



The White Guide

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The White Guide

Pfizer is committed to our purpose of breakthroughs that change patients' lives, which includes upholding the highest standards when we interact with physicians, healthcare organizations (HCOs), patients, and other stakeholders.

Pfizer takes compliance very seriously and expects every colleague to do the same. Because you are accountable for understanding and meeting our company's compliance requirements, it is essential that you have a clear understanding of the contents in *The White Guide*.

The White Guide is designed specifically for United States (U.S.) Colleagues to help ensure that your activities comply with the laws, regulations, guidance, industry codes, any applicable Corporate Integrity Agreements (CIAs), and State Attorneys General Agreements that govern our actions.

In addition, *The White Guide* is not intended to cover every activity or issue that may present itself. Therefore, if an activity is not specifically prohibited by *The White Guide*, it does not mean it is permissible or compliant. As a result, you are expected to apply the principles in *The White Guide* broadly and seek guidance from your manager or Compliance if you have a question.

Furthermore, *The White Guide* is regularly updated to help ensure that we meet or exceed the complex and evolving legal, regulatory, and industry requirements in our business as well as the expectations of patients and providers.

Non-compliance with the policies contained in *The White Guide* could 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.

Speak Up

Acting with integrity requires that colleagues promptly disclose potential violations and cooperate with investigations of possible violations. Every colleague is expected to **Speak Up**, which means that if you reasonably believe that an employee has violated the law or Pfizer policy, you have a duty to report that information immediately via the following channels:

- Manager or Another Manager
- Human Resources
- Legal
- Compliance
 - Via the Compliance Helpline at **866-866-7349** or pfizer.ethicspoint.com
 - Via e-mail at corporate.compliance@pfizer.com
 - Via telephone at **212-733-3026**
- Office of the Ombuds
 - Via telephone at **1-855-PFE-OMBD (1-855-733-6623)**
 - Via e-mail at ombuds@pfizer.com
 - Via the website at <http://ombuds.pfizer.com>

In addition, Pfizer has open door, anti-retaliation, and confidentiality policies to encourage and protect all Pfizer Colleagues who raise valid concerns.

Furthermore, if you are involved in a compliance investigation in any capacity, such as serving 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 Compliance.

And finally, if the application of any policy is unclear to you, discuss the issue with your manager or Compliance. To learn more and access tools and resources that will help you to act with integrity, visit integrity.pfizer.com.

In closing, remember that our company values are Courage, Excellence, Equity, and Joy. By acting with integrity every day and always embodying these values, we believe we will make great progress in leading the conversation and becoming known as the most patient-centric company.

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Section 1

Laws and Regulations Governing Commercial Activities

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Laws and Regulations Governing Commercial Activities

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[Click here to visit the Glossary and Acronyms.](#)

Chapter 1: 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 and regulations builds trust with patients, Healthcare Professionals (HCPs), institutions, purchasers, and the government. These include but are not limited to:

- Key Healthcare Laws
 - Anti-kickback laws
 - Safe harbors from the Federal Anti-Kickback Statute
 - Federal healthcare program laws and regulations
 - False Claims Act (FCA)
 - Food and Drug Administration (FDA) laws and regulations
 - Federal and state pharmaceutical disclosure/transparency and compliance laws
- Other Relevant Laws and Regulations Related to Field Activities and Customer Interactions
 - State laws
 - State Consumer Protection laws
 - Privacy laws
 - Foreign Corrupt Practices Act (FCPA)
 - Lobbying
- Industry Codes, Guidance, and Government Agreements
 - Pharmaceutical Research and Manufacturers of America (PhRMA)
 - Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers
 - Pfizer's Corporate Integrity Agreements (CIA)
 - Pfizer's State Attorneys General agreements

All Pfizer Colleagues must understand how the laws, regulations, guidance, and industry codes covered in this section provide the basis for Pfizer's compliance program and are woven throughout Pfizer policies.

Chapter 2: Summary of Key Healthcare Laws

Federal and State Anti-Kickback Laws

Healthcare Professionals' (HCPs') treatment decisions or other Pfizer customers' business 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, reduce the overutilization of services, and prevent patient harm.

Anti-kickback 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 for an individual or entity to ask for or receive a payment in exchange for prescribing or recommending a product or service that is reimbursed by the government.

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—such as consulting services—of an HCP or other customer at a fee above the reasonable, [fair market value \(FMV\)](#) for such services in exchange for prescribing or giving favorable treatment to a manufacturer's drug
- Providing valuable services for free or below FMV to an HCP or other customer with intent to induce prescriptions for a manufacturer's products

United States (U.S.) law also provides for the imposition of civil monetary penalties against any person who offers or transfers [remuneration](#) to a beneficiary of a state or federal healthcare program, such as Medicare or Medicaid, which is likely to influence that beneficiary's selection of a particular provider or supplier of a healthcare product or service that will be reimbursed by a federal healthcare program.

Remuneration can be anything of value provided to induce business. In certain states, relevant anti-kickback laws also punish **remuneration** to induce business that is payable by a commercial insurer, not just government-funded healthcare plans. Accordingly, 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.

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 \(HHS\)](#) and the [Office of Inspector General \(OIG\)](#) has defined certain [safe harbors](#).

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

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- **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 FMV 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

Activities that fall entirely within a safe harbor do not violate the Federal Anti-Kickback Statute. However, just because an activity is not clearly within a safe harbor does not mean it is necessarily illegal. Legal should be contacted to discuss each arrangement or activity that potentially implicates the Anti-Kickback Statute before such activity is executed.

Key Food and Drug Administration (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 how we engage with our customers, so all Pfizer Colleagues must understand the basic rules we must follow to ensure compliance with FDA laws and regulations.

The FDA Laws and Regulations related to Promotional Labeling, Advertising, Starters, and the Reporting of Adverse Events and Other Product Safety Information are highlighted below.

Overview of Requirements for Promotional Labeling and Advertising

FDA's Office of Prescription Drug Promotion (OPDP) and **FDA's Advertising and Promotional Labeling Branch (APLB)** regulates promotional labeling and advertising of Pfizer products.

Promotional labeling, generally, refers to printed, audio, or visual communications descriptive of a drug that are devised for the marketing and promotion of the product. Examples of promotional labeling include brochures, letters, detail aids, websites, social media content, exhibits, publication reprints, speaker programs, and verbal statements by sales representatives in a promotional setting.

Advertisements generally include paid placements in journals, magazines, other periodicals, newspapers, and **advertisements** broadcast through media such as radio, television, and telephone communication systems.



All Pfizer promotional materials, whether in print or electronic form—and including all visual aids, brochures, journal advertising, promotional programs, and other sales aids—**MUST**:

- Be truthful, accurate, and not misleading
- Be consistent with the product's FDA-approved labeling
- Be supported by [substantial evidence](#)
- Include a fairly balanced presentation between efficacy and risk information
- 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
- Adhere to additional specific requirements based upon:
 - The medium
 - Is it a broadcast communication or a journal or magazine advertisement?
 - The purpose

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	<ul style="list-style-type: none"> ▪ Is it a reminder or full product communication? – The warning ▪ Is there a boxed warning?
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Generally, most promotional labeling and advertising will include the following:

- Proprietary (Brand) name and established (generic) name
- Risk disclosures such as Boxed Warning, contraindications, warnings/precautions, and side effects via:
 - Important Safety Information in promotional labeling
 - Major statement in broadcast advertisements
 - Consumer Brief Summary for consumer print advertisements
- Full indication(s), including limitations of use where applicable
- At least one dosage form and strength, including quantitative amounts of active ingredients in combination products
- Name of company responsible for marketing the product and its agent or co-promote partner
- Provision for access to:
 - Full PI for promotional labeling communications
 - Professional Brief Summary for HCP-facing journal advertisements
 - Consumer Brief Summary for consumer-facing print (newspaper/magazine) advertisements
 - Adequate provision for broadcast advertisements

Reminder promotion and reminder advertisements are exempt from providing access to the product’s full FDA-approved PI. Reminder promotional communications are only permitted for products without a Boxed Warning, with a limited exception for “price reminders.”

Help-seeking or disease awareness communications discuss a particular disease or health condition and do not mention or make any representation or suggestion of a Pfizer product.

Pfizer strongly encourages the use of Consumer-friendly language in consumer-directed materials.

Additional information regarding requirements for promotional labeling and advertisements is summarized in the following table. Colleagues may also consult with a member of the Brand Regulatory Team for further guidance regarding requirements for promotional labeling and advertisements.

Promotional Labeling and Advertisement Requirements		
Type	Description	Requirements and Guidance
Product Name	<ul style="list-style-type: none"> • The disclosure of the product name in promotional labeling and advertisements is important for proper identification and for ensuring safe and effective use 	<ul style="list-style-type: none"> • Requirements for product name are available in FDA Guidance for Industry Product Name, Placement, Size, and Prominence in Promotional Labeling and Advertisements
Communication of risk information in promotion	<ul style="list-style-type: none"> • Guidance on how FDA evaluates prescription drug and medical device promotional pieces to determine whether they adequately present risk information 	<ul style="list-style-type: none"> • Guidance for communication of risk information in promotion is available in FDA’s Guidance for Industry Presenting Risk Information in Prescription Drug and Medical Device Promotion

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Promotional Labeling and Advertisement Requirements		
Type	Description	Requirements and Guidance
Reminder labeling or reminder advertisements (“Reminders”)	<ul style="list-style-type: none"> Promotional communications that call attention to the name of the drug product but do not include indication or dosage recommendations for use of the product 	<p>Reminders:</p> <ul style="list-style-type: none"> May include dosage form and strength, pricing information, and/or formulary coverage Are exempt from labeling requirements Are permissible for products that do not contain a Boxed Warning in FDA-approved full PI <ul style="list-style-type: none"> Requirements for “reminder-like” promotional communications for products with a Boxed Warning are available in the Pfizer guidance, Treatment of Boxed Warning in Advertising and Promotional Labeling <p>Reminders MUST NOT:</p> <ul style="list-style-type: none"> Make a representation about the product or suggest a use for the product
Major statement	<ul style="list-style-type: none"> The summary of the product’s most important risk information in consumer-friendly language communicated in broadcast advertisements 	<ul style="list-style-type: none"> Major statements are crafted with input from FDA’s OPDP or APLB through responses to request for advisory comments
Adequate provision	<ul style="list-style-type: none"> The approach for allowing an audience to have reasonably convenient access to the product’s FDA approved labeling 	<ul style="list-style-type: none"> For information about adequate provision and other aspects of broadcast advertisements, see FDA Guidance for Industry Consumer-Directed Broadcast Advertisements For Pfizer guidance regarding adequate provision and book of record, see the Pfizer Promotional Policy Committee (PPC) memorandum, “Adequate Provision” and the “Book of Record” in Broadcast Advertisements
Consumer Brief Summary	<ul style="list-style-type: none"> Generally derived from the Patient Package Insert (PPI) or Medication Guide Used in consumer print Direct-to-Consumer (DTC) advertisements and in some print promotional labeling materials 	<ul style="list-style-type: none"> For information about Consumer Brief Summary, see to the FDA Guidance for Industry entitled Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs For Pfizer guidance on Consumer Brief Summary, refer to the PPC memorandum, Labeling Requirements for Consumer Directed Print Material
Help-seeking or disease awareness communications	<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> FDA guidance related to help-seeking or disease awareness communications is available in Industry-Supported Scientific and Educational Activities

