speaker must follow all applicable Centris requirements. The content of a consumer program should be appropriate for a “lay” audience consistent with Pfizer Principles for Clear Health Communication found [here](#).

Key Points to Ensure Compliance

- Pfizer Sales Colleagues may promote Pfizer products at health screenings as long as the exhibit and display booth is physically separate and apart from the screening area.
- If any Pfizer colleague is present during a patient/consumer interaction at a health fair or screening, he or she must clearly identify themselves as a Pfizer employee and may not offer any medical opinions, advice, or consultation, even if the colleague has a license to practice medicine or is any type of healthcare professional.
- The Pricing & Access Legal Team must approve all disease management program arrangements with **Managed Care Organizations (MCOs)**. Such arrangements must be documented in a service agreement that sets forth the basis for payment, as well as the program materials.
- Employees of customer organizations may also be considered consumers. Pfizer interactions with such employees (such as at a health fair) must conform to the same principles applicable to consumer interactions.
- As outlined in [White Guide Chapter 4: Marketing Programs](#), Customer Engagement Programs (CEPs) must be designed, reviewed, approved, and conducted in compliance with [CP #902: Management of Safety Information for CEPs Policy](#) and [CP #902a: Management of Safety Information for CEPs Procedure](#).

Meals, Educational Items, and Items of Value to Consumers**Meals**

Pfizer may provide meals or snacks of limited value to consumers (\$50 or less per person, including food, beverage, tax, and tip) or. Some examples of such items include providing a modest snack or refreshment (e.g., fruit, granola bars, bottled water) to consumers that visit a Pfizer exhibit or display, or providing a modest meal to attendees at a Pfizer consumer speaker program. However, meals may never be provided to solicit business or in a manner that might suggest that the recipient is being bribed or improperly influenced. Pfizer colleagues must not pay for or provide alcoholic beverages to consumers.

Educational Items and Items of Value

Pfizer may provide, where permitted by law, items designed primarily for the education of patients if the items are not of substantial value of \$100 or less. Pfizer may provide non-educational items of nominal value to consumers at exhibits, displays or public events that promote health. Examples of such items may include pedometers, exercise bands, and exercise balls, which may be provided to consumers that visit a Pfizer exhibit or display, or at a public event where Pfizer sponsors a table provided the retail value is no more than \$10 individually and no more than \$50 in the aggregate annually per patient. 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.

Exhibits and Displays

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

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

Providing Food to Consumers at a Display

	I have a display table at a community health fair next week. Can I provide food at my table? What about covering the cost of sandwiches for all the health fair attendees?
	You can provide modest hospitality snacks at a display table where you are interacting with consumers. Any food you provide to consumers must be consistent with the level of interaction you are having with them. In this case, because you are interacting at a display table, it would be acceptable to provide modest snack items like fruit, granola bars, and drinks. It would not be appropriate for you to cover the costs of sandwiches or other food items for all attendees since you are permitted to provide food only to those consumers with whom you interact. Remember, even when you have more extensive interactions with consumers (e.g., at a speaker program) the cost of food, beverage, tax, and tip should never exceed \$50 per attendee.

Consumer Speaker Programs

A speaker program for consumer audiences is a promotional activity controlled by Pfizer at which a speaker presents a Pfizer RC-approved slide deck intended for consumers. As with a speaker program for an HCP audience, Pfizer is responsible for the conduct of the speaker and the content of the presentation to consumers. Pfizer colleagues must adhere to Pfizer policies regarding consumer presentations and should follow any applicable procedures in the speaker program system (Centris) for program set up. Prior to engaging in any speaking engagements, speakers are required to complete training on: (1) Pfizer

Promotional Speaker Compliance Guidelines; and (2) the brand's core product training or topic training slide kit, as applicable.

The content of a consumer program should be appropriate for a "lay" audience, consistent with Pfizer Principles for Clear Health Communication found [here](#). When developing a consumer speaker program slide deck, Pfizer must be mindful that many consumers have different educational backgrounds and their ability to understand medical information varies.

Consumer programs should be broadly advertised such that each program will likely result in an audience of at least three consumers. The chosen venue for the program must be conducive to providing educational information, and Pfizer may not offer entertainment or recreation. An HCP engaged to speak at the program must not provide specific medical advice to a consumer attendee, nor may the speaker use the Pfizer program as an opportunity to promote his or her medical services or practice, or to recruit new patients. Host colleagues are required to monitor all aspects of a consumer program, including content delivered, and make corrections if needed. For more information on speaker programs to consumer audiences, see [Orange Guide Chapter 16: Consumer, Patient, and Employee Interactions](#), and for more information on speaker programs generally, see [White Guide Chapter 4: Marketing Programs](#).

Health Fairs and Public Screenings

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

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

Screenings Offered to Employees of a Single Employer

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

These screenings may not be offered for employees of healthcare providers or payers of healthcare items and services, including hospitals, medical practice groups, or **MCOs** that seek reimbursement from the federal government. The screenings must be limited to current employees and their beneficiaries only and

must expressly exclude retirees who are beneficiaries under the employer's retiree health plan. Also, the screenings cannot be organized or designed in any way to generate referrals for any particular customer.

Pfizer Sales Colleagues may promote Pfizer products at the screenings as long as the exhibit and display booth is physically separate and apart from the screening area. Further, no financial **Return-On-Investment (ROI)** or similar analyses can be tied to the screening event. Any advertising or publicity materials for the event that are created by Pfizer – or for which Pfizer colleagues provide input – should be approved by the relevant **Review Committee (RC)**, including brand RC or the **Payer Channel Access (PCA) RC**.

Screenings Offered to the Public at Large

Screenings offered to the public at large may be organized by a third-party or Pfizer directly. If an IRS 501(c) (3) healthcare-related charitable organization requests Pfizer support for a screening, the request must be submitted directly by the organization to Pfizer's office of **Global Medical Grants (GMG)** via the charitable contribution website at www.pfizer.com/healthcarecharitables. See [White Guide Chapter 7: Support of External Organizations](#), for additional information about healthcare-related charitable contributions.

If a public health screening is organized by Pfizer, the screening proposal must be approved by the management of the team organizing the screening. As with screenings offered to an employer for its employees, the screening cannot be organized or designed in any way to generate referrals for any particular customer. The screening must be conducted by a third-party vendor that is not a healthcare provider/payer and that routinely conducts such screenings. The vendor must enter into an appropriate contract with Pfizer.

Field Commercial Colleagues can promote Pfizer products at these screenings with an exhibit and display as long as the exhibit and display booth is physically separate and apart from the screening area. Again, however, no ROI-type analysis can be tied to the screening event.

Screenings offered to the public must be advertised and open to the community at large. This means the screening should have a broad, community audience and should not be targeted to members of any particular group. This does not mean that an entire city must be invited or that the event must be advertised in a city newspaper. However, the public screening must be advertised in a broad manner and not merely at a particular hospital or in particular medical offices. All advertising and publicity materials for the screening event must be approved by the relevant Medical Review Committee (MRC).

Additional Guidelines for All Screenings



Consumer health fairs and screenings raise privacy issues whenever they involve obtaining Personal Information from individuals, including details that relate to an individual's health status. If an individual's affiliation with Pfizer and Pfizer's sponsorship of the screening are disclosed and apparent, a consumer's

participation in the event is deemed to be his/her consent to share this Personal Information with a Pfizer representative.



Pfizer's ability to use or disclose data obtained at consumer health fairs or public screenings is strictly limited by the terms specified on Pfizer's **Patient Authorization and Release form**, which the screening vendor must require that all screening participants sign. The Pfizer Patient Authorization and Release form is available on http://ecfd13.pfizer.com/sites/PfieldNet/_layouts/15/WopiFrame.aspx?sourcedoc=/sites/PfieldNet/PfieldDocuments/patient_authorization.doc&action=default&DefaultItemOpen=1.. Aggregated de-identified data can be provided to an employer and/or managed care customer only if the screening participant has signed a Patient Authorization and Release form which specifically authorizes that the data can be provided to the employer and/or MCO managing the prescription drug benefit. For more information on the topic of patient consent, see [White Guide Chapter 11: Privacy: Protecting Personal Information](#).

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



Managed Care Customer Health Screening

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

Health Screening Vendors

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

HCP Screener

	Can a doctor or nurse from a healthcare provider/payer, such as a hospital or private practice, conduct the screening free of charge if Pfizer pays for screening materials?
	No, the screening must always be conducted by a vendor that is not a healthcare provider/payer, even where no payment is being made to the screener.

Product Support Programs

Disease Management Programs

Pfizer or an MCO may at times mail Pfizer RC-approved materials, branded or unbranded, to healthcare providers and/or patients, subject to certain payment and authorization requirements under **HIPAA**.

Unbranded Communications

Unless prior authorizations are obtained from MCO's members, Pfizer is limited to providing disease awareness unbranded health information to the MCO's members, if Protected Health Information will be used by the MCO in making the communication.

Branded Communications

If Pfizer seeks to compensate an MCO for sending branded health information and Protected Health Information will be used by the MCO in making the communication, the following must be met:

- Only RC-approved patient-directed materials may be used;
- There must be a written service agreement between Pfizer and the MCO that clearly states the services to be provided and the basis for payment, which must be equal to the fair market value cost of developing and/or conducting the services to be provided;
- The MCO must secure authorization from its members before making the communication if the communication does not relate to a drug or biologic that is currently prescribed to the patient (discussed in the following section);
- The Organized Customer Legal team must approve the proposed arrangement and agreement before any commitment can be made to the MCO;
- The amount paid must be directly attributable to an invoice for mailing costs and calculated on a per-unit (e.g., per letter) basis;
- A lump sum payment to the MCO in excess of actual project costs is not permissible because any excess payment could be interpreted as an attempt to enrich the MCO and as an illegal inducement;
- The proposed mailing must conspicuously disclose Pfizer's financial support; and
- It is preferable, but not required, that a third-party mailing operation perform the services and receive the payment. If a third-party is used, the third-party may only receive fair market value for its services and it may not pass through any additional payment beyond that required to cover direct costs of the mailing to the MCO.

Please consult your team attorney if you have questions on the permitted scope of communications with MCOs and their members.

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

Medication Compliance Programs

From time to time, Pfizer may want to pay for a medication compliance program (sometimes referred to as a “refill reminder” or “adherence” program) to be provided by or through a customer (e.g., an MCO or a pharmacy). These programs typically involve sending scheduled mailings or other communications (e.g., text messages) to patients to remind them to fill or refill a current prescription. Such programs are appropriate promotional activities, and Pfizer may implement these programs without individual patient

authorizations if Pfizer and the customer comply with the terms of the marketing “refill reminder exception” under the HIPAA Privacy Rule. The type of compensation permitted under the refill reminder exception depends on whether the compensation is provided directly by Pfizer to either the customer or a business associate of the customer for the relevant communications. The communications must conspicuously disclose Pfizer’s support.

If Pfizer pays a customer directly, Pfizer may reimburse the customer only for the reasonable direct or indirect costs related to the labor, materials, supply, and capital and overhead costs of making the communications. If Pfizer pays a customer’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, also known as an adjunctive drug; and
- Communications encouraging an individual to switch from a currently prescribed drug or biologic.

For arrangements that do not comply with the requirements of the HIPAA refill reminder exception, the customer must obtain HIPAA-compliant patient authorizations before disseminating the communications.

The team RC must approve any medication compliance program, each of which must also be documented in a service agreement that sets forth the basis for payment, as well as the program materials. If the customer is an MCO, the Organized Customer Legal team must review and approve the proposed arrangement. Because the use of confidential patient medical information to communicate with patients has privacy implications even if patient-identifiable information is not disclosed, please consult the section on Pfizer-Sponsored Third-Party Communications in [White Guide Chapter 11: Privacy: Protecting Personal Information](#).

External Employees as Consumers

Employers are increasingly making decisions regarding the access their employees have to medicine. As a result, Pfizer colleagues may have an interest in calling on employers to present information about Pfizer products relevant to the employer in making these decisions. It is important to understand that working with employers has both business and legal risks, which require careful attention.

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

Also note that discussions with employees, as consumers, must comply with FDA regulations. As noted earlier in this Chapter, additional considerations and limitations may apply to employees of healthcare providers or payers of healthcare items and services, including hospitals, medical practice groups, or **MCOs** that seek reimbursement from the federal government. For more information on interactions with employer representatives (such as benefit managers and medical/non-medical personnel who play a role in administering health benefits for an employer), see [White Guide Chapter 11: Privacy: Protecting Personal Information](#).

For More Information

- [Guidance for the Implementation of the Updated PhRMA DTC Principles.](#)
- Pfizer Principles for Clear Health Communication found [here](#).
- [CP #902: Management of Safety Information for CEPs Policy .](#)
- [CP #902a: Management of Safety Information for CEPs Procedure.](#)
- [Orange Guide Chapter 16: Consumer, Patient, and Employee Interactions.](#)
- [White Guide Chapter 2: Advertising and Promotional Materials.](#)
- [White Guide Chapter 4: Marketing Programs.](#)
- [White Guide Chapter 7: Support of External Organizations.](#)
- [White Guide Chapter 11: Privacy: Protecting Personal Information.](#)
- [White Guide Chapter 13: Promotional Interactions with Employer Groups..](#)
- Refer any other questions to Regulatory or your team attorney.



CHAPTER #13 – PROMOTIONAL INTERACTIONS WITH EMPLOYER GROUPS

Chapter**#13****Promotional Interactions with
Employer Groups**

CONTENTS

Promotional Interactions with Employer Groups

Introduction	223
Coordinate with Director, Employers (DE)	224
Treat Employer Representatives (Decision Makers) as HCPs	224
Tailor Discussion to Individual Employer Representative	225
Benefit Managers.....	225
State/Municipal Employees	225
Unions.....	225
Brokers and Consultants	225
For More Information.....	226

Chapter #13 Promotional Interactions with Employer Groups

Introduction

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

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

Key Points to Ensure Compliance

- Coordinate all employer-related activities with the relevant Director, Employers (DE).
- Treat employees as consumers.
- Always provide fair and balanced presentations to employer representatives that include the proven benefits of the product along with relevant safety information.
- Treat all employer representatives as if they are subject to federal healthcare laws, including the Anti-Kickback Statute, even those employers that may not participate in government programs.
- When interacting with employer representatives, tailor any product discussion carefully to the representative's background, especially if the employer representative does not have a medical background.
- Pfizer colleagues may not direct employers to a specific PBM/HMO or encourage an employer to switch to a different PBM/HMO.



Coordinate with Director, Employers (DE)

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

Treat Employer Representatives (Decision Makers) as HCPs

Pfizer colleagues may interact with medical and non-medical employer representatives, such as CEOs, CFOs, CMDs, and benefit managers. In some cases, these employer representatives play a role in the treatment of patients by influencing the recommendation, purchase, or reimbursement of products. When interacting with these employer representatives, Pfizer colleagues must always give a fair and balanced presentation and, for product information, include the proven benefits of the product along with relevant risk information. All unsolicited inquiries requesting off-label information about unapproved products or uses must be referred to [U.S. Medical Information](#). Pfizer colleagues must treat all employer representatives as if they are subject to federal healthcare laws, including the Anti-Kickback Statute, even those employers that may not participate in government programs. As a result, Pfizer colleagues may never engage in any actual or perceived quid pro quo, including offering or appearing to offer any remuneration or item of value in exchange for prescription or formulary recommendations or referrals.

Employers and Employees

	Should Pfizer employees treat employer representatives (decision makers) and employees in the same manner?
	No. Pfizer colleagues must treat employer representatives as HCPs. Employees should be treated as consumers.

Tailor Discussion to Individual Employer Representative

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

Benefit Managers

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

State/Municipal Employees

Some of the larger employers in an area may be public entities, such as state universities, state agencies, or municipalities. Interacting with these employers may subject you to additional guidelines relevant to interacting with public employees, such as restrictions on gifts or meals or reporting obligations arising from lobbying laws. For more information, see [White Guide Chapter 15: State Laws: HCP and Government Employee Restrictions](#) and [White Guide Chapter 16: Federal Employee Interactions and Lobbying](#). Pfizer colleagues should consult with the Government Relations Director or Legal before interacting with a state or municipal employer.



Unions

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

Brokers and Consultants

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

Materials Used With Employers

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

For More Information

- Contact a member of the Director, Employers team or an attorney from the Pricing & Access Legal Team.
- [White Guide – Chapter 3: Promotional Interactions with Healthcare Professionals.](#)
- [White Guide Chapter 12: Promotional Interactions with Consumers.](#)
- [White Guide Chapter 15: State Laws: HCP and Government Employee Restrictions.](#)
- [White Guide Chapter 16: Federal Employee Interactions and Lobbying.](#)
- [The Orange Guide.](#)



CHAPTER #14 – STARTERS

Chapter

#14

Starters

CONTENTS

Starters

Introduction	229
Starter Allocation	231
Starter Packaging	231
Inclusion of Materials with Starters	233
Distribution of Starters to Approved Recipients	234
Hospitals, VA, and DoD Institutions	236
Starters May Not Be Distributed for Research, Charitable Activities, or To Defray Patients' Pharmacy Expenses	237
Managing Starters	237
Starter Storage Requirements	237
Accurately Document Receipt and Delivery of Starters	238
Completion of eSAFs and SAFs	238
Reconciling Starter Inventory	240
Reminder on Expired Starters	240
Free Trial Vouchers: An Alternative to Starter Distribution	241
Key Points for Developing a Voucher Program and Distributing Vouchers	242
For More Information	242

Chapter #14 Starters

Introduction

Pfizer provides **healthcare professionals (HCPs)** with **free pharmaceutical drug product samples** (referred to as “**starters**”) to give to patients so that they can evaluate the efficacy and tolerability of our products for the patient before filling a prescription. Starters also provide HCPs an opportunity to become familiar with a drug and its properties, thereby enhancing their ability to make appropriate prescribing decisions. The distribution of starters is highly regulated under federal and state law, and the misuse of 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. 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 quantity 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.
- Requests for starters from a Sales Colleague may be initiated during in-person visits, or remotely over approved channels that allow Sales Colleagues to view the HCP and obtain the HCP's signature on an electronic starter request form.
- 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 unit of a drug that is not intended to be sold and is intended to promote the sale of the drug**. Such items must be clearly labeled to reflect their intended use. 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

	<p>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?</p>
	<p>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).</p>



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 unit 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 Starter Compliance 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, North American 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

	<p>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?</p>
	<p>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.</p>

Distribution of Starters to Approved Recipients

Detailed procedures for starter accountability and compliance are set forth in the [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. Sales Colleagues should check with their manager, North America 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, North America 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 an HCP. Significant losses, including inventories with unacceptably large negative variances and all thefts of starters, must be reported by North America 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 North America 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

	<p>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?</p>
	<p>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.</p>

Distribution of Starters to Physicians for Personal Use

	<p>If an HCP asks a Sales Colleague for additional starters because the HCP's spouse suffers from the labeled indication for the Pfizer product, can the colleague give them to the HCP?</p>
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Distribution of Starters to Physicians for Personal Use



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 North America 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 North America 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 & Social Impact 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 a storage facility 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. In rare cases, sales colleagues may request to store starters at home. This should be discussed with your manager to determine if your situation is appropriate for the home storage of starters.

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) 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 North America 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.

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 HCP, 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

	<p>When a Sales Colleague delivers starters to an HCP's office, can the receptionist take the approved device (i.e., tablet or iPad) to the HCP for signature?</p>
	<p>No. The Sales Colleague's device 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.)</p>
	<p>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?</p>
	<p>No, not when the HCP has made the request during an in-person visit by a Sales Colleague. 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, 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 sent.</p> <p>Note that when a request for starters is made over a VCC call, starters may be sent to a location other than the HCP's current location. In other words, starters may be sent to the HCP's office, even though the HCP is located at home for the VCC call. Starters may not be sent to an HCP's home.</p>

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 North America Sample Operations for further guidance.

In addition, all starter losses and thefts should be reported to North America 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 (i.e., starters that still have more than 30 days before expiration) 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 bins or 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 an 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 they receive 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 following principles. Prior to distributing the resources to a given HCP, 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 RxPathways and/or the applicable product hub 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 offered to HCPs for personal use; and
- Vouchers 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 North America Sample Operations, the relevant Sales Manager, or team attorney.
- For Pfizer's policies for complying with the PDMA, see the [Starter Compliance Manual](#).
- 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 #15 – STATE LAWS: HCP AND STATE EMPLOYEE RESTRICTIONS

Chapter

#15

State Laws: HCP and State Employee Restrictions

CONTENTS

State Laws: HCP and State Employee Restrictions

Introduction	247
Summary of Key State/City HCP-Related Healthcare Compliance Laws	248
Summary of Key State Employee Gift Laws	254
Key Points to Ensure Compliance	255
California	256
The Law: The California Drug Marketing Practices Law	256
Definition of Healthcare Professional	256
How the Law Impacts Pfizer Colleague Activities	256
The value of the following items must be included when calculating the annual aggregate limit:	256
The value of the following items are not included when calculating the annual aggregate limit:	256
City of Chicago	257
The Law: Pharmaceutical Representative Licensing Ordinance	257
How the Law Impacts Pfizer Colleague Activities	257
Colorado	258
The Law: Restrictions on Gifts to State Employees	258
Definition of Healthcare Professional State Employee under the law	259
How the Law Impacts Pfizer Colleague Activities	259
Colorado Pricing Disclosure Requirements	260
Connecticut	260
The Law: Connecticut Compliance Program Law & APRN Disclosure Law	260
How the Law Impacts Pfizer Colleague Activities	261
District of Columbia	261
The Law: Prescription Drug Marketing Costs Disclosure Law	261
Definition of Healthcare Professional	262
How the Law Impacts Pfizer Colleague Activities	262

The Law: Pharmaceutical Detailer Licensing Law.....	262
Gifts to D.C. Medication Advisory Committee Prohibited	262
How the Law Impacts Pfizer Colleague Activities	263
Louisiana	264
The Law: Code of Governmental Ethics.....	264
Definition of "Public Servant"	264
How the Law Impacts Pfizer Colleague Activities	264
Massachusetts	265
The Law: Pharmaceutical and Medical Device Manufacturer Conduct Law (Massachusetts Marketing Code of Conduct).....	265
Definition of Healthcare Professional	266
How the Law Impacts Pfizer Colleague Activities	266
Meals	267
Helpful Points.....	267
Other Prohibited Items of Value and Activities	268
Disclosure	268
Non-patient Identified Prescriber Data	269
Michigan.....	269
Starters Policy for Mid-Level Practitioners	269
Minnesota.....	269
The Law: Gift Restriction Law.....	269
Educational Items	270
Meals	270
Consulting Engagements with MN HCPs	270
Definition of Practitioner	271
How the Law Impacts Pfizer Colleague Activities	271
Nevada.....	272
The Law: Nevada Marketing Code of Conduct	272
Pharmaceutical Sales Representatives Registration	273
Pharmaceutical Sales Representative Annual Disclosure Report	273
New Jersey	273
How the Law Impacts Pfizer Colleague Activities	274
Definition of a New Jersey Prescriber	274
Meals	274
Consulting Engagements with New Jersey Prescribers.....	274



New York.....	275
The Law: Restrictions on Gifts to State and Local Officers and Employees	275
Definition of Officer or Employee.....	275
How the Law Impacts Pfizer Colleague Activities	275
Vermont.....	276
The Law: The Prescribed Products Law	276
Definition of Healthcare Provider.....	276
How the Law Impacts Pfizer Colleague Activities	277
Meals	277
Gift Ban	277
Marketing Research	278
Disclosure of Expenditures to Vermont HCPs.....	278
The Law: Vermont Price Disclosure Law	279
For More Information.....	280

Chapter #15 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. Pfizer will continue reporting all meals and other transfers of value required under the Sunshine Act and SUPPORT Acts under the Open Payments provisions to the Federal Government. All colleagues must ensure that their records on these expenditures are accurate and complete.

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 Healthcare Law Compliance section on [Policy Xchange](#); or Compliance tab in [MyPfizerNet](#)
- Send questions to 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
California	Companies shall adopt a comprehensive compliance program which sets specific dollar limits on gifts, promotional materials, and activities.	Accurately and completely record all expenditures on HCPs. Monitor expenditures per HCP and coordinate with your colleagues to ensure compliance with Pfizer's annual limit of \$3,500 per California HCP.
Chicago	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.
Connecticut	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
District of Columbia	<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>
Massachusetts	<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 except in the office or hospital setting when accompanied by an informational presentation or 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 HCP Lookup Tool. You can also check Veeva CRM, which flags most (but not all) MA HCPs.</p> <p>You must make a good faith effort to determine whether an HCP is licensed in Massachusetts.</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 Registered Nurses and Advanced Practice Registered Nurses (NP, CNS, CRNA, CNM, AN) must include the supervising physician's name in the transaction's call notes in Veeva. The Veeva system does not allow us to distinguish between APRNs and Registered Nurses in Michigan, therefore, we must record the supervising physician's name for all nurses that request starters.</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 in Veeva.</p> <p>Michigan state law now permits a Physician's Assistant to order and receive starters directly, without recording a supervising physician's name or DEA registration number.</p>
Minnesota	<p>Gifts to practitioners are prohibited.</p> <p>Pfizer policy prohibits HCP meals to MN practitioners, including nominal meals</p>	<p>Do not invite MN practitioners to any speaker programs that provide meals (even if the program is outside of MN).</p>

State	Important Provisions of the State Law	Key Points to Ensure Compliance
	<p>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. Pfizer policy prohibits providing text books, journal subscriptions, online subscription services (e.g., Epocrates), and anatomical models, to MN practitioners.</p> <p>Pfizer policy also prohibits engaging MN practitioners as paid consultants, except for the following type of projects:</p> <ul style="list-style-type: none"> Reasonable honoraria and expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting Substantial professional or consulting services of a practitioner in connection with a genuine research project Speaking and speaker training Pfizer must report permissible non-gift expenditures that exceed \$100/year. 	<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> <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 is a MN licensed practitioner, you can check the HCP Lookup Tool. Also, Veeva CRM flags most (but not all) practitioners with MN licenses.</p> <p>You must make a good faith effort to determine whether a practitioner 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</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
	<p>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. The license registry applies to individuals who physically reside in or visit Nevada five (5) days or more annually in order to communicate with HCPs.</p> <p>Manufacturers must annually report to Nevada DHHS information about transfers of value and samples provided to Nevada covered recipients by registered pharmaceutical sales representatives.</p>	
New Jersey	<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: (I) Speaker Programs; (ii) Symposia; (iii) Bona fide service contract; (iv) Job interview with Pfizer; and (v) Nominal snacks provided at convention/congress exhibit booth. The restriction applies to Prescribers that practice from a New Jersey location.</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:</p>	<p>Do not provide NJ prescribers with meals over \$15 for breakfast and lunch and \$30 for dinner unless on occasions otherwise exempted.</p> <p>You must make a good faith effort to determine whether a prescriber is licensed in New Jersey and practices in NJ..</p> <p>If you are unsure of whether a prescriber has a NJ license and practices in NJ, you can check the HCP Lookup Tool. 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
	(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 associated with the impacted Bona Fide Services are not subject to the \$10,000 annual aggregate cap.	
Vermont	<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; and (iii) in connection with a job interview for prospective employment. 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. Pfizer must report certain HCP expenditures, as well as samples, copay cards, 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, copay cards, coupons, and vouchers provided to VT-licensed HCPs.</p> <p>Provide VT Price Disclosure Forms to HCPs as appropriate (available on www.pfizer.com/vtprescribers).</p> <p>If you are unsure of whether an HCP has a VT license, you can check the HCP Lookup Tool. 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) per year .	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 \$65 cap on food, drinks, and refreshments provided during a single event .	Before considering engaging a state employee to perform a compensated service, consult with your manager. Before providing a meal or refreshments to state employees, coordinate with your colleagues to ensure the employee is not receiving value greater than \$65 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.
- 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. 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 a sales representative is calling on a Chicago HCP via telephone while 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 sales representative 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 Global HCP Transparency Reporting 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 your team attorney.

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.

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/DCP/Drug-Control-Division/Drug-Control/Expenditure-Disclosure-Form>.