FAQ: FDA Submission of Promotional Materials	
	When do promotional materials need to be sent to the FDA?
	<p>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.</p> <p>In the case of drugs approved via the Subpart H accelerated approval process, or biologics and vaccines approved under Subpart E, however, Pfizer is not required to submit any materials to OPDP or APLB prior to first use.</p> <p>With that said, 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.</p> <p>Furthermore, pursuant to the Pharmaceutical Research and Manufacturers of America (PhRMA) Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines and FDA's draft Guidance for Industry Direct-to-Consumer Television Advertisements—FDA Amendments Act (FDAAA) DTC Television Ad Pre-Dissemination Review Program, Pfizer has committed to seek advisory comments on new television broadcast advertising campaigns.</p>

Starters (Samples)

The **Prescription Drug Marketing Act of 1987 (PDMA)** prohibits the sale, purchase, or trade of drug samples—which are called “starters” at Pfizer. It is illegal for any individual, including a physician, to sell or seek reimbursement for a free starter. Individuals who engage in or encourage such conduct are subject to criminal prosecution.

Furthermore, 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.

Finally, there are several state 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 about starters, refer to Section 3 of [The Orange Guide](#).

Reporting Adverse Events and Other Product Safety Information

The FDA requires companies to submit certain information to the agency for postmarketing adverse events. Pfizer defines an adverse event as any untoward medical occurrence in a subject, patient, or consumer administered a Pfizer product.

See below for Pfizer's Policy on Reporting Adverse Events and Other Product Safety Information.

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Description of Adverse Events and Product Safety Information at Pfizer

Safety reporting is an important responsibility at Pfizer. Pfizer Colleagues may become aware of **Product Safety Information** through a variety of ways such as:

- Routine work activities such as written or verbal communication with HCPs, consumers, and/or patients
- Pfizer-initiated programs such as market research or patient support programs
- Pfizer-sponsored digital media such as those that contain open text fields for responses
- Non-Pfizer media sources such as television, newspapers, magazines, websites, and social media
- Conversations that take place in casual social settings or work-related meetings such as Speaker Programs and detailing

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

Product Safety Information includes any information about the safety, quality, or performance of Pfizer products received from any source—which includes any non-prescription or prescription drug, biologic, biosimilar, medical device (including medical device combination products), vaccine, cosmetic, or food and dietary supplements.

There are four categories of Product Safety Information, listed below:

Types Of Information That Should Be Reported*		
Factor	Description	Examples
1. Adverse Events	<ul style="list-style-type: none"> • Any untoward medical occurrence in a subject, patient, or consumer administered a Pfizer product • All reports of Adverse Events should be forwarded, regardless of the seriousness of the event—whether or not there is a causal relationship with the Pfizer product and regardless of the event being mentioned in the product label/instructions 	<ul style="list-style-type: none"> • Abnormal test findings • Clinically significant signs and symptoms • Changes in physical examination findings • Progression/worsening of underlying disease • Lack of efficacy for a Pfizer product • Drug abuse or dependency • Death
2. Unexpected Therapeutic Effect	A beneficial therapeutic effect of a product aside from the use for which it was given	Patient takes a product for high cholesterol and notices decreased insomnia
3. Product / Medical Device Complaints	<ul style="list-style-type: none"> • Product Complaint: any written, electronic, or oral communication that alleges deficiencies related to the quality or physical properties, condition, package insert, and/or packaging of a product • Medical Device Complaint: any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, instructions for use, or performance of a medical device, including any medical device constituent part of a combination product, and/or Pfizer-sponsored medical software products that are regulated as medical devices—such as mobile apps, website functionality, and so forth 	<ul style="list-style-type: none"> • Blister pack arrived empty • Vial is leaking liquid • Syringe is jammed • Product is/may be counterfeit

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Types Of Information That Should Be Reported*		
Factor	Description	Examples
4. Circumstances That May Lead To Adverse Events	<p>Certain situations should also be forwarded whether or not there are any associated adverse events, including:</p> <ul style="list-style-type: none"> • Drug misuse • Extravasation • Drug overdose • Exposure during pregnancy or breastfeeding • Medication errors • Occupational exposure • Off-label use 	<ul style="list-style-type: none"> • Occupational Exposure: A hospital maintenance worker accidentally splashes a Pfizer medicinal solution in their eye while cleaning up • Off-label use: Product X is prescribed for a child with hypertension when Product X is approved for adult use only

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

How and When to Report Adverse Events and Product Safety Information

If Pfizer Colleagues become aware of reportable safety information, they must report it to the appropriate Pfizer contact within **24 hours of receipt**. All reports of safety information should be forwarded regardless of the seriousness of the event, whether or not there is a causal relationship with the Pfizer product and whether or not the event is mentioned in the product label/instructions.

- For product complaints **only**, colleagues should submit the report by:
 - Phone at **800-438-1985**
- For all other reportable safety information, colleagues should submit the report via any of these channels:
 - Phone at **800-438-1985**
 - E-mail to USA.AEReporting@pfizer.com
 - Pfizer Safety Reporting App (PSR) on their mobile device
 - Veeva Customer Relationship Management (CRM) from their iPad

Colleagues should include as much information as possible in the report, including:

- The HCP's name and contact information
- Details of the event and patient's details such as age, sex, or gestation period for pregnancy reports

Colleagues must not delay submission of their report even if they have only limited information available. If there is any uncertainty about whether the information is reportable, colleagues should submit the report. For further information about safety reporting responsibilities, refer to the [Your Reporting Responsibility](#) website.

Adverse Event Reporting and Privacy

HCPs are permitted to disclose [Protected Health Information \(PHI\)](#) to persons "subject to the jurisdiction of the FDA" for activities related to the quality, safety, or effectiveness of an FDA-regulated product or activity for which the person has responsibility. Also, HCPs are permitted to share PHI about their patients without a [Business Associate Agreement \(BAA\)](#) or patient authorization in limited circumstances.

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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](#).

To learn more about Privacy Laws and PHI, please refer to Chapter 3.

False Claims Act (FCA)

The government's increased role in purchasing or reimbursing for pharmaceuticals has heightened its attention to certain federal laws, including the **False Claims Act (FCA)**.

The 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 HCPs, and encouraging physicians to seek reimbursement from the government for free samples of prescription drug products.

- For example, if a pharmaceutical company paid a kickback to an HCP to prescribe its product, the government could allege that when the claim was submitted to the government to receive reimbursement for the product, the claim was false because the prescription 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 is not eligible for reimbursement.

- For example, if a pharmaceutical company engages in off-label marketing, that could trigger a physician to write a prescription for an off-label use, leading a pharmacist to fill the prescription and then seek reimbursement for the off-label prescription. In so doing, the government's argument would be that the pharmaceutical company has "induced" another party to submit a false claim, resulting in an alleged violation by the pharmaceutical company

Laws and Regulations Governing Purchase or Reimbursement of Medicines by Federal Health Care Programs

Paying or providing benefits to HCPs or beneficiaries to prescribe or use products ultimately reimbursed by federal healthcare programs potentially implicates the federal Anti-Kickback Statute and state all-payer laws, which are state anti-kickback laws that apply to both commercial and government healthcare programs.

In addition, a failure to provide the government with preferential pricing in certain situations may expose a manufacturer to liability under various federal and state laws. Accordingly, pharmaceutical manufacturers provide:

- Preferred prescription drug pricing to federal customers via the Federal Supply Schedule (FSS) and to specific federal purchasers, including the [Department of Veterans Affairs \(VA\)](#) and the [Department of Defense \(DoD\)](#), as required by statute
- Discounts under the Public Health Services (PHS) 340B Drug Pricing Program, as well as through certain state-supported programs, including State Pharmaceutical Assistance Programs (SPAPs) and AIDS Drug Assistance Programs

Furthermore, since many federal healthcare programs such as Medicaid and Medicare purchase prescription drug products or reimburse for their purchase, there are specific implications for pharmaceutical manufacturers related to these programs.

Please see Chapter 3 for more details on Government Healthcare Programs.

Disclosure and Transparency Laws

Open Payments is a national disclosure program from the Centers for Medicare & Medicaid Services (CMS) that promotes a more financially transparent and accountable healthcare system. It emerged after Congress enacted the **Physician Payments Sunshine Act (Sunshine Act)** and has evolved with the passing of the **Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act**.

Open Payments houses a publicly accessible database of payments and other transfers of value that reporting entities—including drug and medical device companies—make to [covered recipients](#) like U.S.-licensed physicians, mid-level providers, and teaching hospitals.

In addition to the Open Payments Program, 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 Manufacturer Price (AMP) 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.

The Sunshine Act, SUPPORT Act, and Pfizer's HCP Payment Disclosure Policy are of particular importance to Field Commercial Colleagues and are covered in more detail below.

Sunshine Act

The [Sunshine Act](#) is designed to increase [transparency around the financial relationships](#) between physicians, teaching hospitals, and manufacturers of drugs, medical devices, and biologics.

Pfizer must comply with certain reporting and disclosure requirements of the Sunshine Act, such as submitting annual data on payment and transfers of value made directly to covered recipients, defined as a U.S.-licensed physician or a teaching hospital.

Indirect payments or transfers of value are also required for reporting. A transaction is considered indirect if it is known that the organization receiving the funding will be conveying a benefit to a covered recipient even if Pfizer does not direct or influence the selection of the recipient or have knowledge of the identity of the recipient.

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

Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act

The [SUPPORT Act](#) is a combination of a number of previously passed House and Senate bills related to addressing the opioid crisis. One of the provisions of this package of bills includes an expansion of the disclosure requirements initially imposed by the Sunshine Act mentioned above.

With the SUPPORT Act, additional practitioners beyond U.S. physicians and teaching hospitals are considered covered recipients. As a result, the law requires applicable manufacturers and Global Privacy Offices (GPOs) to track and report payments made to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives.

Pfizer's Healthcare Professional (HCP) Payment Disclosure Policy

Pfizer's disclosure policy is broader than the requirements of the Open Payments Program as discussed in this chapter, 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. HCP payment disclosure is just one of the many ways Pfizer is fulfilling its commitment to increased transparency and public candor.

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. HCPs and institutions:

- Meals, including snacks/refreshments
- Business travel expenses
- Educational items such as textbooks and reprints
- Research support, including all payments or transfers of value related to Research and Development (R&D) such as clinical site payments, study drug, and equipment that is leased, loaned, or given
- Consulting fees and honoraria
- Promotional speaking fees
- Publication support such as editorial support provided by an agency
- [Charitable Contributions](#)
- Grants
- Royalty and license payments

See Section 2 of *The White Guide* to learn more details about Pfizer disclosures related to meals and educational items.

Please also note the following about Pfizer disclosures related to promotional items and patient materials:

- Promotional Items
 - Generally, Pfizer-created branded and unbranded promotional materials, literature, and other leave-behind written materials are NOT subject to disclosure under Open Payments
- Patient Materials
 - Generally, 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
 - Some items are subject to disclosure under state laws, and all of these items must be tracked for business purposes, including:
 - Co-pay cards
 - Savings cards
 - Pill dispensers
 - Brochures
 - Vouchers
 - Prescription stamps
 - Pamphlets

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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.

	<p>Colleagues MUST:</p> <ul style="list-style-type: none">• 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<ul style="list-style-type: none">– Examples include: Ariba ePay and Purchase Orders, Pfizer Travel & Entertainment (PT&E)'s “My HCP,” “HCP,” “Other HCP” categories, the “Attendee” section of CentrisDirect™, CVENT Attendee registry, and 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 (HCPM ID)
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	<p>Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Approve expense reports or invoices that lack full names and appropriate expense allocation
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Opting Out of Receiving Disclosable Items

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 what occurs if they 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 [MyPfieldNet](#).

	<p>If a U.S.-licensed HCP expresses a desire to opt out of receiving food, beverages, or other disclosable items, the notified colleague MUST:</p> <ul style="list-style-type: none">• Immediately make Pfizer aware of the opt-out by e-mailing all relevant information to PTI@Pfizer.com• Advise the HCP that they may also submit questions or an opt-out request directly to PTI@Pfizer.com• Inform other colleagues who may interact with that HCP, in order to ensure that the HCP's request can be honored• 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 <p>If an HCP who has opted out subsequently chooses to opt back in, the notified colleague or the HCP MUST:</p> <ul style="list-style-type: none">• Contact PTI@Pfizer.com
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Section 1: Laws and Regulations Governing Commercial Activities

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, colleagues should visit the [Global HCP/Healthcare Organization \(HCO\) Transparency Reporting Portal](#) or contact the Transparency Team directly at GlobalHCPTransparencyReporting@pfizer.com. If colleagues have questions about the appropriate use of transparency data, they should consult their Compliance Lead.

FAQ: 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?
	Yes. After Pfizer submits data to CMS, and prior to the information becoming public, HCPs have a 45-day period to review their data and raise inquiries with Pfizer. Pfizer then has an additional 15 days to investigate and respond.
	How should I handle complaints by HCPs about Pfizer's disclosure policy? What if an HCP believes that the information in Pfizer's disclosures is incorrect?
	Pfizer has a dedicated staff to address transparency questions and concerns. Colleagues should e-mail questions to PTI@pfizer.com . If the HCP has a concern about a particular transaction disclosed on Open Payments, colleagues should direct the HCP to raise a dispute in the Open Payments portal directly or send an e-mail to HCPDispute@pfizer.com .

FAQ: 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?

Section 1: Laws and Regulations Governing Commercial Activities

	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—such as 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 future presentation appointments with an accompanying lunch in that office.
	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 Product Attorney with any questions.

State Laws

States are increasingly enacting laws and regulations that impact our business and restrict our activities, including colleagues’ 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 *The White Guide*.

Many states also have laws, called consumer protection 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. Colleagues should direct to Legal any questions regarding state consumer protection laws and their impact on colleagues’ activities.

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 colleagues and Pfizer.

To learn more about State Laws, refer to Section 9 of *The White Guide*.

Chapter 3: Government Healthcare Programs

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. Historically, the government 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 (FSS) 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 Service (PHS) 340B Outpatient Drug Pricing Program, as well as through certain state-supported programs, including State Pharmaceutical Assistance Programs (SPAPs) and AIDS Drug Assistance Programs.

Paying or providing benefits to healthcare providers or beneficiaries to prescribe or use products ultimately reimbursed by federal healthcare programs potentially implicates the federal Anti-Kickback Statute, and such conduct also potentially could run afoul of state all-payer laws regardless of whether the ultimate payer is a federal, state, or commercial entity.

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, including insofar as business with commercial customers implicates federal reimbursement under programs like Medicare and Medicaid.

This Chapter summarizes government healthcare programs. For more information regarding participation in Government Healthcare Programs, including Medicare and Medicaid risk areas, please see Section 6 of *The White Guide*.

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. Instead, 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 (HCP) services and other outpatient care not covered under Part A
 - Also covers some preventive services such as screening exams and lab tests to detect, prevent, or manage a medical condition

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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 (PDPs)** or through **Medicare Advantage-Prescription Drug Plans, also called MA-PD Plans**, under Part C.

Part D enrollees incur cost-sharing obligations, including deductibles and co-payments, although many low-income individuals are eligible for subsidies. 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—they 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 contracts with private health insurance companies and [Pharmacy Benefit Managers \(PBMs\)](#) 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 if 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 **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, or commercial, beneficiaries. In so doing, these Managed Care Customers frequently negotiate discounts with pharmaceutical manufacturers on behalf of both governmental and commercial plans.

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 HCPs and pharmacies for medical services and prescription medicines provided.

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 used 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 (FMV) 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, refer to Section 4 of [The Orange Guide](#).

Health Insurance Exchanges (HIEs)

In 2010, the **Patient Protection and Affordable Care Act (PPACA)** went into effect and introduced state-based exchanges called **Health Insurance Exchanges (HIEs or Exchanges)**. Exchanges are marketplaces 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 that offset premium payments at a certain percentage of income and cost-sharing subsidies that reduce 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 cost-sharing subsidies, kickback risks may exist.

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 PHS Act, established under section 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 the U.S. Department of Health and Human Services (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, family planning entities, and AIDS drug assistance programs; other clinics receiving PHS Act funding; and certain hospitals, including hospitals that provide care to a disproportionate share of indigent patients.

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Section 340B pricing discounts are calculated using metrics from the Medicaid Drug Rebate Program and notably are excluded from Best Price calculations. These discounts generally are deducted from the manufacturer's selling price at time of purchase by an eligible covered entity, although AIDS drug assistance programs may receive a rebate to effectuate the 340B price rather than an upfront discount. In certain cases, Pfizer may owe refunds to Covered Entities in situations in which Pfizer determines that the initial selling price was too high, such as if there are certain changes to the underlying Medicaid pricing data used to calculate the 340B price.

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 (FSS)

The 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 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 VA, the PHS (including the Indian Health Service), the 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 United States (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 (VA) and the Department of Defense (DoD)

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 (BPAs)

BPAs are awarded under an existing FSS contract, and per regulations issued by the General Services Administration (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 issues various formulary scenarios or “condition sets” for manufacturers to bid on and awards BPAs to the companies whose products are consistent with the condition set. In recent years, the VA has limited its use of BPAs because of the need to be competed.

Federal Supply Schedule (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. Manufacturers can control which FSS agencies are able to access the TPR and how long it will be in place.

National Contracts

To obtain lower pricing, the agencies can seek competitive bids from manufacturers for products that have multiple generics on the market and award a National Contract to the manufacturer that offers the lowest price. Once awarded, the agencies will buy the product only from the National Contract holder unless a particular patient is unable to tolerate that product.

State Pharmaceutical Assistance Programs (SPAPs)

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 excludes from Best Price only rebates paid to SPAPs that have been qualified by CMS as an SPAP. Pricing discounts offered to an unofficial SPAP may impact Pfizer's Best Price.

Chapter 4: Summary of Other Relevant Laws and Regulations

Privacy Laws

We are all familiar with the notion of privacy from our own daily lives. Privacy is often described as an individual's desire to keep their Personal Information confidential and—by extension—to determine when, how, and to what extent any Personal Information is used and shared with others.

Some Personal Information identifies who we are and where and how we live. Other Personal Information is medical in nature, while other forms of Personal Information relate to finances, political affiliations, and philosophical beliefs. For Pfizer purposes:

Personal Information includes any information that—alone or in combination with other data—identifies, relates, or is linkable to an identifiable individual or in some cases a household or can be used to identify a person or household either directly or indirectly. Examples include a person's name or initials, address, telephone number, e-mail address, or Internet Protocol (IP) address.

Sensitive Personal Information (SPI) is a subset of Personal Information that is generally considered to include more private details about an individual and may trigger additional requirements under the law. SPI may include:

- Geolocation data
- Financial information
- National identifiers such as Social Security number or information about an individual's race, ethnicity, religion, sex life/sexual orientation
- Information about a person's physical or mental health, such as a person's medical history, physical or mental condition, diagnosis or treatment protocol, or—under certain state laws—biometric data

Protected Health Information (PHI) is a subset of SPI pertaining to health data.

One of the most important federal healthcare laws in the area of privacy is called the **Health Insurance Portability and Accountability Act of 1996 (HIPAA)**, as amended by the **Health Information Technology for Economic and Clinical Health Act (HITECH Act)**. These are referred to collectively as HIPAA.

HIPAA imposes strict limitations on the use and disclosure of PHI by covered entities and their **[business associates](#)**.

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

The collection and use of Personal Information is also regulated by other federal and state laws and regulations, including state health privacy laws or state security breach notification laws that apply in cases where certain Personal Information is lost or improperly accessed and used. Examples of activities involving collection or access to Personal Information of others include health screenings, surveys, clinical outcomes research, and mentorships as well as managing Personal Information in one's possession—such as on a computer.

Pfizer's Key Privacy Principles

There are key Pfizer principles regarding the protection of Personal Information, including PHI and SPI.

Pfizer's corporate principles require that the confidentiality and security of Personal Information be maintained in accordance with state and federal law.