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 [DC Safe Rx Pharmaceutical Detailers License](#) 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 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 \$65 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 \$65

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 or in-hospital meals which you need to comply with. Office staff are not required to be listed by name for in-office or in-hospital meals 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 Points

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 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 Registered Nurses and Advanced Practice Registered Nurses (NP, CNS, CRNA, CNM, AN) must include the supervising physician's name in the transaction's call notes in Veeva. The Veeva system does not allow us to distinguish between APRNs and Registered Nurses in Michigan, therefore, we must record the supervising physician's name for all nurses that request starters.
- 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.
- Michigan state law now permits a Physician's Assistant to order and receive starters directly, without recording a supervising physician's name or DEA registration number.

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, pharmacists and veterinarians are all included in the definition of practitioner in Minnesota.

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 and Veeva CRM, 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 reside or visit NV 5 days or more annually or reside in NV.
- Manufacturers must submit a complete list of all Sales Representatives who are in scope for the Nevada registry 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 per sales rep per HCP.

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.

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. 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 includes any New Jersey Prescriber who holds an active New Jersey license and physically practices in New Jersey. 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 \$15 or \$30 excludes tax, tip and any delivery charge.
- 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.

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;
- Nurses and 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. 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.
- Consult the State Healthcare Law Compliance section on [Policy Xchange](#); or Compliance tab in [MyPfizerNet](#)
- Send questions to StateHealthcareLawCompliance@pfizer.com



CHAPTER #16 – FEDERAL EMPLOYEE INTERACTIONS AND LOBBYING

Chapter

#16

Federal Employee Interactions and Lobbying

CONTENTS

Consumer, Patient, and Employee Interactions

Introduction	284
Federal Employee Interactions	284
Promotional Activities	285
Impact of Formulary Status on Ability to Promote	285
Site Visits/Providing Promotional Materials/Educational Materials	288
Starters	288
Gifts to Federal Employees	289
General Rules	289
Educational Items	290
Refreshments	290
Inviting Government Employees to Speak or Present at Events	291
Inviting Government Employees to Attend Events (Non-Speakers/Presenters)	292
Supporting Independent Medical Education	294
Summary of Guidelines Regarding Federal Employee Interaction	294
General	294
For DoD or IHS facilities, if provision of meals is permitted, the following conditions must also be met:	295
Lobbying	296
Federal Lobbying	296
Who Is a "Lobbyist?"	297
What Is Lobbying?	298
Reporting Lobbying Time and Expense	299
State-Specific Laws	300
States' General Lobbying Disclosure Laws	301
States' Lobbying Laws Impacting Marketing	301



State Restrictions on Gifts to Legislators	302
State Formularies	302
Campaign Contributions.....	302
The Pfizer Political Action Committee.....	303
General.....	303
For More Information.....	304
State Laws: HCP and State Employee Restrictions	306

Chapter #16 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. 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.
- (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 <https://www.pbm.va.gov/PBM/NationalFormulary.asp> Web site.*

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

	<p>The VA provider mentioned to me he tried prescribing Product X but was told he must first try Product Y. What should I do?</p>
	<p>Representatives may acknowledge in general the existence of a CFU and refer the provider to their internal website or pharmacy for more information. The specific VA product CFU cannot be discussed by representatives unless permitted by the brand RC. 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.</p>



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 (including samples) must be submitted in advance for approval by the VA Medical Facility Director. Additionally, all usage information about the product must be forwarded to the VA Pharmacy Executive 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. Pharmaceutical company representatives are strictly prohibited from providing drug samples to VA providers outside of the Pharmacy Service for any reason, including VA staff member’s personal use.

Additionally, if donated products (including samples) 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. Information about the trial use of the product must be forwarded to the VA Pharmacy Benefits Management Office and/or the VISN Formulary Committee.

In general, donated drugs should not be labeled as “sample” or similar wording. However, on rare occasion, the VA will make exceptions to this labeling 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

	<p>I’ve been told by an HCP at a VA facility that pharmaceutical companies cannot leave starters with the VA. Is this correct?</p>
	<p>VA policy permits pharmaceutical companies to provide samples/starters to VA medical facilities upon approval by the VA Medical Facility Director. Samples/starters must be delivered to the Office of the Chief of Pharmacy Services for proper storage, documentation, and dispensing. The distribution of samples/starters directly to VA HCPs is inconsistent with the VA’s policy. Moreover, if the products are intended to be used solely to allow VA clinicians to gain familiarity with the product, such use must be pre-approved by the VISN Pharmacist Executive and/or VISN Formulary Committee</p>

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. 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 only 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 Team Attorney 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 Team Attorney 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 in writing by the DAEO of any such engagement. 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

	<p>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?</p>
	<p>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.</p>



Speaker Program Meals

	<p>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?</p>
	<p>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.</p>



Part-Time VA Employees

	<p>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?</p>
	<p>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.</p>

Compliance Responsibility

	<p>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>
	<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. 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 and modest refreshments 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 any 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 by the employee's DAEO.
- 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.
- Do not suggest, offer or provide campaign contributions in exchange for a promise to perform any official act.

Key Points to Ensure Compliance

- 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

	<p>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?</p>
	<p>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.</p>

Determining Time Engaged in Lobbying Activities

	<p>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?</p>
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Determining Time Engaged in Lobbying Activities



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 7th, of that year.**

Determining Time Engaged in Lobbying Activities

	<p>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?</p>
	<p>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.</p>

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.

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.


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.

General

Leaving Educational Items with Public Employees

	<p>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?</p>
	<p>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.</p>

HCPs Who Sit on State Formulary Committees

	<p>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?</p>
-------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

HCPs Who Sit on State Formulary Committees



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.

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 [GNT01-GSOP 1.0 "Independent Medical Grants"](#).
- For more information about the Pfizer PAC, visit 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.



CHAPTER #17 – PUBLICATIONS

Chapter

#17

Publications

CONTENTS

State Laws: HCP and State Employee Restrictions

Introduction	307
Publication Planning.....	309
Authorship and Disclosure	310
Compendia	311
Payments to Authors and Contracting with Authors	311
Supplements	312
Publication of ISR, R-CRC and RC Study Results	312
For More Information.....	313

Chapter #17 Publications

Introduction

Pfizer supports the timely submission of manuscripts associated with Pfizer-sponsored clinical studies whether the results are positive, negative or neutral. Pfizer also supports other types of publications, such as congress abstracts, posters and presentations, review articles, manuscripts, including those coming from health economics/outcomes research studies, abstract and manuscript Plain Language Summaries (PLS) and enhanced publication content (EPC) such as videos, infographics, podcasts and audio recordings that are part of the publication or linked directly to the publication, and used to enhance the reader's experience.

This chapter summarizes the policies and procedures for managing Pfizer-supported publications in scope for [PUB01-GSOP Pfizer Scientific Publications](#) including author selection, informing external authors of Pfizer's publication policies, payments to authors, contracts with authors, publication development and disclosure of Pfizer support.

Publications subject to the requirements of this Chapter include:

- Submissions to peer-reviewed medical and scientific journals including:
 - Primary and secondary manuscripts from a Pfizer-sponsored clinical study
 - Narrative and systematic review articles, brief communications, letters to the editor
- Submissions to scientific congresses such as abstracts, posters, and presentations;
- Publications based on Registrational Clinical Research Collaborations (CRCs) (CT44-GSOP)
- Certain publications from Research Collaborations (RCs) (RC01-GSOP)
- Publications based on epidemiology analyses, surveillance studies, health economics and outcomes research, real-world evidence that are done in support of a Pfizer product, even if they do not mention a Pfizer product (e.g., disease state/therapeutic area reviews)
- Books and book chapters

Note that non-clinical publications are separately addressed by [RD SOP 204 nonclinical Publications SOP.pdf \(sharepoint.com\)](#).

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

Key Points to Ensure Compliance

- **Publications are not marketing tools.** While they may eventually be used in a promotional context, the planning and development of publications must be based on medical and scientific needs and must be independent of commercial and brand strategies.
- Commercial, marketing and sales colleagues must not be involved in the funding, preparation, planning, review or content development of publications, and must not influence or attempt to influence the publication planning process or content of publications.
- All members of a **Scientific Publication Committee (SPC)** must understand their roles and responsibilities and the applicable Pfizer policies.
- The selection of authors must be consistent with the **International Committee of Medical Journal Editors (ICMJE)** authorship criteria (<http://www.icmje.org>) and the **Pharmaceutical Research and Manufacturers of America (PhRMA)** Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results.
- **Authors must satisfy all 4 ICMJE criteria for authorship and anyone who meets all 4 criteria should be listed as an author – this applies to internal and external authors.** General supervision of a research group that is conducting or supervising a project, or solely performing data analysis, is not sufficient for authorship.
- Pfizer does not compensate authors who are investigators in a Pfizer-sponsored study for work associated with the preparation of the primary abstract, congress presentation, or manuscript regarding that study.
- In those rare circumstances where **Healthcare Providers (HCPs)** or **Healthcare Institutions (HCIs)** are paid to author or produce publications, Pfizer must ensure that payments are consistent with **Fair Market Value (FMV)** determination and other applicable requirements of Pfizer policy, including [CP207: Global Policy on Interactions with Healthcare Professionals \(GPIHP\)](#) and [My Anti-Corruption Policies and Procedures \(MAPP\)](#). In addition, Pfizer must contract directly with HCPs for work on publications; a third-party may not contract with an HCP on Pfizer's behalf.

Pfizer publications fulfill the Company's commitment to the truthful, accurate, and objective disclosure of data from Pfizer-sponsored or collaborative clinical studies in a timely manner, regardless of whether or not the results are favorable to Pfizer. They are **not** developed to encourage the use of a Pfizer product in order to impact prescribing, purchase or recommendation. Specific timelines apply to submission of primary manuscripts disclosing the primary end point(s) results of Pfizer-sponsored interventional clinical studies in

patients and preventive interventional studies in healthy subjects (e.g., prophylactic vaccine studies) to a peer-reviewed journal – for these studies **a primary manuscript must be submitted to a peer-reviewed scientific journal within 18 months of the study's primary completion date (PCD).**

Pfizer colleagues must ensure that any engagement of HCPs or HCIs to author or develop publications does not give rise to inappropriate financial relationships with, or influence over, those HCPs or HCIs. Importantly, the process by which authors are selected and compensated, if not structured appropriately, may violate federal or various states' anti-kickback statutes. For example, if an HCP is being paid to author a publication, but in reality, is not actually contributing or performing any author responsibilities, the government might question whether the HCP was chosen and/or paid as an inducement for his or her continued or increased prescribing of a Pfizer product. Even if an HCP has contributed substantially to the development of a publication, it could still raise questions whether any compensation received was based on FMV or could be viewed as a potential kickback. Conversely, omitting an individual's name as an author on a scientific article, when the individual's contribution satisfied the ICMJE criteria, may be viewed as a form of research misconduct.

Publication Planning

Publications supported by a Pfizer product team are managed by the product's multidisciplinary **SPC** which is responsible for developing and implementing the publication plan. The SPC's purpose is to ensure that clinical study results are published in a timely manner, identify gaps in medical knowledge about the product and determine whether existing science can address those gaps through a Pfizer-supported publication, and ensure publication integrity and compliance with Pfizer publication policies and procedures.

The SPC is chaired by the Clinical/Medical Lead responsible for overseeing the publication program for a product and may include other Medical and Clinical colleagues (who can also be *ad hoc* members), a Biostatistician, and a Publications Specialist who is a member of the Publications Management Team.

Commercial, Marketing and Sales Colleagues are not permitted to be members of the PSC. In addition, **Commercial, Marketing and Sales Colleagues are not permitted to:**

- Attend PSC meetings and receive PSC meeting minutes;
- Influence the decision-making process as it relates to publication planning;
- Make decisions regarding prioritization of publications;
- Select or suggest authors or scientific congresses and journals;
- Make decisions regarding the order of authors' names on the by-line;
- Author a medical or scientific publication;
- Review or comment on draft publications;

- Contract with a vendor for publications or pay a vendor for publications; and
- Liaise with authors or vendors to discuss publications.

Authorship and Disclosure

Pfizer adheres to the authorship criteria established by the [ICMJE](#) as well as the Pharmaceutical Research and Manufacturers of America (PhRMA) Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results, [link](#). In accordance with the ICMJE guidelines, authors must meet all four of the following conditions:

- Substantial contributions to the conception or design of the study, acquisition of data, or analysis and interpretation of data; and
- Drafting the publication or revising it critically with respect to important intellectual content; and
- Final approval of the version to be published; and
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Only individuals who meet **all** 4 of the ICMJE criteria should be named as authors on Pfizer publications and all those who fulfill these criteria should be named in the byline. Those who do not meet the criteria for authorship but have contributed in some way to the publication may be acknowledged elsewhere, as appropriate. Pursuant to the ICMJE criteria, general supervision of the research group that is conducting or supervising a project is not sufficient for authorship. Participation solely in study design, collection or analysis of data also does not justify authorship – **substantial involvement in drafting and/or revising the publication is required**. All individuals providing editorial and medical writing support must work under the direction of the authors.

A former or current member of a study's Data Monitoring Committee (DMC) cannot author a publication, even if the study has been completed and the DMC disbanded. This is because DMC members have privileged access to unblinded interim data and other safety and efficacy-related information. Therefore, to avoid actual or perceived bias in publications related to the study, DMC members may not serve as authors.

In addition to the ICMJE criteria, authors of a Pfizer-supported publication must ensure that development of a publication is consistent with journal or congress guidelines, including applicable disclosure obligations. Further, the authors should obtain and adhere to the publisher's requirements for acknowledging financial and material support and any other actual or perceived conflicts of interest. Authors must acknowledge in the publication all those who provided editorial support, the funding source, and the author's relationship with Pfizer. Authors must also determine the content and type of publication, the order of names on the

byline, and where the publication will be submitted. All authors should be given a reasonable amount of time to review and approve a proposed publication.

PUB01-GSOP includes specific recommended wording for disclosure/acknowledgement statements in a variety of situations. For example, where a publication reports the results of a Pfizer-sponsored study, the statement should read, “This study was sponsored by Pfizer.”