	<p>Pfizer Colleagues MUST:</p> <ul style="list-style-type: none">• Always disclose that they are a Pfizer employee when interacting with patients<ul style="list-style-type: none">– For example, wear a Pfizer-branded name tag at all times when attending a consumer health fair or during a mentorship or preceptorship• Employ appropriate safeguards designed to protect Personal Information they have access to, including the Personal Information of customers or patients• Avoid situations likely to lead to the inadvertent disclosure of Personal Information, including SPI, such as being present at or near private conversations between HCPs and patients• Limit use of free form or open text fields and situations that may lead to social media sharing of Personal Information• Immediately notify Legal if they become aware that Pfizer, a business partner, or a service provider has received SPI or more extensive Personal Information than intended, expected, or necessary for the business purpose• Only use HCP prescriber data for legitimate business purposes, such as the development of their team's promotional strategy<ul style="list-style-type: none">– This information is confidential, so it is vital not to use this prescriber data in a manner that compromises its confidential nature or one's integrity as a Pfizer Colleague
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	<p>Pfizer Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Request or collect SPI for any reason, unless there is a clear business need for such SPI, and they have specific approval from Legal to do so• Request, collect, or retain access to Personal Information about HCPs, their employees, or the employees of Pfizer customers like Health Plans or Group Purchasing Organizations (GPOs), for any reason• Enter into a Business Associate Agreement (BAA)<ul style="list-style-type: none">– Pfizer usually does not perform work on behalf of an HCP, Health Plan, or other "covered entity" under HIPAA– If they are asked to sign a BAA, they may instead offer either the <i>Pfizer Privacy Pledge</i> or <i>Patient Health Information Confidentiality Agreement</i> template found on MyPfieldNet, as appropriate<ul style="list-style-type: none">▪ If this does not satisfy the party making the request, the colleague must consult with Legal
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Read below for more in-depth details on privacy as it relates to patient data, HCP data, and Pfizer Colleague data.

Patient Privacy

Securing Consent and Personal Information from Consumers

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

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

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

These guidelines apply only when consumers are asked to provide Personal Information, such as name, address, e-mail address, or telephone or fax number. Pfizer may not discriminate against or exclude consumers from participating in programs based on the fact that consumers do not opt in or opt out of providing their Personal Information. The same applies to the subsequent selling of the consumer's Personal Information.

Steps to Protect Patient Privacy

Avoid Processing Personal Information

Processing includes access to, collection, retention, and use of Personal Information. It is important to avoid processing Personal Information unless, and only as long as, there is a legitimate business need for doing so. Processing Personal Information imposes legal obligations on Pfizer including an obligation to keep that information confidential and secure.

Disclosure of certain types of Personal Information—even if accidental—can expose Pfizer to legal liability, create a risk of fraud or even identity theft for the information owner, and erode confidence in Pfizer and its commitment to privacy and information security.

Except as expressly authorized by Legal, Pfizer Colleagues must avoid collecting, maintaining, or using SPI. If colleagues inadvertently come into contact with SPI or are asked to collect it, they should contact Legal immediately to discuss Pfizer's policies on safeguarding such information.

Avoid Intentional and Inadvertent Disclosure of Sensitive Personal Information (SPI)

HCPs and OCs—such as health plans and hospitals—and other Pfizer customers are subject to many restrictions regarding the use and disclosure of SPI about their patients and members. With certain exceptions, they are not permitted to disclose a patient's or member's SPI to a third party, such as Pfizer, unless they receive prior written authorization from the patient or member.

Pfizer Colleagues must avoid situations in which they may be exposed to SPI without an individual's written authorization or applicable consent.

In the event a Pfizer customer or other person working on behalf of a customer or covered entity exposes a Pfizer Colleague to SPI without having obtained the required authorization, the colleague should not document or reproduce the information in any form. The colleague must strictly maintain the confidentiality of such information in accordance with Pfizer's policies.

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Even if an individual has authorized the use or disclosure of SPI—such as during a mentorship—Pfizer Colleagues must still abide by the rules discussed in this Chapter and consult Legal as needed to ensure compliance with Pfizer policies and applicable laws regarding the use, disclosure, and destruction of any SPI to which colleagues are exposed. Please also keep in mind that SPI generally must be encrypted when transferred and stored.

Seek Only Aggregated or De-Identified Data

Under limited and specific circumstances, and in consultation with Legal, it may be appropriate for colleagues to receive certain “aggregated” or “de-identified” patient information from an HCP, an OC such as a health plan or hospital, or other third party.

- **Aggregated** data is information about multiple individuals that is compiled and does not allow for the re-identification of any one individual
- **De-identified** data are data that cannot be attributed to any specific individual or used to identify any individual and usually has been stripped of certain key identifiers which, either alone or in combination with other available information, could link the information with a specific individual or be used to identify a specific individual
 - Key identifiers include the individual’s name, elements of the individual’s address, date of birth or death, telephone number, patient identification number, treatment dates, and Social Security number, among others
 - HIPAA regulations and certain state privacy laws include strict standards for what qualifies as de-identified—therefore, colleagues must consult Legal before assuming information has been properly de-identified

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

Obtain Patient Consent via Written Authorization Where Appropriate

In certain circumstances, it may be appropriate or even necessary for Pfizer to receive SPI from patients or consumers as part of certain approved activities. Pfizer Colleagues must ensure that the appropriate patient consent, a written HIPAA authorization, has been obtained by the HCP or OC prior to:

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

The signed authorization form should be maintained by the HCP as part of the patient’s medical record, and a copy should be given to the patient by the HCP. There is no need or reason for Pfizer Colleagues to have a copy of the completed form, so they should not collect or retain a signed copy. Colleagues must consult their Product Attorney or the GPO to determine whether an authorization is necessary and whether the template available contains the appropriate legally required terms.

Report Data Incidents

If a Pfizer Colleague unintentionally gains access to or becomes aware of any compromise of or potential unauthorized access to or use of Pfizer data, including Personal Information, they must:

- Promptly report the incident to Pfizer’s Global Security Operations Center (GSOC) pursuant to [Corporate Policy 411, Information Incident Response Policy](#)
 - GSOC can be reached at **212-733-7900** or GSOCwatchroom@pfizer.com

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- Notify Legal
- Report lost or stolen computers or other devices containing Pfizer data to their local Service Desk/Help Desk
 - The worldwide list of contact telephone numbers is available online at ITSupport.pfizer.com
- Avoid using the term “breach” when reporting a suspected incident involving Personal Information

Handling Consumer Access and Deletion Requests

Certain state privacy laws give broad consumer rights to patients and customers as well as HCPs with regard to their Personal Information and how Pfizer may use it.

Consumers, as defined under the applicable law, may have the right to obtain access to, get a copy of, or ask Pfizer to delete the Personal Information that Pfizer holds and processes about them. Such requests may reach Pfizer via telephone, e-mail, mail, or otherwise, and colleagues should immediately forward any such requests to their Product Attorney and/or the GPO to ensure Pfizer can meet the deadline to respond under the law. Colleagues may not directly respond to any such request unless instructed to do so.

Certain laws allow Consumers to also opt out from sales of their Personal Information at any time. Such laws define sales broadly to include any selling, providing, making available, or disclosing Personal Information in exchange for any consideration or thing of value, not just money. If a colleague receives any such opt-out request, they must also immediately forward it to their Product Attorney and/or the GPO.

Business Associate Agreements (BAAs) and Confidentiality Agreements

Sometimes a customer that is a covered entity such as an HCP or OC may incorrectly request that a Pfizer Colleague sign a HIPAA BAA. A BAA is an agreement that is entered into between a covered entity—such as an HCP or a health insurer—and a business associate, which generally is defined as an entity or person who performs work for or on behalf of a covered entity with respect to PHI.

Certain types of vendors are automatically considered business associates. However, Pfizer generally does not perform this type of work on behalf of covered entities. Because of this, a confidentiality agreement will usually meet the needs of covered entities that mistakenly request BAAs. Therefore, to address such requests, Pfizer has developed two Pfizer template forms: *The Privacy Pledge* and *Patient Health Information Confidentiality Agreement*, which can be downloaded from [MyPfieldNet](#). If colleagues have any questions about whether a BAA is appropriate, they should consult with Legal.

	<p>Field Commercial Colleagues MAY:</p> <ul style="list-style-type: none">• Offer <i>The Privacy Pledge</i> and <i>Patient Health Information Confidentiality Agreement</i> to the HCP as assurance of their intent to keep Personal Information and SPI, including PHI, confidential
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	<p>Field Commercial Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Enter into a BAA individually or on Pfizer’s behalf
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FAQ: Business Associate Agreements (BAAs)	
	What should I do if an HCP insists that I sign a BAA before I enter the patient clinic? Can I sign the BAA to avoid being shut out?
	No. You must not sign a BAA, even if required by an HCP in order to be allowed access to a facility. You may offer to sign the Pfizer <i>Privacy Pledge</i> or <i>Patient Health Information Confidentiality Agreement</i> template found on MyPfieldNet . Providing a copy of one of these documents with your signature is usually sufficient to satisfy the HCP's concerns about patient privacy. If the HCP continues to insist on a BAA, please promptly contact Legal, who may be able to provide assistance to you.

FAQ: Signing Customer Confidentiality Agreements	
	If an HCP insists that I sign a facility's Confidentiality Agreement, even after I sign and show the HCP Pfizer's <i>Privacy Pledge</i> and <i>Patient Health Information Confidentiality Agreement</i> , can I sign what the HCP wants me to sign?
	Maybe. Sometimes these agreements are acceptable to sign, but you may never do so unless Legal has first reviewed and approved the agreement.

FAQ: Chart Reviews	
	Is it permissible to conduct chart reviews as part of our collaborative studies/programs with customers? If I sign a BAA, would that make it allowable?
	No. It is Pfizer policy that colleagues should never conduct a chart review. In addition, as discussed earlier, field-based colleagues must not sign BAAs under any circumstance. If the confidentiality agreements referenced above do not satisfy the party requesting a BAA, you must consult Legal.

Healthcare Professional (HCP) Privacy

Healthcare Professional (HCP) Personal Information

As a general policy, Pfizer restricts access to Personal Information to individuals who “need to know” the information as related to their job duties. In general, most Pfizer Colleagues, including Sales Colleagues, do not need access to

Section 1: Laws and Regulations Governing Pfizer Field Activities and Customer Interactions

Personal Information about HCPs, their employees, or the employees of Pfizer customers like Health Plans or GPOs 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
- Biometric data, such as fingerprints, voiceprints, or retinal scans

Healthcare Professional (HCP) Prescriber Data

From time to time, Pfizer uses prescriber data to facilitate effective marketing communications with HCPs. HCP prescriber data also serves other purposes, including the tracking of Pfizer product adverse events.

In addition, the proper use of prescriber data can help colleagues focus their activities on those HCPs who would most likely benefit from a promotional presentation on one of their products. This information is confidential, however, so it is vital not to use this prescriber data in a manner that compromises its confidential nature or one's integrity as a Pfizer Colleague.



Pfizer Colleagues MUST:

- Only engage in an on-label discussion directly with the HCP to solicit and learn information about their clinical approach and use of specific products in order to tailor the colleague's promotional presentation
- Only use HCP prescriber data for legitimate business purposes, such as the development of their team's promotional strategy
- Limit access to HCP Prescriber Data to individuals with a legitimate business need
 - In developing and distributing reports that contain HCP prescriber data, colleagues should provide instructions to recipients that when reviewing the report, they should filter for HCPs that are on their Territory Credit Lists (TCLs) or within their territory or area of responsibility, prior to reviewing the data
 - Likewise, before reviewing HCP prescriber data, colleagues should make reasonable efforts to filter for HCPs that are on their TCLs or within their territory or area of responsibility to ensure information is utilized only by those with a legitimate business need



Pfizer Colleagues MUST NOT:

- Directly convey the data they possess on their prescribing, nor may they use prescribing data to directly or implicitly exert pressure or coerce HCPs to prescribe a particular product
- Share an HCP's prescriber data with other individuals and entities outside of Pfizer, as this would compromise its confidentiality

Section 1: Laws and Regulations Governing Pfizer Field Activities and Customer Interactions

Healthcare Professional (HCP) Prescriber Data Opt-out

The **American Medical Association (AMA)** administers a program by which HCPs can opt out of having their prescriber data released to pharmaceutical companies for use in marketing. Pfizer is required to check the opt-out list quarterly and has 90 days to comply with an HCP's request. Pfizer shall also maintain its own opt-out list internally and check against it.

If an HCP has opted out, Pfizer will respect that preference and will not use their prescriber data in connection with promotional activities. If a Pfizer Colleague learns that an HCP on whom they call has asked for their prescriber data not to be released, even though the colleague will not have access to the HCP's prescriber data, they should be especially careful to avoid any discussion of prescribing habits in their promotional presentations to the HCP.

The AMA program allows HCPs to report specific instances of inappropriate behavior by pharmaceutical sales representatives or companies. Thus, it is important that colleagues familiarize themselves with these rules and conduct their activities accordingly. Using prescriber data inappropriately not only compromises colleagues' credibility with the HCP but is also a violation of Pfizer policy.

Pfizer Colleague Privacy

In addition to protecting the privacy of patients' and customers' Personal Information, Pfizer is also committed to protecting colleagues' privacy from inappropriate use by or disclosure to third parties.

Moreover, Pfizer also wants to ensure that when colleagues' information is entrusted to third parties, it is properly protected from unauthorized disclosure. Pfizer's *Institutional Access Guidelines* demonstrate this commitment to colleagues and their privacy. These guidelines can be found on [MyPfieldNet](#).

Providing Colleagues' Personal Information When Required by Vendor Credentialing Processes

Many hospitals and health care institutions are conditioning site access on colleagues' submission of Personal Information, and sometimes SPI, about themselves, in addition to compliance with other vendor credentialing requirements. Often the stated purpose of these submissions and requirements is to make sure that people with access to personnel, patients, and visitors do not have serious communicable illnesses or a history of violent acts.

Required Personal Information can include immunization status, copies of medical records demonstrating inoculation or immunity to certain illnesses, whether colleagues have had a background check and its outcome, colleagues' training history, and professional qualifications.

Pfizer respects the hospital's or vendor's desire to secure the health and safety of its personnel, patients, and visitors. This is the rationale behind the creation of the *Institutional Access Guidelines*.

In particular, Pfizer has created a Vendor Credentialing Team to help colleagues respond to these requests. The team's contact information is available on [MyPfieldNet](#).

Regardless of whether a customer or institution asks for colleagues' Personal Information directly or indirectly through a vendor hired to collect data on their behalf, Pfizer wants colleagues' privacy to be respected and colleagues' Personal Information appropriately protected.

Here are some key points to remember:

Section 1: Laws and Regulations Governing Pfizer Field Activities and Customer Interactions

	<p>Pfizer Colleagues MUST:</p> <ul style="list-style-type: none">• Always tell their manager if a hospital, institution, or institution's vendor wants them to provide their Personal Information to gain site access<ul style="list-style-type: none">– If the hospital, institution, or vendor has a written credentialing policy, be sure to provide a complete and current copy to the Vendor Credentialing Team to review in advance• Only give the hospital or vendor Pfizer's approved template Confidentiality Letter Agreement available through a link in the Guidelines, accessible on MyPfieldNet
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	<p>Pfizer Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Sign any BAA or other legal document without consulting their manager and Legal• Share their Personal Information before the HCP or vendor signs an approved Confidentiality Agreement to protect their information• Modify Pfizer's approved template Confidentiality Letter Agreement without Legal's approval in advance• Sign a Confidentiality Agreement without approval from Legal
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Legal will review relevant hospital and HCP policies to ensure that any agreements are acceptable for colleagues to sign and do not pose potential legal issues for Pfizer. Legal will also review the agreements in light of Pfizer's interests and cannot offer colleagues personal legal advice regarding their personal privacy or other concerns.

Once Legal has approved an agreement, it is the colleague's responsibility to carefully read and understand it because the colleague will be held accountable by the institution for compliance with it. Violations of an institution's policies may lead to the colleague or Pfizer being denied the ability to visit or hold programs at that institution.

Corporate Policies on Your Responsibility for Safeguarding Personal Information

Colleagues should also familiarize themselves with the following Pfizer corporate policies and guides:

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

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

	<p>Pfizer Colleagues MUST:</p> <ul style="list-style-type: none">• Encrypt their computer• Properly destroy media or paper containing Personal Information• Promptly report lost or stolen Pfizer equipment and other potential data incidents<ul style="list-style-type: none">– Contact Pfizer's GSOC (212-733-7900 or GSOCwatchroom@pfizer.com) or the local IT Service Desk
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- The worldwide list of contact telephone numbers is available online at ITSupport.pfizer.com



Pfizer Colleagues MUST NOT:

- Leave their Pfizer equipment or Personal Information unattended or in an unsecured location, such as an unlocked car
- Use unencrypted e-mail to transfer Personal Information outside of the Pfizer network

If additional questions arise about appropriate information handling and security procedures, colleagues should consult the Privacy reference guide or speak with the GPO or their Product Attorney.

State Data Privacy 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 (for example, 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.

Privacy Implications Outside of the United States (U.S.)

Although this Chapter is largely focused on certain United States (U.S.) privacy topics, it is important to consider whether any sales and marketing activities conducted in the U.S. may have privacy implications for complying with the laws of other countries.

Colleagues should consult their Product Attorney or the GPO if a proposed activity presents potential privacy implications for individuals outside of the U.S. or involves the transmission of Personal Information collected in one country to another country. A privacy implication includes any collection, use, processing, 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 one's computer or a database is likely considered an international transfer of Personal Information. International data transfers typically require specific contractual language and/or legal review in order to lawfully transfer data outside of the country of origin.

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, they generally expect that the person or entity will 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

Section 1: Laws and Regulations Governing Pfizer Field Activities and Customer Interactions

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 and instead is 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 404, Protecting the Privacy of Personal Information](#).

Foreign Corrupt Practices Act (FCPA)

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—including any department, agency, instrumentality, or public international organization.

- For example, HCPs at foreign government-owned hospitals may qualify as foreign officials under the FCPA

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.

Pfizer Colleagues who are allowed to participate in any interaction in which a payment or other benefit may be given to a non-U.S. HCP must follow [My Anti-Corruption Policy and Procedures \(MAPP\)](#). This could occur, for example, when engaging a non-U.S. HCP as a consultant.

Lobbying Laws

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.

Who Is a Lobbyist?

Under federal law, a [lobbyist](#) is any individual who is employed by Pfizer and has:

- Made more than one lobbying contact within a three-month period
- Spends at least 20% of their 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, which is three-month intervals. However, it is important to remember that even if a colleague is not a lobbyist, federal law requires Pfizer to report their time spent supporting the lobbying efforts of others within the Company.

Federal Lobbying Law

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 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 colleague 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 colleagues' interactions with HCP, 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 *The White Guide*, colleagues should check with their GRD or Legal about the relevant laws in their region, since the specific state or local laws applicable to them may vary depending upon the state in which they work.

State-Specific Lobbying Laws

There are two types of lobbying disclosure laws enacted by states that may require colleagues 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.

To learn more about federal and state lobbying laws, refer to Section 9 of *The White Guide*.

Chapter 5: Industry Codes and Guidance Related to Field Activities and Customer Interactions

Pharmaceutical Research and Manufacturers of America (PhRMA)

Pharmaceutical Research and Manufacturers of America (PhRMA) represents the nation's leading biopharmaceutical research companies. The members of PhRMA believe that ethical relationships and behavior in all interactions with Healthcare Professionals (HCPs) are critical to their success in developing and delivering medicines to help patients live longer and healthier lives. Pfizer is committed to following its principles.

While PhRMA has published several Codes and Guidelines, the ones most relevant to the responsibilities of Pfizer's United States (U.S.) Field Commercial Colleagues are highlighted below.

PhRMA Code on Interactions with Health Care Professionals (HCPs)

Developed and adopted by many of the country's leading research-based pharmaceutical and biotechnology companies, including Pfizer, the PhRMA Code applies to relationships with physicians and other HCPs.

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 to help enhance patient care.

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

Principles on Interactions with Patient Organizations

Biopharmaceutical companies share many common interests with patient organizations including, most importantly, a common commitment to patients and shared mission to discover cures and fight disease.

In this joint mission of innovation and service to patients and caregivers, companies frequently work together with patient organizations to sponsor research, provide educational and support services for patients, and award grants to benefit the mission of patient groups. Biopharmaceutical companies and patient organizations enjoy productive collaborative relationships, which benefit the public health.

PhRMA believes that such relationships should be structured to ensure the independence of the patient organization and appropriately support the organization's mission.

Accordingly, PhRMA established *Principles on Interactions with Patient Organizations* to help ensure that relationships between biopharmaceutical companies and patient organizations remain true to their goal of advancing biomedical research, health care innovation, and access to patient care and services.