Either prior to or during development of a publication, the **Pfizer Publication Owner (PO)**, or designee, is responsible for ensuring that an External Author Letter is sent to each potential external author that describes, and requests written acknowledgment of, Pfizer’s policies on authorship and disclosure. In addition, prior to submission of a manuscript or abstract reporting the results of a Pfizer-sponsored interventional study or non-interventional post-authorization safety study (NI-PASS), Pfizer requires the completion of a Data Checklist to help ensure the quality of the underlying data. The PO, study statistician and Publications Specialist must also perform a Final Check to confirm that the manuscript is compliant with Pfizer’s policy and that the data are accurate and support the statistical interpretation.

Compendia

Generally, Pfizer does not actively engage with compendia regarding Pfizer products. Colleagues in U.S. Medical Information who receive an information request from an External Drug Compendium to review a product monograph may review the document for accuracy and completeness. All other Pfizer colleagues who receive an information request from an External Drug Compendium should consult with the relevant Product Counsel prior to responding.

In addition, colleagues in U.S. Medical Information may be notified of, or independently identify, inaccurate or incomplete product information (e.g., errors in dosages, omission of safety information) in External Drug Compendia product monographs. In these cases colleagues may proactively inform the External Drug Compendia of any such errors pursuant to the [Guidance Document: Contacting External Drug Compendia](#). Any other Pfizer colleague that identifies or is made aware of any errors should notify the U.S. Medical Information colleague responsible for the relevant product.

Payments to Authors and Contracting with Authors

Pfizer does not pay investigators of a Pfizer-sponsored interventional or non-interventional study for work associated with the preparation of the primary abstract, scientific congress poster/presentation, manuscript or abstract or manuscript PLS for the study. However, Pfizer may pay authors, including investigators, for the development of publications such as secondary publications, post-hoc analyses, meta-analyses and review articles.

When an HCP or Healthcare Institution (HCI) author is being paid for the development of a publication, Pfizer must contract with any make payments to the HCP/HCI directly and follow the requirements of CP207 *Global Policy on Interactions with Healthcare Professionals (HCPs)* and CP102 *Purchasing Policy and Procedure*. In addition, Pfizer's Anti-Corruption Policy and Procedure (MAPP) apply to all Pfizer colleagues interacting with any non-US government official or when engaging with entities connected to such officials.

External authors who will be compensated for their work on a Pfizer publication must enter into a written agreement describing the scope of work to be performed, the fees to be paid in connection with the publication, and the compliance obligations of the authors, including representations that they will adhere to the authorship criteria and disclosure obligations described above, before work on the publication begins.

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

Note that Pfizer does not compensate authors for their time presenting a poster or an oral presentation at a congress or similar meeting. However, Pfizer may provide authors of Pfizer publications with funding for registration and reasonable travel expenses associated with such presentations. Support for congress travel must comply with CP304 *Global Meetings & Congress Policy and Procedure*.

Supplements

Journal supplements are collections of papers that deal with related issues or topics. They may be published as part of a regular issue of a journal or as a separate issue, and generally are funded by sources other than the journal's publisher. Pfizer-sponsored supplements are permitted under Pfizer policy and are governed by promotional standards and must comply with [Global Content Policy: Commercial Standards for Promotional Materials](#). Supplements are not in scope for PUB01-GSOP and must not be managed by a SPC.

Publication of ISR, R-CRC and RC Study Results

As with publications related to the results of Pfizer-sponsored studies, Pfizer supports the exercise of academic freedom and encourages investigators to publish the results of an **Investigator-Sponsored-Research study (ISR), Research Collaboration (RC), or Registrational Clinical Research Collaboration (R-CRC)**, whether the results are favorable for a Pfizer product. In our contracts, Pfizer requests an opportunity to review proposed publications or other public disclosures of such studies prior to publication. Pfizer also expects the investigator or institution to comply with recognized ethical standards concerning publications and authorship, including the disclosure of Pfizer support of the study in any publication of study results.

All R-CRC publications and certain RC publications must comply with PUB01-GSOP and [PUB01-GSOP-RF04 Clinical Research Publications Checklist](#). Publications from ISRs are independent and out-of-scope for PUB01-GSOP.

Support for and management of ISRs, R-CRCs and RCs and any subsequent publications (as well as publications related to Pfizer-sponsored clinical studies) is further described in [White Guide Chapter 9: Pfizer-Sponsored and Non-Sponsored Clinical Research Including Investigator-Sponsored Research Studies \(ISRs\)](#).

For More Information

- [CP #402: Scientific and Technical Publications and Presentations](#)
- [CP #207: Global Policy on Interactions with Healthcare Professionals \(GPIHP\)](#)
- [My Anti-Corruption Policies and Procedures \(MAPP\)](#)
- [CMCD CT20-POL: Public Disclosure of Pfizer Clinical Study Data and Authorship](#)
- [ICMJE Guidelines on Authorship and Contributorship](#)
- [PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results](#)
- [PUB01-GSOP Pfizer Scientific Publications](#)
- [PUB01-GSOP-RF04 Clinical Research Publications Checklist](#)
- [Guidance Document: Contacting External Drug Compendia](#)
- [White Guide Chapter 9: Pfizer-Sponsored and Non-Sponsored Clinical Research Including Investigator-Sponsored Research Studies \(ISRs\)](#)
- Refer any other questions or concerns to a member of Pfizer's Publications Management Team. Click [Publications - PMT Product Contact List - All Documents \(sharepoint.com\)](#)



CHAPTER #18 – MEALS, EDUCATIONAL ITEMS, AND HCP PAYMENT DISCLOSURE

Chapter

#18

Meals, Educational Items, and HCP Payment Disclosure

CONTENTS

Meals, Educational Items, and HCP Payment Disclosure

Introduction	316
Meals to HCPs	318
General Rules and Restrictions	318
Meals Provided by Field Sales Colleagues and Their Immediate Managers	320
Meals Provided by Senior Sales Colleagues, Headquarters Colleagues, and Account Management Colleagues Permitted to Host Out-Of-Office Meals	324
Legitimate Business Reason	324
Meal Planning & Execution	325
Attendance by Other Colleagues at Meals Hosted by Senior Sales, HQ, and Account Management Colleagues	326
Business Meals Provided Sterile Injectables Colleagues	328
Educational Items to HCPs	329
HCP Payment Disclosure Policy	330
Overview	330
Items Included in Reporting	330
Disclosure of the Value of Meals	331
Disclosure of the Value of Educational Items and Non-Disclosure of Patient Materials	331
Recording Disclosable Payments and Items	332
Opting Out of Receiving Disclosable Items	333
Access and Use of Open Payments and other Transparency Data for Analytics	334
For More Information	335

Chapter #18 Meals, Educational Items , and HCP Payment Disclosure

Introduction

The Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals (PhRMA Code) provides that occasional meals may be offered to U.S. **Healthcare Professionals (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 “Sunshine Act”. Starting January 1, 2021, reporting expanded under the SUPPORT Act to also include payments and transfers of value provided to the following HCPs under the “Open Payments” provisions:

- Physician Assistant
- Nurse Practitioner
- Clinical Nurse Specialist
- Certified Registered Nurse Anesthetist
- Certified Nurse Midwife
- Anesthesiologist Assistant

Certain state laws and federal institutions create additional restrictions and disclosure obligations (broader than the Open Payments provisions) regarding payments and other items provided to U.S. HCPs, as described in the State Laws: HCP and State Employee Restrictions Chapter 15 and the Federal Employee Interactions and Lobbying Chapter 16 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 and disclosure of meals, educational items, or other items 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 to comply with the PhRMA Code, an incidental meal can only be provided where there is a reasonable expectation, and reasonable steps are taken to confirm, that each attendee has a substantive interaction or discussion with a Pfizer colleague
- 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 15 and the Federal Employee Interactions and Lobbying Chapter 16 in this Guide. Additional information is also available on [Policy Xchange](#) under the State Healthcare Law Compliance tab and on [MyPfieldNet](#) under the Compliance tab.
- Licensed prescribers and pharmacists 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.

Key Points to Ensure Compliance

- HCPs may permanently “opt out” of being offered meals, snacks, or educational items by contacting PTI@Pfizer.com. If an 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/SUPPORT Acts are posted on the [Open Payments website](#) maintained by CMS.
- 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 [Policy Xchange](#).
- 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)**, excluding out-of-office speaker program meals (see Chapter 9) 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 Open Payments and State Laws. In addition, solely providing alcoholic beverages or excessive amounts thereof is prohibited and not considered conducive to a business discussion. 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.

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?
Sales Representative	No	Yes	Yes	Yes	No
District Manager	No	Yes	Yes	Yes	No
Regional Business Director, Regional President, National Sales Lead	Yes	Yes	Yes	Yes	Yes
Greenstone and Sterile Injectables	Please see Business Meals Provided by Greenstone and Sterile Injectables Colleagues Section				
Account Manager, including AD, DE, KAM, VAM, ADM (only if such colleague does not directly supervise Sales representatives)	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
HQ Marketing/Medical	Yes	Yes	Yes	Yes	Yes

Several states and the U.S. Department of Veterans Affairs (VA)/Department of Defense (DoD) also impose meal limitations and reporting requirements that are stricter than the PhRMA Code and/or our Pfizer policy. See Chapter 17 and Chapter 4 of the Orange Guide for more information. 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.

Before providing any meals or other items of value to HCPs, colleagues should refer to the State Laws: HCP and State Employee Restrictions Chapter 17 and the Federal Employee Interactions and Lobbying Chapter 4 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 State Healthcare Law Compliance tab on [Policy Xchange](#) and under the Compliance tab in [MyPfieldNet](#).

Account Manager Out-of-Office Meals with HCPs

	<p>Can a KAM host an out-of-office meal with an HCP who serves as the medical director of a hospital system?</p>
	<p>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 (i.e., approximately 20%) or less 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.</p>

Meals Provided by Field Sales Colleagues and Their Immediate Managers

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 restriction applies whether the Sales colleague is providing the meal incidental to an in-person or virtual presentation. The only times a Sales representative or their immediate manager may provide an out-of-office meal is when they are in-person with HCP attendees during a Pfizer speaker program where a trained speaker (typically a contracted external HCP) is presenting (either in-person or virtually) RC-approved information about Pfizer products, disease states, or other healthcare topics, using content 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 permissible for colleagues to provide in-office meals to



appropriate attendees as an ancillary offering to virtual informational presentations in accordance with the Guidance on Promotional Meals with VCC [\[link\]](#)

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 or virtually present under certain circumstances. 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., >20 attendees), including virtual presentations, 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 should 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. If an office or customer fails to comply with Pfizer's meal requirements, which are consistent with the PhRMA Code, the Pfizer colleague should discuss with their manager the appropriateness of providing a presentation over a meal with them in the future.






“Meals” Defined

	Does taking an HCP out for a cup of coffee constitute a meal?
	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), unless further restricted by state law or other laws or policies. Offering a snack (as defined above) out of an HCP's office or hospital

should be limited to only one or two HCPs at a time. Offering a snack in conjunction with a virtual or remote interaction is prohibited.

In all cases, the value of any food or beverages provided to a U.S. HCP, 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.

Providing a Meal to Office Staff

	<p>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?</p>
	<p>Yes, the PhRMA Code provides that when providing information presentations in-office for HCPs it is permissible to provide an occasional, incidental meal to members of an HCP's staff as a business courtesy. However, such incidental meals must only be provided when there is a reasonable expectation, and reasonable steps are taken to confirm that each attendee has a substantive interaction or discussion with the Pfizer colleague. Colleagues should be thoughtful about only providing meals to those office members who have a legitimate need to be provided the education. Colleagues must also confirm that all attendees are not further restricted from receiving meals by state law or other laws or policies.</p>
	<p>Can a Pfizer colleague provide lunch to HCPs or medical office staff who do not attend the informational presentation or receive educational information?</p>
	<p>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. This requirement applies whether the colleague is presenting in-person or virtually.</p>
	<p>Can a Pfizer colleague set up a monthly appointment, in an HCP's office, that includes a meal or snack?</p>

Providing a Meal to Office Staff



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?





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

	<p>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?</p>
	<p>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.</p>

Providing Meals to Pharmacists

	<p>May you provide a meal to a pharmacists or pharmacy technicians?</p>
	<p>Yes, however you may not provide a meal to a pharmacist or pharmacy technician in Vermont or Minnesota. For Massachusetts, Nevada and D.C., pharmacists and pharmacy technicians any food and beverage expenses must be reported and disclosed individually.</p>

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. All out-of-office meals hosted by senior Sales Colleagues, HQ colleagues, and Account Management colleagues, must follow the requirements of this Chapter.

Legitimate Business Reason

To determine whether the legitimate business reason requirement is satisfied, appropriate colleagues hosting out-of-office 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 RC-approved content. 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 GPC.

Sales Colleagues Attending Non-Speaker Program Restaurant Meals

	<p>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?</p>
	<p>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.</p>
	<p>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?</p>
	<p>No, this would not be in the spirit of the PhRMA Code or Pfizer policy.</p>

Legitimate Business Reason

	<p>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?</p>
	<p>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.</p>



Business Meals Provided Sterile Injectables Colleagues

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 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.

Before providing any meals or other items of value to customers, colleagues should refer to the State Laws: HCP and State Employee Restrictions Chapter 15 and the Federal Employee Interactions and Lobbying Chapter 16 in this Guide.

ACT	Host Restaurant Meals?	Host In-office Meals?	Host In-hospital Meals?	Host Speaker Programs?	Host Meals at Conventions?
Sterile Injectables Colleagues with Administrative Customers	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 Sterile Injectables Customers


	<p>I am meeting with an HCP with a purely administrative role. We are meeting in his office. What can I spend?</p>
	<p>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.</p>

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 Open Payments. 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.

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 and pharmacists 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 15 and the Federal Employee Interactions and Lobbying Chapter 16 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 [Policy Xchange](#) under the “State Healthcare Law Compliance” tab and [MyPfieldNet](#) under the Compliance tab. Sales Colleagues should also consult the State Law Restriction field in Veeva CRM.

Out-of-Pocket Gifts for HCPs

	<p>Can I pay for a gift for an HCP out of my own pocket if I do not expense it?</p>
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Out-of-Pocket Gifts for HCPs

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 [The Summary of Pfizer Policies on Business Conduct \(the “Blue Book”\)](#) and [Corporate Policy \(CP\) #203: Conflicts of Interest](#) require you to avoid even the appearance of a conflict of interest.

HCP Payment Disclosure Policy**Overview**

Pfizer’s disclosure policy is broader than the requirements of the Open Payments provisions and defines “HCP” more broadly. This is because certain states have different reporting standards, and individuals other than those described in the Open Payments provisions can influence or cause the administration, prescription, purchase, or recommendation of prescription medicines.

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.

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

	<p>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?</p>
	<p>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).</p>

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 educational materials that enhance an HCP's skills (such as textbooks and journal reprints) are considered reportable transfers of value under Open Payments.

Generally, Pfizer-created branded and unbranded promotional materials, literature and other leave-behind written materials are NOT subject to disclosure under Open Payments. Likewise, items that are to be used by or with patients, such as an anatomical model or patient education materials, are NOT disclosable under Open Payments. 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:



- Copay 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 (i.e. HCPM ID); and
- Never approve expense reports or invoices that lack full names and appropriate expense allocation.

Identifying HCP Meal Attendees in Sales Colleague Expense Reports

	<p>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?</p>
	<p>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, pharmacists and office staff, do not need to be identified by name, unless the meal is with a NV HCP for any dollar amount, or a DC HCP that is \$25 or more or a MA HCP that is \$50 or more. In these circumstances all individuals must be listed individually in the expense report. 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 Chapter 15 in this Guide, for further details on who qualifies as an HCP in Nevada, Massachusetts and D.C.</p>

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; 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.

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 [Policy Xchange](#) and [MyPfieldNet](#).







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.


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 [Global HCP/HCO Transparency Reporting Portal](#) or contact the Transparency team directly at GlobalHCPTransparencyReporting@pfizer.com. If you have questions about the appropriate use of transparency 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.
	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. The representative should discuss with their manager the appropriateness of scheduling presentation appointments with an accompanying lunch in the office in the future.
	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 ENGAGE2@pfizer.com or your team attorney with any questions.

The Disclosure Process

	Will U.S-licensed HCPs have the opportunity to review their transparency data before it is posted on the CMS Open Payments website?
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The Disclosure Process

	<p>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.</p>
	<p>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?</p>
	<p>Pfizer has a dedicated staff to address transparency questions and concerns. Colleagues should e-mail questions to PTI@pfizer.com. 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 e-mail to HCPDispute@pfizer.com.</p>

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 Policy Xchange](#), or e-mail StateHealthcareLawCompliance@pfizer.com.
- For more information regarding processes for capturing and recording promotional meals in PT&E, refer to the guidance available [here](#).
- 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 State Healthcare Law Compliance tab on [Policy Xchange](#) or in the [Compliance tab in MyPfieldnet](#).
- For more information on Pfizer's HCP transparency practices, refer to the [Global HCP/HCO Transparency Reporting Portal](#) or e-mail GlobalHCPTransparencyReporting@pfizer.com.
- 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](#).
- Additional information is also available on [Policy Xchange](#) under the State Healthcare Law Compliance tab and on [MyPfieldNet](#) under the Compliance tab.



CHAPTER #19 – SAVINGS AND FREE TRIAL PROGRAMS

Chapter**#19****Savings and Free Trial Programs**

CONTENTS

Savings and Free Trial Programs

Introduction	338
Key Points to Ensure Compliance	338
Applicability	340
Pfizer Savings and Free Trial Programs	341
Overview	341
Savings Programs	341
Discount and Direct Purchase Programs	342
Free Trial Programs	342
Legal Framework for Savings and Free Trial Programs	343
Anti-Kickback Statute	343
Beneficiary Inducement Statute	344
State Laws	344
Savings and Free Trial Programs Development and Implementation	344
Materials Describing Savings and Free Trial Programs	345
State Law Requirements	346
For More Information	347

Chapter #19 Savings and Free Trial Programs

Introduction

Pfizer believes that all patients should have access to the medicines prescribed by their **Healthcare Providers (HCPs)**. To that end, Pfizer develops and offers various patient savings programs that reduce a patient's out-of-pocket costs or offer medicines at a discounted price (such as copay coupons/cards,

Key Points to Ensure Compliance

- Savings and Free Trial Programs must be structured, reviewed and approved by Pricing & Access Legal, and implemented consistent with this Chapter and through a centralized process managed by **Biopharma Operations** as described in this Chapter and the Savings and Free Trial Programs **Standard Operating Procedure (SOP)**.
- Each Pfizer Savings and Free Trial Program must conform with all applicable laws and regulations, and be structured and implemented consistent with administrative guidance, including the 2014 OIG Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons and other OIG guidance.

Compliance with this Chapter is critical to ensure that the Savings and Free Trial Programs comport with evolving government laws and guidance. 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

- Program owners wishing to initiate a new program or make changes to an existing program must complete the Savings and Free Trial Program Approval Form and submit it to NA CO.
- Every Savings or Free Trial Program must be reviewed and approved by [Pricing & Access Legal](#) prior to implementation through the process outlined in the SOP.
- Program owners must not engage a new Savings or Free Trial Program vendor or enter into new or amended **Statements of Work (SOW)** without coordinating with Biopharma Operations, who must lead any such engagement. All vendors that implement Pfizer Savings or Free Trial Programs must comply with applicable business rules and standard operating procedures, Pfizer policies, and each such vendor's applicable policies.
- Pfizer Savings and Free Trial Program vendors administering programs that are designed to exclude Federal Health Care Program beneficiaries and/or patients in certain states must apply robust government exclusion controls.
- Each Pfizer Savings and Free Trial Program must be designed to meet a sound business need that takes into account the specific characteristics of the Pfizer medication, patient population, competitive landscape, and other patient support offerings available or proposed for the product; such business need must focus on appropriate patient access to the medication after an independent prescribing decision has been made, and must not be intended to influence a prescribing decision.
- Pfizer Savings and Free Trial Programs are intended for the exclusive use and benefit of eligible program patients. Pfizer Savings and Free Trial Programs are not intended to, and may not be designed to, benefit HCPs, pharmacies, or other third parties that are not patients.
- Pfizer must provide Savings and Free Trial Programs to patients only where prescribers have made an independent clinical decision that the Pfizer product is medically appropriate for the individual patient.
- Program owners may use HCP prescribing volumes as a proxy for measuring patient need when determining appropriate allocation of Savings and Free Trial Program offers; however, such allocations to HCPs must not be intended to reward the HCPs' prescribing of Pfizer products..

Key Points to Ensure Compliance

- Brand Teams should work with the **Global Products Counsels (GPCs)** and **Business Unit (BU)** Compliance to ensure that Savings and Free Trial Program distribution channels and allocation strategies are appropriate and consistent with this Chapter, and applicable state and federal law, taking into account scrub lists, opt-out lists, and state law restrictions. The GPC may consult with [Pricing & Access Legal](#), as necessary.
- Pfizer must ensure that all Savings and Free Trial Programs maintain adequate controls to limit program use to eligible patients, including appropriate terms and conditions and patient enrollment/activation requirements, as applicable.

Applicability

This Chapter applies to all U.S. Pfizer colleagues and contractors that perform activities related to Savings and Free Trial Programs. This includes, but is not limited to, Pfizer colleagues from the following functional areas: Brand teams, Compliance, Global Health & Social Impact, Legal, and **Biopharma Operations**. Any programs, tools or resources offered directly by Pfizer that offer free product or financial assistance with a patient's out-of-pocket costs are subject to this Chapter and the Savings and Free Trial Programs SOP. This Chapter does not apply to the **Pfizer Patient Assistance Program (Pfizer PAP)** and the Institutional Patient Assistance Program (which provide free product to eligible patients who demonstrate financial need), Starters, and the Interim Care Program (or similar programs intended to address an insurance delay). Information on these programs can be found in White Guide Chapter 10: The Pfizer PAP and Donations to ICPAPS and White Guide Chapter 14: Starters.

A program owner is the colleague with primary responsibility for design and execution of Pfizer Patient Savings Programs, which offer patient savings (typically without regard to financial need) on product prescriptions, in the form of either a reduction in cost-sharing (e.g., copay or co-insurance) or reduced cash price. Program owners must consult with Biopharma Operations and Pricing & Access Legal prior to implementation of a proposed program if they have questions about the applicability of this Chapter and the SOP.

Savings or discount programs that offer financial assistance with a patient's out-of-pocket costs that are sponsored and operated by third parties (e.g., third-party payers, pharmacy benefit managers, or retail pharmacies) are not subject to this Chapter; however, Pfizer colleagues interested in such third party programs not operated by Pfizer must consult with [Pricing & Access Legal](#) and BU Compliance prior to entering into any such programs.

Pfizer Savings and Free Trial Programs

Overview

Pfizer Savings and Free Trial Programs include both commercial programs offered by Brand teams, which are centrally operated by Biopharma Operations, and certain programs offered by Global Health & Social Impact. Free trial programs are not based on financial need and offer a limited free supply of medicine to patients newly prescribed a Pfizer medication so they can determine efficacy and tolerability.

Savings Programs

Copay Programs⁹

Copay Programs help to reduce patients' out-of-pocket costs for a Pfizer drug. Copay Programs may be offered in many forms, including paper copay coupons (distributed by Pfizer or downloadable from a product website), physical or virtual copay cards, electronic coupons (typically offered through the pharmacy adjudication system or prescriber's electronic medical records or e-prescribing system), debit cards, or customer rebates.

Cost Sharing Programs



- Copay Coupon/Card – a program that reduces a patient's out-of-pocket costs immediately at the point of sale.
- Electronic Copay Savings Program – sends an offer electronically directly to a pharmacy or dispensing physician that reduces an eligible patient's out-of-pocket cost for a product immediately at the point of sale without the patient presenting a physical coupon or card.
- Debit Card – a preloaded card that may be used at the point of sale to pay the pharmacy/dispensing HCP for the patient's out-of-pocket costs.
- Customer Rebates – an offer of post-purchase reimbursement from Pfizer directly to an eligible patient for his/her out-of-pocket cost (e.g., copay or co-insurance amount) for a prescription after the patient pays the cost at the point of sale and submits the receipt and other required documentation as proof of purchase to the Pfizer program vendor.
- Copay programs do not include: Direct Purchase/Discounts (e.g., Viagra Direct), PBM Rebates, etc.

All proposals for Copay Programs must be reviewed by Pricing & Access Legal and may require additional controls to ensure compliance with applicable laws and OIG Guidance. In general, Copay Programs are available for commercially-insured patients only and require Pricing & Access Legal review and approval. Pfizer may consider offering Copay Programs to uninsured or cash paying patients.

Copay Programs must not be used by Federal Healthcare Program beneficiaries for product that is reimbursed by a Federal Health Care Program, such as Medicare, Medicaid, or TRICARE.

⁹ The May 23, 2018 Corporate Integrity Agreement refers to these types of programs as "cost-sharing" programs.

Copay Programs and Federal Beneficiaries

	<p>May Copay Program offers be used by patients using Medicare, Medicaid or other federal health care program?</p>
	<p>No. Copay Program offers (e.g., copay cards or copay coupons) must never be used by a federal healthcare beneficiary patient whose product is reimbursed by a Federal Health Care Program, such as Medicare, Medicaid, or TRICARE, or any other federal or state healthcare program.</p> <p>Note: While Brand teams may consider offering Copay Programs to uninsured or cash paying patients, which may include Federal Health Care Program beneficiaries (who will purchase the product outside of their government program benefit), Pricing & Access Legal review and approval is required.</p>

Discount and Direct Purchase Programs

Discount and Direct Purchase Programs allow uninsured and/or underinsured patients to either:

- (1) Use a program card to purchase certain Pfizer medications at a reduced cash price, outside of any insurance benefit, through participating pharmacies; or
- (2) Purchase certain Pfizer medications directly from Pfizer at a fixed cash price outside of the patient's insurance benefit.

These programs are offered to eligible patients without regard to the purchase of any other product or service and typically without regard to the patient's income. Participating patients with insurance must not seek reimbursement from their insurance provider or count the cost of product purchased through these programs toward their plan's deductible or any out-of-pocket cost calculations/limitations. This means, for example, that if a patient has Medicare Part D and is permitted to participate in this type of program, then if they seek to purchase a prescription outside of their Medicare Part D benefits they must not seek reimbursement from their Part D plan or count the cost of product purchased through these programs towards their **True Out of Pocket (TrOOP)** costs.

Free Trial Programs

Vouchers and other free trial programs provide patients with a limited supply of free product to allow patients and prescribers to evaluate the safety and efficacy of the product for a patient newly prescribed the product. Vouchers and free trial programs must not be provided for the purpose of financial assistance. These programs are analogous to a Starter; however, the free product is provided directly to the patient by a program vendor or a participating pharmacy, rather than from a physician. Vouchers and free trial programs must not be positioned to HCPs or provided for the purpose of addressing long term issues, such as patient

access, insurance coverage or financial assistance. Brand teams must provide implementation guidance to sales representatives about the appropriate characterization of these resources, including messaging that directs patients to RxPathways or the product specific HUB to understand other resources that may be available to address patient access to the medication and financial need. Sales representatives may distribute both starters and vouchers to the same HCP office in accordance with the following principles. 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

Federal Health Care Program patients may be eligible to participate in properly structured voucher and free trial programs. However, the free product must be provided to patients without regard to the purchase of any other product or service, and the free product must not be eligible for reimbursement by any insurer.

Legal Framework for Savings and Free Trial Programs

Anti-Kickback Statute

The OIG broadly defines “copayment coupons” as any form of direct support offered by manufacturers to insured patients, including print coupons, electronic coupons, debit cards, and direct reimbursements. If offered to Federal Health Care Program patients (where the federal program covers and reimburses the product), such programs constitute remuneration offered to consumers to induce the purchase of specific prescription drugs and thus implicate the AKS.

Although manufacturers typically expressly prohibit the use of copayment coupon programs for products that are reimbursable by Federal Health Care Programs due to the risk of violating the law, in recent years the OIG has observed that steps taken to exclude such use are generally inadequate. In 2014, the OIG issued a report and a Special Advisory Bulletin questioning the effectiveness of safeguards manufacturers have in place to ensure that patients do not use copayment coupons to obtain prescription drugs paid for by Medicare. The OIG concluded that manufacturers are responsible for operating their copayment coupon programs in compliance with federal law and must take appropriate steps to prevent their programs from inducing the purchase of drugs paid for by the Federal Health Care Programs. The OIG stated that failure to take such additional steps may be considered evidence of intent to induce the purchase of drugs paid for by these programs, in violation of the AKS.