Principles on Interactions with Patient Organizations can be viewed on the [PhRMA website](#).

PhRMA Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines

PhRMA also published [Guiding Principles on Direct to Consumer Advertisements About Prescription Medicines](#) to ensure that Direct-to-Consumer (DTC) communications provide accurate, accessible, and useful health information to patients and consumers.

Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers

The Office of Inspector General (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
7. Responding promptly to detected problems and undertaking corrective action

All seven elements are embedded throughout Pfizer's compliance program.

Chapter 6: Pfizer's Government Agreements Related to Field Activities and Customer Interactions

Government Agreements

Biopharmaceutical companies enter into Government Agreements to settle investigations that arise due to certain practices or behaviors that companies may have allegedly engaged in that may violate certain federal or state laws.

There are two types of Government Agreements that Pfizer Colleagues must be aware of:

- A **Corporate Integrity Agreement (CIA)** is a written agreement with the Office of Inspector General (OIG) that typically imposes certain integrity obligations—such as training, reporting, or audits—for a specified period of time, typically five years from the date the CIA is executed.
- A **State Attorney General Agreement** is a written agreement with one or more state Attorneys General that imposes certain integrity obligations for a specified period of time or as an ongoing obligation. Pfizer may also enter into agreements with city or municipal governments or regulatory agencies that require certain integrity obligations.

Obligations impacting Pfizer Colleague activities by these agreements are implemented throughout the policies and procedures that govern those relevant activities.

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.

For additional information on Pfizer's State Attorneys General Agreements, refer to the [State Attorneys General Agreements](#) page on the Compliance website.

Chapter 7: Violations and Penalties

Violations and Penalties

The Office of Inspector General (OIG), the United States (U.S.) Department of Justice (DOJ), the Food and Drug Administration (FDA), state Attorneys General, and certain local governments aggressively enforce anti-kickback, advertising and promotional, and other laws and regulations discussed in this Section.

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 Prescription Drug Marketing Act of 1987 (PDMA) 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.

Chapter 8: Additional Resources for More Information

Adverse Event Reporting

- For more information on safety reporting, see [Corporate Policy 903, Your Responsibility to Report Information about the Safety, Quality, and Performance of Pfizer Products](#)

Disclosure/Transparency

- For more information on Pfizer's Healthcare Professional (HCP) transparency practices, refer to the [Global HCP/Healthcare Organization \(HCO\) Transparency Reporting Portal](#) or e-mail GlobalHCPTransparencyReporting@pfizer.com
- For more information on Open Payments, please see the [Centers for Medicare & Medicaid Services \(CMS\) website](#)

State Laws

- For information on relevant state law restrictions, refer to Section 9 of *The White Guide*
- To determine whether an HCP is licensed in Massachusetts, Minnesota, New Jersey, or Vermont, Sales Representatives should consult the physician profile within Veeva Customer Relationship Management (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](#)

Privacy

- For more information on system policies, see
 - [Corporate Policy 403, Acceptable Use of Pfizer Information Systems](#)
 - [Corporate Policy 411, Information Incident Response Policy](#)
 - [Corporate Policy 903, Your Responsibility to Report Information about Safety, Quality or Performance of Pfizer Products](#)
- For more information on protecting the privacy of Personal Information, see [Corporate Policy 404, Protecting the Privacy of Personal Information](#)
- For more information on records management, see [Corporate Policy 405, Records & Information Management Policy and Procedure](#)
- For more information on handling sensitive information, see [Handling Sensitive Information: Safeguarding Our Information](#)
- For copies of the *Privacy Pledge* and *Patient Health Information Confidentiality Agreement*, see the "Compliance" tab on [MyPfieldNet](#)

Federal Employee Interactions and Lobbying

- Lobbying questions may be referred to the relevant Government Relations Director (GRD), the Washington, D.C. Pfizer office, or Legal
- Federal Employee Interaction questions may be referred to your lead National Account Manager or Legal
- For more information about the Pfizer Political Action Committee (PAC), visit the PAC Section of the [United States \(U.S.\) Policy and Government Relations Site](#)

Section 1: Laws and Regulations Governing Pfizer Field Activities and Customer Interactions

Pharmaceutical Research and Manufacturers of America (PhRMA)

- For more information about the Pharmaceutical Research and Manufacturers of America (PhRMA) Code, refer to the [PhRMA website](#)
- For Q&A on the PhRMA Code, see the [Global Policy Xchange on Biopharma Ops On Demand](#)



The White Guide

Section 2

Guidelines for Healthcare Professional (HCP)-Related Engagements and Communications

Section 2

Guidelines for Healthcare Professional (HCP)- Related Engagements and Communications

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[Click here to visit the Glossary and Acronyms.](#)

Chapter 1: Introduction

Engaging and educating Healthcare Professionals (HCPs) are essential activities for Pfizer Colleagues. Compliance with the law and Pfizer policies is a vital component of successfully interacting with HCPs, and Pfizer may be held legally responsible for anything that colleagues say or show to customers.

Within *The White Guide*, an HCP is defined broadly as any individual who has a direct role in patient diagnosis and/or treatment.

HCPs include but are not limited to:

- Physicians
- Physician Assistants (PAs)
- Nurses
- Nurse Practitioners (NPs)
- Pharmacists

For the purposes of *The White Guide*, individuals who may or may not work directly with patients but have influence over the recommendation, purchase, or prescribing of Pfizer products should also be treated as HCPs.

The definition of an HCP may also differ in certain contexts, such as under certain state laws—therefore, Colleagues should always consult relevant state laws prior to engaging with HCPs. These laws may be found in Section 9 of *The White Guide*. Furthermore, when interacting with an HCP, colleagues need to be aware of who the HCP's employer is and/or if they have additional responsibilities above and beyond patient care. Specific guidance to ensure compliant interactions and activities with all types of HCPs is covered in Section 3 of [The Orange Guide](#).

Additionally, this section summarizes Pfizer policy regarding advertising and [promotional labeling](#) for the United States (U.S.) biopharmaceutical business. The Core Promotional Compliance Principles for HCP engagements and communications are also covered in this section. Promotional labeling and [advertisements](#) must be truthful, accurate, and not misleading. All promotional communications must also include a fairly balanced presentation between efficacy and risk information. For an overview of requirements for promotional labeling and advertising to HCPs, refer to Section 1 of *The White Guide*.

Finally, this section summarizes guidance for common HCP engagements and communications, including HCP consulting arrangements.

Chapter 2: Core Promotional Compliance Principles for Promotional Communications

Promotional labeling and advertisements promote Pfizer products and educate about the disease states treated by those products. Pfizer's Core Compliance Principles pertaining to promotional communications are intended to help ensure that the development, review, approval, and use of those materials comply with all applicable laws, regulations, policies, and procedures while effectively mitigating risks and meeting business objectives.

For an overview of the requirements for promotional labeling and advertisements, please refer to Section 1 of *The White Guide*.

Pfizer's Core Compliance Principles for Promotional Communications must be followed at all phases of development, review, and communication of content:

1. Provide accurate, truthful, not misleading, and fairly balanced information
2. Use **Review Committee (RC)**-approved communications supported with adequately substantiated evidence
3. Be consistent with product labeling and only discuss approved products and indications, with narrow pre-approval exceptions
4. No actual or perceived [quid pro quo](#)

Process requirements for content development and review are included in Pfizer's Global Content Policies listed in the last chapter of this Section, *Additional Resources for More Information*. Exceptions to these policies or principles must be approved in writing by the relevant Chief Counsel.

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.

Pfizer's Core Compliance Principles for Promotional Communications apply to any Pfizer Colleague engaged in a promotional interaction with an HCP.

For a more detailed discussion of Pfizer's policies applicable to Sales Colleagues, refer to Section 3 of [The Orange Guide](#). For additional information of Pfizer's policies applicable to Medical Colleagues, refer to Chapter 5 of [The Green Guide: Governance for External Medical Activities](#).

Pre-Approval Communications

Coming Soon & Institutional Advertising and Promotional Communications

Generally, the [Food and Drug Administration \(FDA\)](#) permits two types of advertisements for drugs before approval: **Institutional Advertising** or **Coming Soon Advertising**. For a particular investigational product, Pfizer can engage in these two types of advertising during the pre-approval period but should not make claims of safety, efficacy, or use for the investigational product. It is important to evaluate all planned pre-approval external messaging to ensure

Section 2: Guidelines for Healthcare Professional-Related Engagements and Communications

adequate separation between Coming Soon and Institutional Advertising, whether by time period, channel, segment, or otherwise.

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. Any representation—whether it is 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 that is 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**. Therefore, Coming Soon Advertising is generally limited to the period after the FDA has provided commentary on the draft United States Prescribing Information (USPI). Coming Soon Advertisements must meet the requirements of a reminder advertisement, which are described in Section 1 of *The White Guide* and therefore must not contain any representations about the product. Please note that “Coming Soon” communications are limited to Headquarters (HQ)-sponsored advertising and promotion and are not permissible from Customer Facing Colleagues (CFCs).

FAQ: Pre-Approval Communication	
	When can I 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.</p> <p>In limited circumstances it may be appropriate to discuss an unapproved product or indication with a customer as part of a non-promotional interaction, such as an advisory board or scientific exchange or within certain communications with payers. All colleagues must receive appropriate approvals before proactively discussing any unapproved product or indication with an HCP or consumer or other customer. For guidelines on communication with payers related to an unapproved product or new indication of an approved product, see United States (U.S.) Guidance for Pre-FDA Approval Interactions with Healthcare Decision-Makers and Payers for more information.</p>

Pre-approval Information Exchange (PIE): Communications with Healthcare Decision Makers

Under certain circumstances, Medical Colleagues and certain Commercial Colleagues—not including Sales Representatives—may engage in communications with Healthcare Decision Makers such as formulary committees, payers, and other similar entities related to investigational assets and investigational uses of approved products. This type of interaction is referred to as **Pre-approval Information Exchange (PIE)**.

In consultation with **Global Product Counsel (GPC)**, colleagues must determine on a case-by-case basis whether to execute a PIE. Factors to consider in this assessment and guidelines on how to successfully and compliantly execute a PIE are provided in the [U.S. Guidance for Pre-FDA Approval Interactions with Healthcare Decision-Makers and Payers](#).