In addition, while there is no safe harbor for vouchers or other free trial programs, the OIG has said that sample programs (e.g., Pfizer’s Starter Programs) that comply with the **Prescription Drug Marketing Act (PDMA)** generally will not raise AKS risks because physicians are prohibited from reselling or potentially billing third-party payors (including Federal Health Care Programs) for samples they receive for free from manufacturers. Further, the OIG has applied its guidance on samples to a program that provided a free

one-time trial supply that allowed physicians and patients to test the product's safety and tolerability and incorporated various safeguards to prevent Federal Health Care Programs from bearing any cost.

Beneficiary Inducement Statute

The beneficiary inducement statute prohibits any person from offering anything of value to any Medicare or Medicaid beneficiary that such person knows or should know is likely to influence the beneficiary to order or receive a federally reimbursed product from a particular provider, practitioner, or supplier.

While pharmaceutical manufacturers like Pfizer are not considered “providers, practitioners, or suppliers” for purposes of the statute, the statute applies to manufacturer programs that could influence a Medicare or Medicaid beneficiary to choose a particular pharmacy or physician. Thus, if a Savings and Free Trial Program would encourage a beneficiary to use a particular healthcare provider or pharmacy, the program may implicate the beneficiary inducement statute.

State Laws

Certain states have enacted laws that limit the use of copay coupons, copay cards, vouchers, and other Savings and Free Trial Programs in those states. Some state laws require Pfizer to report certain data relating to Savings and Free Trial Programs. Many states also have laws that seek to protect consumers from inappropriate marketing and sales practices. Virtually all states have broad laws prohibiting “unfair” or “deceptive” trade practices, which have been interpreted to require that manufacturers provide clear and conspicuous information regarding terms and conditions of the program offer on the offer materials (e.g., card or voucher) and any related advertising.

Pfizer colleagues should consult with Biopharma Operations and [Pricing & Access Legal](#) if they have questions regarding the applicability of state laws to Savings and Free Trial Programs. More information on State Laws can be found in White Guide Chapter 15.

Savings and Free Trial Programs Development and Implementation

Either Commercial colleagues or colleagues in Global Health & Social Impact may be program owners of Savings and Free Trial Programs. Accordingly, they are responsible for identifying the types of Savings and Free Trial Programs to offer to patients for a particular Pfizer medication, and they manage the budget for their respective Savings and Free Trial Programs.

Savings and Free Trial Programs must be structured, approved, and implemented consistent with this Chapter and through a centralized process managed by Biopharma Operations, as described in the Savings and Free Trial Programs Standard Operating Procedure. In order to initiate new programs or make changes to existing programs, a program owner must complete the Savings and Free Trial Program Design Form and submit it to Biopharma Operations.

Biopharma Operations is responsible for overseeing the development, approval, and implementation of all Pfizer Savings and Free Trial Programs, in coordination with Pricing & Access Legal and the relevant Savings and Free Trial Program owner. This includes, among other things, owning and managing all Savings and Free Trial Program vendor relationships, in coordination with Pricing & Access Legal, Global Procurement, and the relevant program owner. Program owners may not engage a new Savings and Free Trial Program vendor or enter into new or amended **Statements of Work (SOW)** without coordinating with Biopharma Operations, who will lead any such engagement.

Pricing & Access Legal and GPC provide legal guidance to Brand Teams, Global Health & Social Impact, and Biopharma Operations with respect to Savings and Free Trial Programs. **Every Savings or Free Trial Program must be reviewed and approved by Pricing & Access Legal prior to initial implementation or implementation of changes to the programs through the process outlined in the SOP.**

The relevant Savings and Free Trial Program owner, in coordination with Biopharma Operations and in consultation with the GPC, is responsible for facilitating the allocation and distribution of physical and digital Savings and Free Trial Program offers, consistent with this Chapter, the Savings and Free Trial Programs SOP, and applicable state and federal law.

The chart below contains tips on what Pfizer colleagues must do and must not do when developing a Savings or Free Trial Program:

DO	DO NOT
Consult with Biopharma Operations on the development, approval, and implementation of all Pfizer Savings and Free Trial Programs.	Engage a new Savings or Free Trial Program vendor or enter into new or amended SOW without coordinating with Biopharma Operations.
Complete the Savings and Free Trial Program Design Form and submit it to BIOPHARMA OPERATIONS for every new and changing Savings or Free Trial Program prior to implementation.	Design a voucher program to address access issues or financial need.
Prior to initiating a new Savings or Free Trial Program or making changes to existing programs, you must submit the Savings or Free Trial Program Design Form to Biopharma Operations and receive approval from Pricing & Access Legal.	Contract with a new or different vendor without Legal and Biopharma Operations approval of the Savings or Free Trial Program Design Form.

Materials Describing Savings and Free Trial Programs

All materials describing Savings and Free Trial Programs, including the terms and conditions, and any limitations or patient eligibility requirements, regardless of the intended audience, must be reviewed and approved by the applicable Review Committee and must be:

- Accurate and not misleading;

- Clear and transparent regarding the offering, patient eligibility, and program terms and conditions; and
- Compliant with the requirements outlined in this Chapter and the Savings and Free Trial Program SOP, REG-08 and its associated work instructions, and all other relevant Pfizer policies, SOPs, and guidance.

State Law Requirements

Below is a summary of relevant state law requirements. It is not intended to be a complete list. Brand teams should consult with Biopharma Operations and [Pricing & Access Legal](#) to ensure compliance with these requirements, and any new laws.

Controlled Substances. A number of states have adopted broad restrictions on various manufacturer practices relating to controlled substances, including coupons and other forms of copay relief. Massachusetts, for example, prohibits discounts, rebates, vouchers, or other reductions in an individual's out of pocket expenses, including copayments and deductibles for any Schedule II opioid prescription drug. Manufacturers that have products that are regulated as controlled substances can provide copay support programs only on a limited basis. Any proposed Pfizer copay programs for a product that is scheduled as a controlled substance are subject to review and approval by the applicable GPC, with consultation with [Pricing & Access Legal](#) as appropriate.

California. California prohibits manufacturers from offering discounts, repayments, product vouchers or other reductions to an individual's out-of-pocket health plan expenses for a drug if a lower cost generic drug is covered by the patient's health plan on a lower cost-sharing tier and that is the therapeutically equivalent to the drug, or if the active ingredients of the drug are available without a prescription at a lower cost.

This prohibition does not apply to, among other things, the following:

- Branded drugs until the first "Therapeutically Equivalent" generic product approved by the FDA has been nationally available for at least three months (note: this does not apply to biologics/biosimilars);
- The individual has completed any applicable step therapy or prior authorization requirements for the branded prescription drug as mandated by the individual's health plan; or
- A discount, repayment, product voucher, or other reduction in an individual's out-of-pocket expenses is not associated with his or her health insurance, health care service plan, or other health coverage.

Program owners should consult with Biopharma Operations for more information about the applicability of California law to a particular program.

Massachusetts. Massachusetts prohibits discounts, rebates, product vouchers or other reductions in an individual's out-of-pocket expenses (including copayments and deductibles) for both any prescription drugs that have an AB-rated generic equivalent and for any Schedule II opioid prescription drug. In addition, for prescription drugs that are not Schedule II opioids or that do not have an AB-rated generic equivalent,

Massachusetts prohibits manufacturers from offering discounts, rebates, product vouchers, or copay support programs if the manufacturer excludes or favors any pharmacy in the redemption of such discount, rebate, product voucher or copay program voucher (e.g., if patients can use a copay card at a limited number of pharmacies in the state).

Colorado and Louisiana. Copay offerings are not permitted to be offered directly to pharmacists in Louisiana and Colorado.

Tennessee. Contact Biopharma Operations for information regarding requirements to register programs with the TN Division of Commerce & Insurance.

For More Information

- Savings and Free Trial Programs Standard Operating Procedure.
- Global Commercial Content: [Review and Approval Procedure – U.S. Addendum.](#)
- Chapter 2 (Advertising and Promotional Labeling).
- Chapter 10 (The Pfizer PAP and Donations to ICPAPS).
- Chapter 11 (Privacy: Protecting Personal Information).
- Chapter 14 (Starters).
- White Guide Chapter 15 (State Laws).



CHAPTER #20 – NON-DISCOUNT ARRANGEMENTS WITH SPECIALTY PHARMACIES AND OTHER ACCOUNTS

Chapter**#20****Non-Discount Arrangements
with Specialty Pharmacies
and Other Accounts**

CONTENTS

**Non-discount Arrangements with Specialty
Pharmacies and Other Accounts**

Introduction	350
Anti-Kickback Analysis	350
Overview of Interactions with Specialty Pharmacies	352
Types of Contractual Relationships Between Pfizer and SPPs.....	353
Non-Discount Arrangements	353
Discount Arrangements with SPPs.....	354
Materials Provided to SPPs	354
Privacy Requirements & SPP Data.....	354
Field Commercial Colleagues and Interactions with SPPs.....	355
SAS NAD Interactions with SPPs.....	355
Other Field Commercial Colleague Interactions with SPPs	355
Sales Interactions with Specialty Pharmacy HCPs and SPP Office Staff	355
Interactions with Specialty Pharmacy Sales Representatives.	356
Approval Process for Sales Representative Interaction	357
Field Commercial Colleague SPP Interaction Approval Process.....	357
For More Information.....	357

Chapter #20 Special Types of Services Agreements – Interactions with Specialty Pharmacies

Introduction

Pfizer enters into a variety of contractual arrangements, including non-discount arrangements, with its customers, to procure goods or services on behalf of Pfizer. Specialty pharmacies sometimes referred to as **Specialty Pharmacy Providers (SPPs)** are amongst these customers. This Chapter discusses non-discount arrangements between Pfizer and SPPs or other accounts. Chapter 20 of the Orange Guide contains additional discussion about non-discount arrangements with SPPs when Pfizer enters into such arrangements with specialty pharmacies to participate in Defined Networks or to provide Supplemental Services to patients that have been prescribed a Pfizer product; Chapter 15 and Chapter 20 of the Orange Guide contains a discussion of non-discount arrangements with SPPs and organized customers, including managed care organizations, retail pharmacies, group purchasing organizations, and integrated delivery networks.

Anti-Kickback Analysis

The Anti-Kickback Statute prohibits payments intended to induce the purchase, prescription, endorsement, or recommendation 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. The Anti-Kickback Statute and safe harbors are critical to consider when entering into non-discount arrangements with any customer, including a specialty pharmacy. 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)**. Any discussions regarding arrangements to purchase, prescribe or recommend a Pfizer product, or to improve the price or discount at which a customer can purchase Pfizer’s products, must be separate and apart from any discussions regarding a proposed service agreement with an account. Discussing these separate and otherwise legitimate arrangements together could lead to conflation between the discounts (i.e., including best price reporting) and services safe harbors thereby removing safe harbor protection and subjecting Pfizer to potential liability under the Anti-Kickback Statute.

To ensure compliance, when entering into non-discount arrangements with SPPs or accounts remember the following principles:

- Ensure the non-discount arrangement serves a legitimate business purpose. Only purchase those goods or services for which Pfizer has a bona fide need. Paying for unneeded (including duplicative) goods, services or data can increase the risk that the arrangement is viewed as an illegal kickback.
- Do not attempt to procure a service from an account that the account is already legally obligated to provide whether by statute, regulation, or contract.
- Do not interfere with carefully defined contractual arrangements between Pfizer and an account, including by providing any items of value to SPP or account personnel other than as expressly stated in Pfizer's contract with the SPP or account.
- To avoid pricing concerns, do not combine discount arrangements with other types of transactions. Do not discuss discount arrangements under which an SPP or account 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 SPP or account – this applies to actual conversations with Accounts as well as written documents or presentations.
- Do not imply unstated performance requirements (including therapeutic conversion) in discount or non-discount (e.g., distribution or services agreements). In the event a SPP or account makes a statement(s) regarding switching patients in exchange for discounts or service fees, immediately refer such statement(s) to either the applicable global product counsel or Pricing & Access Legal for appropriate follow up.
- Do not leverage Pfizer's ability to purchase goods or services from a Customer in order to induce or influence the purchase, prescribing or recommendation of Pfizer products from that Customer. For example, do not condition the purchase of data from an account on formulary access for a Pfizer product.
- Do not interfere with the independent clinical judgement of HCPs (including prescribers and SPP clinicians) or offer any payments in exchange for patient referrals. Do not encourage SPP or account personnel to suggest to patients or a prescribing HCP that the patient should switch to a Pfizer product from their existing therapy.
- Do not interfere with the relationship between the patient and his/her HCP (including both prescribers and SPP clinicians).
- Do not steer or implement SPP or account arrangements to steer HCPs or patients to one particular SPP to the exclusion of other SPPs within a Defined SPP Network.
- Do not use 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.
- Always ensure you are paying FMV for the good or service based upon Pfizer's FMV analysis. Paying too much for a good, service, or data increases the risk that the arrangement may be viewed as a kickback.

- Consult your team attorney or [Pricing & Access Legal](#) for all arrangements covered under this Chapter 20. Pricing & Access Legal will ensure all arrangements are appropriately memorialized in a written contract and help mitigate compliance risks by structuring the non-discount arrangement so that it meets the applicable anti-kickback safe harbor (i.e., Personal Services safe harbor).

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. Pfizer is required to ensure all service agreements meet the Personal Services safe-harbor.

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.

Overview of Interactions with Specialty Pharmacies

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, distribution, and patient access to therapy. SPPs have also developed expertise in overcoming payer access challenges and have been shown to help improve clinical and economic outcomes for patients with complex, chronic, or rare conditions. SPPs employ health care professionals, including both pharmacists and nurses, provide patient education, help ensure appropriate medication use, and 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 discount arrangements. These arrangements are separate from the non-discount arrangements Pfizer enters into to procure services.

Pfizer enters into non-discount arrangements with specialty pharmacies to participate in Defined **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.