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	<p>PIE communications MUST:</p> <ul style="list-style-type: none">• Be designed and executed for the specific purpose of facilitating Healthcare Decision Makers in planning and budgeting for coverage, reimbursement, and contracting upon potential approval and market availability of a Pfizer investigational product or investigational use of an approved product• Be unbiased, factual, accurate, truthful, not misleading, objective, and non-promotional in content, presentation, and tone• Clearly and prominently disclose unambiguously the regulatory status of the investigational product or use throughout, using disclosure language suggested in the PIE Guidance
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	<p>PIE communications MUST NOT:</p> <ul style="list-style-type: none">• Claim that an investigational product or use has been approved, or is effective or safe• Recommend off-label use(s)• Encourage future prescribing• Engage in actual or perceived quid pro quo
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Please note that postmarketing submission requirements to **The Office of Prescription Drug Promotion (OPDP)/ Advertising and Promotional Labeling Branch (APLB)** at first use do not apply to PIE communications.

For additional guidance about how to compliantly engage in a PIE and the process/procedure for obtaining approval for a PIE, refer to [U.S. Guidance for Pre-FDA Approval Interactions with Healthcare Decision-Makers and Payers](#). For additional information contained in FDA Guidance for Industry, refer to Section C of [Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities](#).

The Core Principles for Promotional Communications

1. Provide accurate, truthful, not misleading, and fairly balanced information

Advertising and promotional labeling, which include promotional materials and statements made in a promotional setting, must be truthful, accurate, and not misleading.

Promotional communications may be considered false and misleading if relevant risk and safety information is not communicated in conjunction with benefits. Further, product claims may be rendered false and misleading if not supported by appropriate scientific evidence/data or are not consistent with the FDA-approved full prescribing information.

Therefore, promotional communications must be sufficiently complete to enable the HCP to form their own opinion about the therapeutic value of the product.

Some examples that may render a promotional communication false and misleading include:

- Promotion of an unapproved, investigational product
- Promotion of an unapproved use for an approved product
- Overstatement of efficacy through claiming the product is effective in a broader range of conditions or patients than demonstrated with [substantial evidence](#)
- Claims of efficacy from patients treated with dosages different from that included in the full prescribing information

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- Failure to disclose efficacy results which could be due to concomitant therapy or placebo effect
- Use of nonclinical data to suggest clinical significance unless demonstrated clinically
- Use of literature, quotes, or references to support a claim that is not otherwise adequately supported
- Minimization of safety or risk by way of insufficient content and/or misleading presentation
- Claiming or implying another product is safer or more effective than another product when not demonstrated by substantial evidence
- Communicating information about two or more products in a manner that falsely or misleadingly conflates the properties of the respective products
- Claiming or implying comparison of two or more products without sufficient level of evidence
- Communicating either outdated or selected (“cherry-picked”) data
- Inaccurate communication of study design or methodology
- Claiming efficacy or safety conclusions from a study with inadequate design, scope, or conduct
- Communicating statistical significance for data lacking an appropriate level of statistical rigor
- Using retrospective analyses to claim or imply results that are not adequately and sufficiently supported
- Communicating product information in a manner to claim or imply greater experience with the product than can be substantiated
- Use of headline, subheadline, visual representations, or other graphics in a misleading manner

FAQ: Visual Representations	
	A Brand Team wants to include photographs of families, such as children and parents, in their promotional materials. Are there any concerns with doing this?
	<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.</p> <p>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 ensure they are not misleading in light of the product’s indication or any claim made about the product.</p>

The FDA requires all promotional communications include [fair balance](#) between a product’s benefits and risks. Therefore, relevant safety information must be communicated and in comparable prominence to efficacy information so that the communication is fairly balanced.

Efficacy and safety must be presented in comparable scope, depth, and detail. In other words, greater and more robust efficacy communications must be accompanied by greater and more robust safety disclosures. Relevant warnings—including boxed warnings where applicable, precautions, side effects, and other material safety information—must be communicated for an HCP to make an informed decision about a product.

In general, promotional materials are evaluated in their entirety, as well as by each spread and section in assessing for a fairly balanced presentation. Factors such as font, layout, contrast, headlines, paragraphing, white space, and other techniques used to achieve emphasis must be presented comparably between efficacy claims and safety information.

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Further, claims of “safe” must not be used without qualification. Products may be described as “well tolerated” provided the claim is substantiated with safety context and balance, including but not limited to warnings, contraindications, and other safety information.

FAQ: Fair Balance	
	Can promotional materials for a product claim that the product is “safe?”
	<p>No. The word “safe” cannot be used without qualification since all products have risks. A product may, however, be described as having a “well-studied safety profile” if that can be substantiated by medical evidence.</p> <p>Appropriate safety information, such as boxed warnings, contraindications, warnings/precautions, and side effects must also always be provided to balance and provide context to such a statement.</p>

2. Use Review Committee (RC)-approved communications supported with adequately substantiated evidence

Sales and marketing materials intended to promote our products or educate about associated disease states for use in the United States must be reviewed and approved for use through the multi-disciplinary promotional RC process following Pfizer’s Global Content Policies listed in the last chapter of this Section, *Additional Resources for More Information*.

These materials include:

- Content submitted to FDA OPDP or APLB by **Date of First Use (DOFU)**
- Requests for Advisory Comments from OPDP or APLB
- Pre-approval disease awareness or pre-launch communications

Pfizer Marketing Teams and RC are encouraged to provide “Implementation Guidance” and/or “In-Context Training” for Sales Colleagues regarding key or complex promotional pieces such as visual aids, key sales aids, or reprints. The guidance and training should outline how to compliantly communicate the promotional content, including providing boundaries as to what Sales Colleagues can and cannot say relative to the content in the material.

Therefore, Sales Colleagues must only use materials that have been RC approved for their role and apply the guidance in the applicable Implementation Guide and In-Context Training when detailing customers.

	<p>Statements made in a promotional setting are considered promotional labeling and MUST be:</p> <ul style="list-style-type: none">• Consistent with the responsibilities of their role• Consistent with the claims/content in RC-approved materials• In alignment with guidance and training
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When communicating in a promotional setting, colleagues MUST NOT:

- Alter RC-approved materials in any manner including crossing out content, adding sticky notes, or applying handwritten notes
- Show or share any materials marked “DO NOT DETAIL” or “Internal Use Only” with external colleagues including HCPs or other customers
- Make or imply claims not provided on RC-approved materials, including comparative or superiority claims in efficacy or safety, unless the claim is specifically included in RC-approved promotional materials
- Make comparative efficacy or safety claims based on data in products’ respective full prescribing information
- Compare results from two separate clinical trials due to differences in design, patient population, and other factors

Product “claims” characterize the efficacy, safety, dosing, drug class, or other attribute of a product. All claims must be consistent with FDA-approved labeling and supported by adequately substantiated evidence.

The RC review and approval process is designed such that RC-approved materials are rigorously evaluated for the level of scientific substantiation/evidence required to support claims included in materials.

A product may be considered “misbranded” if promotional labeling or advertising communicates claims that are not supported by the adequate level of substantial evidence. Some claims require a rigorous level of substantial evidence which, in general, includes two well-designed, randomized, double-blind, placebo-controlled clinical trials.

In some situations, the level of evidence needed for certain claims may vary. RC will evaluate promotional content in relation to the FDA-approved labeling and other FDA feedback, including labeling discussions and advisory comments from OPDP or APLB.

For an overview of substantiation of claims, please refer to appendix III in the [Global Content Policy: Commercial Standards for Promotional Materials](#).



Colleagues MUST ensure that:

- Promotional claims are sufficiently substantiated by the product labeling or adequate level of substantial evidence
- Claims of efficacy or safety are supported by up-to-date evaluation of evidence that is consistent with FDA-approved labeling, including evidence that is scientifically appropriate and statistically sound
- Quotations are referenced, consistent with labeling, and have adequate substantiation
- Claims are not stronger than evidence warrants
 - Each claim is only as strong as the evidence that supports it
- Product claims are narrowly tailored to match the findings of the evidence/data
- Non-clinical data or studies are clearly identified as non-clinical and not used in a misleading manner such as to suggest or imply clinical relevance where clinical relevance cannot otherwise be established
- References and data used to support “data-on-file” is readily available and retrievable upon request

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- Claims of statistical significance are supported by adequate level of statistical assessment and are not used to imply greater efficacy or fewer risks than established by adequate scientific or medical evidence

FAQ: 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.

Detailing Medium

Sales Colleagues are expected to detail RC-approved digital materials using their approved device, such as a tablet or iPad, whenever possible.



Brand Teams MUST gain approval from the relevant GPC if they are seeking:

- Exceptions from this general rule
- To use only paper materials and no digital materials for detailing

For more information around Global Content Policies Related to RC Review and Approval and Guidelines for Advertising and Promotion, please refer to the last chapter of this Section, *Additional Resources for More Information*.

3. Be consistent with product labeling and only discuss approved products and indications, with narrow pre-approval exceptions

Regulatory authorities in each country, including the FDA, typically dictate the content of the approved product labeling. Promotional communications must be consistent with the FDA-approved labeling.

In certain circumstances, brand RCs may approve content that is not specifically contained in the label but is not inconsistent with the FDA-approved labeling.



Pfizer Colleagues MUST:

- Only promote FDA-approved products and FDA-approved uses (including indications and dosing) of its products
- Ensure Promotional communications are consistent with FDA-approved labeling and based upon RC-approved promotional materials and implementation guides

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- Follow the process for unsolicited medical requests (UMRs) if asked an unsolicited question about an unapproved product, unapproved indication, or any other clinical content that is not permitted to be discussed in a promotional setting
- Remember that off-label promotion is taken seriously by both Pfizer and regulatory agencies
- Remember that investigational uses for products or those under FDA review lacking approval are considered off-label, and statements or claims for such products or uses are not permissible in a promotional setting



Pfizer Colleagues MUST NOT:

- Discuss any investigational product, uses, or indications that have not been approved or are under FDA review, regardless of how appealing or robust the scientific evidence
 - Pre-approval promotion can jeopardize the approval of a new product or indication that may result in severe penalties
 - Please note narrow exceptions applicable to pre-approval communications mentioned earlier in this chapter
- Refer to an unapproved investigational product or indications when communicating with an HCP, including when trying to schedule a meeting
- Solicit or prompt HCPs to ask questions about unapproved products or indications in any promotional interaction

4. No actual or perceived quid pro quo

Quid pro quo is Latin meaning “this for that.” Colleagues must never engage in actual or perceived quid pro quo.