Types of Contractual Relationships Between Pfizer and SPPs

Non-Discount Arrangements

Defined Distribution Networks: Through distribution agreements, Pfizer contracts with certain SPPs that meet pre-defined and consistently applied objective inclusion criteria to dispense a particular Pfizer brand 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. Any Defined SPP Network must comply with all laws, regulations and administrative guidance, including; the 340B “Must Offer” requirements and the personal services and management contracts Safe Harbors to the Anti-Kickback Statute. Additionally, the network must comply with Pfizer internal policies and procedures. Defined SPP Network inclusion criteria are determined by the **Specialty Access Solutions (SAS)** COE and Pricing & Access Legal. All pharmacies seeking access to a Defined SPP 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. Such agreements are only entered into where there is a *bona fide* business and/or patient need for the services, for which payment is consistent with **Fair Market Value (FMV)**, and the services contracted are not part of a SPP’s Core Services. Supplemental Services must be: (i) non-promotional in nature; (ii) limited to patients with a prescription for a Pfizer Product consistent with an FDA-approved indication and dosing regimen; and (iii) transparent as to Pfizer funding.

All Supplemental Service arrangements with SPPs are developed by the SAS COE within Payer and Channel Access and must be approved by Pricing & Access Legal.

Discount Arrangements with SPPs

Separate from distribution or services agreements, Pfizer may engage in discount arrangements with SPPs, such as channel discounts. Such discount arrangements are negotiated by SAS **National Account Directors (NADs)**. Discount arrangements must be negotiated and contracted separately from distribution agreements or service agreements. Discount arrangements must not be contingent upon the performance of Supplemental Services. Certain SAS COE team members (i.e., Directors, Strategy and Innovation; Directors, Operations and Execution; and Directors, Analytics of the SAS COE) are specifically firewalled from discussions concerning SPP product discounts and should not participate in these discussions.

Materials Provided to SPPs

Pfizer may provide certain Pfizer-approved materials to SPPs for distribution to patients. Development of SPP-related materials is managed by the SAS COE and Pricing & Access Legal is responsible for the review of patient educational materials intended to be provided to/by the SPP. SPP materials must be educational in nature. Other than SPP welcome kits/ brochures, SPP materials must not contain Pfizer product brand names.

Privacy Requirements & SPP Data

Privacy laws also limit the scope of permissible activities that Pfizer may engage in when SPPs are interacting with patients on Pfizer's behalf. For example, the **Health Insurance Portability and Accountability Act (HIPAA)** and some state privacy laws restrict certain activities in which SPPs, and 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, SPPs and Accounts may implement such programs without securing patient authorizations; however, in such cases Pfizer and the applicable SPPs and 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 White Guide Chapter 11: Privacy: Protecting Personal Information. Please consult a [Pricing & Access attorney](#) or your team attorney if you have questions on the permitted scope of SPP or Account interactions and communications involving patients or clinicians.

Any patient data procured through a SPP Supplemental Services agreement must be de-identified, consistent with applicable privacy laws and regulations. Pfizer-sponsored SPP communications transmitted over telephone systems including any automatic dialing systems, artificial, or prerecorded voice

messages, SMS text messages, and fax communications, must comply with the **Telephone Consumer Protection Act (TCPA)**. These programs may not be implemented at an SPP until an executed contract is in place, and contracted activities may not commence until appropriate training and other on-boarding activities have been completed. Pfizer colleagues may not share any de-identified prescription data or other proprietary information such as Fingertip Formulary with Specialty Pharmacy personnel or prescribers.

Prohibitions on ROI Analysis. Pfizer prohibits personnel from conducting any analysis of SPP data or reports (e.g., **return on investment (ROI)** analysis that would violate applicable laws, regulations and/or company policies and procedures). To mitigate the risk of any impermissible analysis, no Pfizer personnel other than the SAS COE colleagues may calculate any measures of program impact on product utilization or financials or ROI.

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 **Specialty Access Solutions National Account Directors (SAS NADs)** serve as the primary Pfizer contact for Organized SPP Customers and work to support the engagement of SPPs through contracting activities, contract implementation, and SPP program onboarding, among other things. A listing of such Organized Customers can be found at the SPP Engagement Matrix at this [link](#). SAS NADs also manage relationships through aggregators that contract with the non-Organized SPP 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 Networks (IDNs)** or academic medical centers that are approved to dispense Pfizer brands. These institutions may be supported by KAMs or similar Account Management roles. 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 Pricing & Access Legal before engaging with SPP personnel. The process for obtaining such approval is set forth below.

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 HCPs or others (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 below, 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. If 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.

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.

Approval Process for Sales Representative Interaction

Field Commercial Colleague SPP Interaction Approval Process

To ensure that commercial colleagues' interactions with SPPs are consistent with these principles, a team seeking approval for such interactions must obtain approval from their global product counsel, Pricing & Access Legal and for organized SPPs the Payor Channel Access team. Among the factors to be considered are:

- The duration and frequency of these interactions;
- The training requirements associated with the SPP engagements; and
- The risk mitigation strategies and tactics associated with these interactions.

Requests for approvals must be reviewed periodically. Periodic renewal of the required approval will help to ensure that the factors on which the initial approval was based still exist, and that sufficient guidance, training, and monitoring are in place. As with other field-based roles, colleagues partaking in such activities may be subject to ongoing monitoring, field rides, and audits.

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

- For more information about HIPAA, see White Guide Chapter 11: Privacy: Protecting Personal Information.
- General Questions regarding this chapter should be referred to your manager and/or the Pricing & Access Legal Team.
- Orange Guide – Chapter 12: Discount Arrangements and Contracting.
- Orange Guide – Chapter 15: Service Agreements and Other Non-Discount Arrangements with Accounts.
- Orange Guide – Chapter 20: Special Types of Services Agreements – Interactions with Specialty Pharmacies.



CHAPTER #21 – PATIENT SUPPORT ROLES

Chapter**#21****Patient Support Roles**

CONTENTS

Patient Support Roles

Introduction	360
Patient Support Role Descriptions	360
Field Reimbursement Managers (FRMs)	360
Field Access Specialist and Patient Access Coordinators (PAC)	361
HCP-Facing Clinical Educators (CEs)	361
Patient-Facing Clinical Educators (CEs)	361
Patient Affairs Liaisons (PALs)	362
Key Points to Ensure Compliance for Patient Support Roles	362
Guidance Principles for Patient Support Roles	362
Provide only Limited Support	362
Non-Promotional Nature of Patient Support Roles	364
Independence from Colleagues with Marketing or Sales Responsibilities	364
Educating HCPs and Patients about Patient Support Roles	365
Appropriate Selection of Patient Support Role Customers/Audiences	365
Patient Support Role Creation Process and Approval	366
Contract Patient Support Organization	367
For More Information	367

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”). Patient Support Roles are field-based, external-facing roles that seek to expand access to, reimbursement of, and education about Pfizer products in a non-promotional manner. As of this Chapter’s publication, Patient Support roles include **Field Reimbursement Managers (FRMs)**, **Field Access Specialists (FAS)**, **Patient Access Coordinators (PAC)**, **Clinical Educators (CEs)** and **Patient Affairs Liaisons (PALs)**. Although Patient Support Roles may sit in the commercial business, they are separated from the sales and marketing organization and are not intended to promote Pfizer products. This Chapter provides guidance for teams who interact with, and colleagues who directly and indirectly manage, Patient Support Roles, and supplements applicable policies and procedures including the [Blue Book](#) and the Orange Guide Chapter 21.

To ensure compliance with applicable laws, the following principles govern 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 product.

Patient Support Role Descriptions

As of the writing of this Chapter, the Patient Support Roles include the following:

Field Reimbursement Managers (FRMs)

FRMs are subject-matter experts on reimbursement, access, and coverage issues affecting Pfizer products. They 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 after a script for a Pfizer product has been written for the patient. 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 societies and associations meetings to keep apprised of reimbursement and coverage

Rev. 12/21

Page 360 of 381

developments that may affect Pfizer products. FRMs can also coordinate with Pfizer Hubs concerning individual patient cases, where the patient is receiving reimbursement support services (non-PAP). In addition to this chapter, FRMs should consult role- and/or BU specific guidance on their activities and interactions.

Field Access Specialist and Patient Access Coordinators (PAC)

The FAS are field reimbursement colleagues subject to the same FRM guidance outlined in this Chapter. FRMs and FAS are collectively referred to “Field Reimbursement Colleagues” throughout this Chapter. FAS may engage in the same limited reimbursement support activities as the FRM, along with proactive outreach to hubs and HCPs related to reimbursement support services only. FAS also may work with Patient Access Coordinators or “PACs”, colleagues who interface directly with patients to provide limited reimbursement support. FAS and PAC may communicate with the hub access counselors to review new hub enrollments and identify pending actions for new cases (excluding any PAP related activity), including outlining missing information and who will conduct outreach to address. Communications between FAS, PAC and the hub may only relate to patients with a signed PAC opt-in. For patients who have opted-in to receive support, PACs may make a proactive welcome call to explain the hub enrollment process and timing, follow up on missing information for non-PAP cases, and reactively address patient questions either by sharing approved information found in their CRM or transferring patients to the hub. The data and information that FAS and PAC require for communications with customers must reside only a secure legal approved platform. FAS and PAC may not share case notes with other colleagues, unless designated as a back-up in the CRM to cover for a counterpart’s leave or vacation. Teams may elect to have either FAS or PACs only to provide reimbursement support, depending on the specific access needs for the relevant patient population. The two roles are not required to be deployed together. In addition to this chapter, FAS and PACs should consult role- and/or BU-specific guidance on their activities and interactions.

HCP-Facing Clinical Educators (CEs)

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 Clinical Educators (CEs)

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)

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.

Key Points to Ensure Compliance for Patient Support Roles

- Patient Support Roles may provide only Limited Support
- Support may not replace services HCPs would otherwise conduct or pay office staff or a third party to perform.
- Activities must be connected to a Pfizer product, and may not constitute routine business support or address practice-level issues.
- Patient Support Roles are non-promotional:
 - They may not engage in promotional activities;
 - Patient Support Roles must remain independent from and may not be directed by HQ and Field Commercial Colleagues with sales marketing or sales responsibilities; and
 - Patient Support Roles may not be used to promote or differentiate Pfizer or its products.
- Patient Support Roles activities and materials must be on-label.
- Ensure Patient Support Roles, materials and tactics protect patient privacy.

Guidance 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 the purchase, prescription, endorsement, or recommendation of 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 physicians to prescribe Pfizer products. To

mitigate this risk, Patient Support Roles must never offer patients 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 or expenses that the HCP, patient, or caregiver would otherwise incur may be seen as providing independent value and are therefore prohibited. See the below chart for examples of prohibited activities that 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, PACs, CEs and PALs may not provide “on call” medical services and are prohibited from providing medical advice to HCPs, patients or caregivers. Patient-Facing PACs, 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.

Field Reimbursement Colleague Individual Patient Benefit Investigation

	Can a FRC conduct a benefits investigation for an individual patient?
	<p>Yes, when appropriately trained, the FRC 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. FRCs 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. FRCs must also be sure to respect patient privacy. The FRC must confirm that the patient has authorized the FRC’s involvement, and the FRC 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.</p>

Non-Promotional Nature of Patient Support Roles

Patient Support Roles, while externally-facing roles, are prohibited from promoting Pfizer products. To remain non-promotional, Patient Support Roles must ensure their activities and interactions, with both external parties and internal colleagues, are not, and do not appear, promotional.

FRMs, FAS, and PAC must not promote or detail any Pfizer product, and must not discuss clinical product information with HCPs or office staff. 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. Therefore, Patient Support Roles' RC approved materials may not contain promotional claims about Pfizer products. Rather, Patient Support Role materials should be narrowly tailored to supporting patient access to and education about Pfizer products. All Patient Support Role activities and materials must be on-label.

In addition, Patient Support Role activities must not have promotional tactics, goals or objectives. Patient Support Role operating plans, tactical plans and goals must 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 must not be measured by prescription, sales, or revenue generation. 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.

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.

Independence from Colleagues with Marketing or Sales Responsibilities

To remain non-promotional, Patient Support Role activities must be independent from promotional activities and influence. Patient Support Role activities may not be directed by Pfizer colleagues with sales or brand sales marketing responsibilities. Consistent with this, Patient Support Role managers (the "Patient Support Role Team Lead") and managers of Patient Support Role Team Leads, should not have any sales or brand sales marketing responsibilities. Marketing materials created for Patient Support Roles should come from dedicated Market Access marketers and must be RC-approved. Teams seeking to create Patient Support Roles should work with Legal Division to ensure appropriate reporting lines.

Patient Support Roles must limit their interactions with colleagues who have sales and marketing responsibilities. See the Orange Guide Chapter 21 for more information.

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 must 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. 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. Teams may create materials for the purpose of educating HCPs and patients about Patient Support Roles, their availability and how they can facilitate patient access to and education about Pfizer products. However, such materials should not “promote,” make claims about, or position Patient Support Roles as providing “value” to or conducting “services” for the HCP or staff. And all such materials should be reviewed and approved by the applicable RC. Discussion of patient support roles should occur after a promotional detail and Sales Colleagues may not return to a promotional discussion.

Appropriate Selection of Patient Support Role Customers/Audiences

Patient Support Roles must not have off label discussions and should 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 HCPs with whom Patient Support Roles engage, Sales Colleagues and Account Managers can notify the Patient Support Role Colleague manager via the PACE app 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 or FAS, the Sales Colleague may alert the FRM or FAS lead via the PACE app, and the lead will triage the issue to the assigned FRM or FAS to. In such instances, the Sales Colleague should not collect or transmit any personal health information. 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.

Patient Support Role Creation Process and Approval

To ensure that Pfizer's Patient Support Role activities are consistent with these principles, a team seeking to create a Patient Support Role or make a material change to an existing Patient Support Role must obtain approval from the Pfizer Legal Division. Legal will evaluate the risks and benefits of implementing the role or its proposed activities. Among the factors to be considered are:

- How, consistent with its non-promotional nature, the Patient Support Role will support access to the Pfizer product;
- The relative efficacy, safety, and cost of the Pfizer product;
- The clinical appropriateness of any increased utilization that may result from the proposed Patient Support Role activities;
- Whether, when viewed independently or in connection with other relevant Pfizer offerings, the proposed Patient Support Role activities could constitute independent value to an HCP, patient or caregiver; and
- The need for and feasibility of any risk mitigation strategies and tactics.

Patient Support Role approvals must be renewed periodically. Periodic renewal of the required approval will help to ensure that the factors on which the initial approval was based still exist, and that sufficient guidance, training and monitoring are in place. The frequency with which approvals must be renewed will be set forth in more detailed guidance governing the process to approve Patient Support Roles. As with other field-based roles, colleagues in Patient Support Role activities will be subject to ongoing monitoring, field rides and audits.

The Legal Division will create a process to facilitate the review and approval of team requests to create or materially change an existing Patient Support Role and renew approvals as necessary. Contact your team attorney or [Pricing & Access Legal](#) for more information on the approval and renewal process.

Contract Patient Support Organization

Pfizer may contract with vendors to carry out Patient Support Role activities. In addition to business factors, Vendors should be selected based on their reputation for compliance and ability to facilitate robust training and self-monitor activities. Patient Support Role vendors will be expected to: (i) comply with all applicable Pfizer policies and state and federal laws and report any deviations thereof; (ii) participate in any trainings deemed necessary by Legal and Compliance; and (iii) complete any training or compliance certifications deemed necessary by Legal or Compliance. All vendor personnel involved in the execution and management of Patient Support Roles must be trained on the legal principles and relevant Pfizer policies governing their role prior to participating in such activities.

Vendors must execute a contract with Pfizer prior to carrying out any activities on Pfizer's behalf. The contract must adequately set forth vendor's business and compliance obligations. Any compensation to which the vendor may be entitled must be fair market value for bona fide services. Vendor compensation may not consider the number of prescription or referrals the vendor's activity may generate. Teams seeking to hire vendors to carry out Patient Support Role activities must work with Procurement and the Legal Division, and submit to any process supporting, vendor selection and hiring.

Teams seeking to create a Patient Support Role should work with their Global Product Counsel and Pricing & Access Legal to help ensure compliance.

For More Information

- For more information, see the Orange Guide: Chapter 21 - Patient Support Roles.
- Refer any questions to your manager, Legal or Compliance.



CHAPTER #22 – INDEPENDENT MEDICAL GRANTS

Chapter**#22****Independent Medical Grants**

CONTENTS

Independent Medical Grants

Introduction	370
Key Points to Ensure Compliance	370
Investigator Sponsored Research	372
Scientific Validity	372
Nature and Basis of Pfizer Support	373
Independence and Investigator Responsibilities	374
Regulatory and Ethical Framework	375
IND Requirements	375
Institutional Review Board (IRB)/Independent Ethics Committee (IEC) Approvals	375
Publication of ISR Study Results	376
General Research Grants	376
General Research vs. ISR Grants	376
Independent Quality Improvement and Medical Education Grants	377
Overview	377
Application Submission	378
Application Review, Notification, and Payment	378
Pfizer May Not Influence Grant Funded Activities	379
Promotional Opportunities at Medical Education Conferences	380
Complimentary Exhibit or Display Space	380
For More Information	381

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. Independent Medical Grant types include:

- **Investigator Sponsored Research (ISR)**
- General Research
- Quality Improvement
- Independent Medical Education

Key Points to Ensure Compliance

Pfizer's IMG processes 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 areas of program scope.

Interactions between Pfizer and requesting organizations must be conducted in a manner that ensures independence of the research, project or activity that is being supported. Pfizer colleagues must not control or influence the development or content of an IMG request or the resulting research, project, initiative, or medical education activity.

Pfizer's evaluation of an IMG request must not be influenced by a grant requester's or grantee's, or their organization's generation of past or potential future business for Pfizer but is determined solely by the required evaluation of the components of the proposal (e.g., scientific merit of the grant, potential grantee's qualifications to conduct the proposed activities described in the grant request). Pfizer does not provide IMGs based upon past, present, or future prescribing, purchasing, or recommending of Pfizer product(s) by HCPs or healthcare organizations.

A grant must never be offered or provided as an inducement to approve, reimburse, prescribe, purchase, or recommend a Pfizer product or to influence the outcome of a clinical trial, or to improperly benefit Pfizer's business activities.

The amount of financial support must be appropriate relative to the nature of the research or program and not dependent on Pfizer's relationship with the grant requester or their organization.

Pfizer does not accept tangible benefits (e.g., goods or services) in return for supporting a grant. Refer to USFR-SOP-03-01 and R&D SOP 202 for information on requirements and process for external funding requests involving receipt of tangible benefits.

Pfizer does not own the results (e.g., data) or end product (e.g., medical device) developed as a result of the grant.

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, 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 should not 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 colleagues should not be involved in the design, conduct, supervision, management, or monitoring of any study/project/education that is supported by an IMG. Such actions would be out of compliance with the SOP governing IMGs,

GNT01-GSOP – Independent Medical Grants. In addition to the above risks, involvement of Pfizer colleagues in these initiatives could result in Pfizer becoming subject to liability for the study generally and/or for ensuring regulatory compliance of the study.

Investigator Sponsored Research

ISR grants, by definition, are those grants that support research that involves a Pfizer asset. Either the grant includes investigational product (e.g. drug, vaccine, medical device) and/or the intent of the research is to study a Pfizer therapy. Pfizer accepts proposals for ISR grants submitted by interested investigators and institutions through its online web portal. Investigators may propose **clinical studies** of approved and investigational uses of marketed products, or investigational Pfizer compounds and devices; **in vitro** or **animal studies**; **observational studies**; or other types of **independent research on disease states**. Pfizer cannot support requests that involve ongoing or pre-existing research projects. To ensure Pfizer receives all necessary information, Pfizer requires the investigator to submit requests through the **Global Medical Grants System (GMGS)** at <https://www.pfizer.com/purpose/independent-grants>.





Pfizer Medical (non-Commercial) and Research teams may also choose to implement a **Competitive Grant Program** for research relating to a particular product, disease, or area of scientific inquiry. These programs typically have a defined set of research criteria and are limited to a certain timeframe. They are publicized broadly to a specific audience via professional journals or websites and typically have an expert review panel make final grant decisions.

- The recipients of ISR study support must be chosen on the basis of the merits of their research proposals and their scientific qualifications.
- An asset's or product's ISR strategy is determined by the Medical Asset or Medical Affairs Leadership. Commercial colleagues may not attend strategy development meetings or otherwise influence or participate in the decision to fund an ISR study. Refer to Refer to GNT01-GSOP – Independent Medical Grants for additional guidance on ISR strategy determination.



Scientific Validity

Grant request reviewers, Pfizer colleagues representing various aspects of expertise, review ISR proposals for medical and scientific merit and study feasibility. Grant request reviewers consider the investigator's qualifications, including his or her experience, training, and capability to perform all sponsor responsibilities such as filing for any necessary regulatory approvals. The ISR investigator must agree, in accordance with standard industry grant agreement terms, to provide Pfizer with a copy of final study results and any resulting publications for Pfizer's review. All information related to an approved ISR grant, including the scientific rationale for support, is documented in the **Global Management System (GMS)**. Reviewers and Approvers must record their assessment and decision to approve or reject a request directly in GMS. There is no option to conditionally approve a grant request.

ISR Support

	<p>Can a Pfizer colleague provide information on how to request an ISR grant?</p>
	<p>Yes, colleagues can provide information on how to request an ISR grant, but they cannot assist an HCP with the development of the protocol or the grant application. Pfizer posts Areas of Interest on the Independent Grants section of Pfizer.com, so colleagues should direct HCPs to the website if they have questions about grant support. In addition, Pfizer also publishes Requests for Proposals through our Competitive Grants Program, and HCPs can respond if they choose.</p>
	<p>Can Pfizer support an ISR grant request involving an off-label use of a Pfizer product?</p>
	<p>Yes. Research involving investigational use for an unapproved indication is not considered “off-label” use of a Pfizer product and would be eligible for ISR support only if the proposed research is intended to provide valuable scientific or clinical information, improve clinical care, lead to new or improved treatments, or otherwise benefit patients. Any decision to support such a proposal must be based on the scientific merits of the proposal and must not be an attempt to influence the HCP’s prescribing behavior. Pfizer may only support ISR requests and associated investigators based on their credentials and research capabilities. Colleagues may respond to an HCP’s unsolicited questions about the process for ISR requests but should not proactively encourage or seek out ISR proposals for any reason.</p>

ISR Support

	<p>Could our clinical personnel help an ISR applicant with a proposed protocol?</p>
	<p>No, Pfizer must not be involved in any aspect of study protocol or project development, nor the conduct or monitoring of the research/quality improvement program. For ISR grants that include a Pfizer asset, or the research is assessing a Pfizer asset, medical colleagues may provide feedback on an ISR request solely for the purposes of: (1) safety assessments and safety reporting, including study drug dosing and handling, or (2) describing why a specific ISR request was denied. Medical colleagues can also discuss research and quality improvement areas of interest, track study progress and require, minimally, a study status report twice per year.</p>

Nature and Basis of Pfizer Support

An ISR grant may include **Pfizer product** (including marketed or investigational products, finished goods, and/or pure substance), **funding**, or **both product and funding**. ISR grants are only provided to support

Rev. 12/21

Page 373 of 381

specified, prospectively approved research projects. ISR grants may not be provided to support general research, educational or training programs, or studies being conducted on behalf of Pfizer nor where services are being provided for Pfizer's benefit, such as development of software, technology, or methodologies to which Pfizer would be granted ownership. In accordance with customary industry intellectual property practices, Pfizer might require certain non-exclusive license rights to Pfizer product-related inventions arising from Pfizer grant funding. ISR grants may not support studies that would involve or are intended to assist Pfizer with new product registration, a change in Pfizer product labeling, or other regulatory approval efforts.

Refer to [GNT01-GSOP](#) – Independent Medical Grants and [CMCD CT44-GSOP: Clinical and Research Collaborations](#), for additional details.

Further, when considering ISRs for a given asset program, it should be understood that Pfizer does not own the data and therefore cannot use study results for promotion. Brand teams, however, may seek RC approval for promotional use of a published ISR study reprint, if it meets the guidelines outlined in [White Guide Chapter 2: Advertising and Promotional Materials](#).

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

Funding for an ISR study must represent fair market value for the activities being funded, including applicable institutional overhead. As part of Pfizer's review of an ISR study proposal, the Grant Approver must assess the reasonableness of the study budget.



Pfizer support can only be provided once an ISR agreement has been fully executed and Pfizer has received all of the required documents outlined in the agreement.

Independence and Investigator Responsibilities

All ISRs must follow [GNT01-GSOP – Independent Medical Grants](#) requirements. Since ISR grants support independent research, all ISR 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. Pfizer may provide feedback on an ISR proposal solely for the purposes of: (1) safety assessments and safety reporting, including study drug dosing and handling; or (2) describing why a specific ISR proposal was denied. Pfizer can also discuss research areas of interest, track study progress and require, minimally, a study status report twice a year. For any studies undertaken by a third-party researcher where Pfizer is collaborating on clinical study design, conduct, or

data analysis, or where Pfizer intends to use and rely on the data, [CMCD CT44-GSOP Clinical Research Collaborations](#) applies, not [GNT01-GSOP – Independent Medical Grants](#).

Safety Information & Adverse Event Monitoring – ISRs

	<p>Are Pfizer study teams obligated to report safety information from an independent ISR study? Can the ISR sponsor choose what type of information to report to regulatory authorities?</p>
	<p>Study sponsors cannot choose what safety information they report to regulatory authorities. The ISR sponsor is required to record and evaluate all safety information received from any source and provide expedited reports to regulatory authorities and Pfizer of adverse events that are both serious and unexpected. However if a Pfizer colleague becomes aware of an adverse event, Pfizer must also report it in accordance with CMCD AEM01-POL: Adverse Event Monitoring (AEM) System. For ISRs, all investigators, IRBs and IECs, as well as the relevant regulatory authorities, should be immediately informed of significant unanticipated problems such as new safety information. If significant safety information is discovered after study participants have agreed to be involved in the study, the study participants must be provided this new information, regardless of whether it may affect their willingness to continue to be involved in the study.</p>

Regulatory and Ethical Framework

IND Requirements

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

Institutional Review Board (IRB)/Independent Ethics Committee (IEC) Approvals

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

Publication of ISR Study Results

Pfizer supports the exercise of academic freedom and encourages investigators to publish the results of ISR studies, whether or not the results are favorable to a Pfizer product. As with sponsored studies, Pfizer may request an opportunity to review proposed publications or other public disclosures of the results in advance to prevent inadvertent disclosure of Pfizer proprietary information. Pfizer may request a delay in publication, if necessary, to protect intellectual property rights. Pfizer also expects the investigator or institution to comply with recognized ethical standards concerning publications and authorship, including the disclosure of Pfizer support of the study in any publication of study results. Note that it is not permissible for Pfizer to author, contribute to the content or edit a manuscript that is based on an independent investigator-sponsored clinical study supported with an ISR grant.

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

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.

**NOTE:* Fellowships supported by GMG use RFPs under the GMG Competitive Grants Program with final decisions rendered by Expert Review Panels. To support unsolicited fellowships (i.e., those funding requests to support fellowships initiated by organizations, and not initiated by Pfizer), colleagues should refer to their divisional external funding SOP.

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 [GNT01-GSOP – 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. Pfizer colleagues may not submit a request on an investigator's behalf. Since General Research grants do not involve a Pfizer asset, grantees are not obligated to report Adverse Events to Pfizer, but they are required to record and evaluate all safety information received from any source and provide expedited reports to regulatory authorities of adverse events that are both serious and unexpected. However if a Pfizer colleague becomes aware of an adverse event, Pfizer must also report it in accordance with [CMCD AEM01-POL: Adverse Event Monitoring \(AEM\) System](#).

Independent Quality Improvement and Medical Education 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 accredited **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 Proposals (RFP)** prepared by GMG in collaboration with Expert 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 Expert 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. 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 Expert 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 www.pfizer.com/independentgrants , or the dedicated e-mail address GMG@pfizer.com .

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

Colleagues 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 (FMV). From time to time the 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 equally offered to all potential exhibitors.

For More Information

- More information on Independent Medical Grants can be found on the GMG website, www.pfizer.com/purpose/independent-grants.
- For more information on SOPs please refer to the [goFindIt portal](#).
- Questions may be referred to GMG, a Medical colleague, your manager, or Pfizer Legal counsel.