Pfizer Colleagues MUST NOT:

- Either offer, or appear to offer, any [remuneration](#) or item of value in exchange for inducing an HCP to prescribe a product or to place a product on formulary
 - HCPs should base their decisions to prescribe or recommend Pfizer products based solely on the best interest of the patient and not on any item of value offered to the HCP
- Give something of value, even something of nominal value, to induce directly or indirectly the prescribing or recommendation of a product by an HCP
 - This is why in-kind transfers of value, such as indicating our patient support offerings will save office staff time or offering to assist in preparing applications or paperwork, are not permissible
- Incur any expenses with an entity that is owned in whole or part by an HCP or other customer
 - An example of an interaction that is not permissible would be doing business with a catering company or restaurant owned by an HCP

On occasion, in the course of promotional and other interactions, such as consultant meetings or conventions, Pfizer Colleagues may have a bona fide reason to provide a meal or other item(s) on an occasional basis to an HCP. All colleagues, including HQ/Marketing Colleagues, are required to comply with Pfizer policies and laws—including state

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law restrictions regarding when, how, and by whom meals, educational, or other items may be provided to HCPs. For further guidance, see Sections 2 and 9 of *The White Guide*.

Appropriately Describing Patient Access and 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. Patient Access and Reimbursement Support carries a high risk of perceived quid pro quo.

	<p>When creating materials that focus on patient access and reimbursement support resources, colleagues must ensure that the content and purpose of these resources is:</p> <ul style="list-style-type: none">• Clear, factual, and non-promotional in purpose or tone• Consistent with the Patient Access Toolkit
	<p>Materials <i>MUST NOT</i> communicate that these offerings or resources:</p> <ul style="list-style-type: none">• Are a reason to prescribe the product• Differentiate the product from competitors• Provide <u>independent value</u> to a doctor by relieving administrative burden or otherwise providing a service to the doctor

Some Pfizer brands may offer brand-specific reimbursement and patient support activities that are carried out by field-based colleagues. For more information regarding the creation of these types of programs, please see the [Patient Support Hub Guidance Standard Operating Procedure \(SOP\)](#). Furthermore, see Section 4 of *The White Guide* and Section 3 and Section 5 of [The Orange Guide](#) for further guidance on appropriate interactions regarding these patient support activities.

Chapter 3: Guidance for Common Engagements and Communications Involving Healthcare Professionals

The general term “marketing program” is used in *The White Guide* to describe engagements, activities, and communications that promote Pfizer products by providing Healthcare Professionals (HCPs) or consumers with educational, scientific, and clinical information consistent with Food and Drug Administration (FDA) regulations.

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).

In this chapter, we will review the guidance for common engagements, activities, and communications involving HCPs, such as:

- Reprint Use in Product Promotion
- Internet, Social Media, and Other Digital Promotion
- Commercial e-mails
- Paid Media
- Starters and Free Trial Vouchers
- Non-Speaker Program Meals Provided to HCPs
- Speaker programs
- Educational items to HCPs
- Promotional Opportunities at Third-Party Meetings and Conventions
- Company Sponsored Programs (CSPs)

Reprint Use in Product Promotion

A brand RC may review and commercial approve clinical reprints for promotional use by Field Commercial Colleagues. Most reprints approved for use will generally 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](#).

Further, in accordance with agreements between Pfizer and certain state Attorneys General, there are additional requirements and restrictions that apply when an RC is considering a reprint for promotional use.

Pfizer MUST NOT:

- Disseminate information regarding an off-label use of a Pfizer product if that use was submitted to the FDA for approval and the FDA either
 - refused to approve the application
 - 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

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- Distribute 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

In addition, reprints relating to the use of opioids for chronic pain must be accompanied by information relating to the potential risks of addiction, abuse, and misuse associated with extended-release opioids.

Before approving a reprint, the brand RC 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 \(United States \[U.S.\] Addendum\)](#), any reprint reviewed for approval under this guidance may also be referred by the brand RC to the relevant Business Unit RC (BURC).

Internet, Social Media, and Other Digital Promotion

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

Detailed information on the requirements of digital promotion by tactic can be found under the [Advertising & Promotion Guidelines tab](#) on [Global Policy Xchange on Biopharma Ops on Demand](#). These guidance documents can also be found on the [Digital Review Team site](#).

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 HCPs or consumer can opt out of receiving future e-mails
- An Internet-based mechanism for opting out, such as a reply e-mail address or a link to a website
 - This mechanism must remain in effect for at least 30 days after the commercial e-mail is sent and an opt-out request must be honored within 10 business days of receipt
 - Brand Teams are not allowed to share or sell an e-mail address of someone who has opted out
- A clear and conspicuous identification that the e-mail is an advertisement or promotions sponsored by Pfizer
 - The Act does not require specific language, so teams may choose how to describe the e-mail as an advertisement
 - Using 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:

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- Facilitate or confirm an agreed-to commercial transaction
- Give warranty, recall, safety, or security information
- Give information about a change in terms, features, or Account balances for ongoing relationships
- Provide information about employment relationships or benefits
- Deliver already purchased goods or services

A transactional e-mail may contain advertising if the primary purpose of the e-mail is transactional and not promotional. E-mails that are not primarily commercial or transactional, and are considered “other” e-mails, are also exempt from the above requirements.

The Act also 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.

Furthermore, there are 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 the relevant Global Product Counsel (GPC) if your program involves referral or multi-party e-mails.

And finally, the Act 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 must coordinate with Biopharma Ops/Global Business Services (GBS) HCP/Patient Engagement Center and their relevant GPC to ensure compliance with all applicable laws and regulations.

For more information, please consult [Pfizer U.S. E-mail Guidelines](#).

Paid Media

Paid Media refers to advertising and promotional efforts where the Pfizer Biopharmaceuticals Group (PBG) pays to place ads or other content on media and other platforms not owned or controlled by Pfizer. It is used to reach patients, HCPs, or other targets with branded or unbranded communication.

Examples of paid media include:

- Video commercials on Broadcast Television (TV) or YouTube
- Banner ads on Medscape
- Sponsored article in The New York Times
- Paid search on Google
- Newsfeed placements on Facebook

Media Services are related to paid media and includes the following:

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

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While paid media efforts are an important tool to reach patients and HCPs, there are also multiple risks including fraud, privacy, and reputation. To protect Pfizer, PBG policy requires that Paid Media be centrally led and governed by the Pfizer Media Team across the following Pfizer requirements:

- **Control and Tracking:** visibility of all media spend and practices, and the ability to pause or stop
- **Protection of Media Spend:** [Fair market value \(FMV\)](#), auditing, appropriate terms and conditions
- **Media Vendor Management:** Single Pfizer voice and process as well as proper vendor vetting
- **Respect Privacy:** Adherence to Pfizer's Privacy Policy as well as privacy laws and regulations
- **Reputation:** Media practices and placements consistent with Pfizer values and policies

Paid Media Procedures apply to all colleagues across functional areas, U.S. Businesses, and divisions that are engaging in paid media and media services that are funded by and for the benefit of PBG. To be compliant with these procedures, colleagues are required to adhere to the following standard operating guidelines:

- All PBG paid media and media services must be initiated and implemented through the Media Team and its processes, guidelines, and tracking systems
- Only the Media Team can implement, negotiate, or purchase paid media or media services on behalf of PBG
 - Colleagues must not sign contracts for paid media or media services
- The Media Team serves as the single point of contact for media vendors
 - Includes evaluating media vendors against existing Pfizer buying guidelines
 - For vendors with media and non-media offerings, vendors must be referred to the Media Team for paid media and media service offerings
 - Non-media colleagues must not engage in media-related discussions, sign contracts, or bundle media in with non-media offerings
- The Media Team selects and manages external media agency resources, which must be used for all PBG paid media and media services
 - Creative, digital, or Public Relations (PR) agencies cannot engage in media activity
- The Media Team is responsible for all media services related to data, tools, and analytics used for media activation, optimizations, reporting, and measurement
- For Co-promotes, whereby the Co-promote media AOR is leading media and not the Pfizer Media Team, Pfizer Brand Teams are responsible for ensuring core media requirements are met for compliance, privacy, auditing, FMV, and vendor selection.

Key activities that are out of scope for this policy include **Pfizer Corporate-funded paid media**, **HCP Congress Media**, whereby media is planned directly with Congress, and **In-pharmacy Media**.

For questions related to the Paid Media Policy, please contact the **Pfizer Media Team**.

Starters and Free Trial Vouchers

Pfizer provides HCPs with free pharmaceutical drug product samples, referred to as “**starters**,” so they can evaluate the efficacy and tolerability of our products for a patient before filling a prescription. Starters also give 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.

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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 as a starter.

By law, biopharmaceutical 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.

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, 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 use a product for a limited time for the purpose of allowing the prescribing HCP to evaluate efficacy and tolerability.

Improper use of vouchers can implicate state and federal false claims acts as well as anti-kickback laws and could also be deemed to impact the "best price" of a product, which is the discount the Company is required to give the Medicaid program on every unit of product it reimburses.

For more information on Starters and Free Trial Vouchers, refer to Section 3 of [The Orange Guide](#) and the [Starter Compliance Manual](#).

Non-Speaker Program Meals Provided to Healthcare Professionals (HCPs)

Pfizer policy and the Pharmaceutical Research and Manufacturers of America (PhRMA) Code permit colleagues to provide non-speaker program meals to U.S. HCPs on occasion in appropriate circumstances, such as meals in connection with informational presentations or discussions providing scientific or educational value, so long as:

- The meal is modest as judged by local standards
- The meal is never the primary focus of the interaction
- The presentation and ancillary meal occur in a venue and manner conducive to informational communication
 - Recreational and entertainment venues are prohibited
 - An HCP's spouse or other guest is prohibited, unless the spouse or guest is otherwise an appropriate attendee under Pfizer policies
 - Take-out meals or meals to be eaten without the Pfizer Colleague present, or virtually present under appropriate circumstances, are prohibited

Furthermore, it is important to note that all non-speaker program meals are reported for purposes of Open Payments and State Laws.

General Pfizer Policy Regarding Non-Speaker Program Meals

- Non-speaker program meals provided in an in-office or in-hospital setting, including virtual, must not exceed \$40 per attendee
 - Including food, beverage, tax, tip, and delivery charges
 - No other expenses, such as room fees, may be paid to the office or hospital in connection with meals conducted in an in-office or in-hospital setting
- Out-of-office non-speaker program meals by approved colleagues to U.S. HCPs must not exceed \$150 per attendee
 - Including food, beverage, tax, tip, and delivery charges



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- Excluding out-of-office speaker program meals
 - See Speaker Program information in this chapter for additional requirements
- Any pre-dinner food or beverages must be included in the \$150 limit
- Solely providing alcoholic beverages or excessive amounts thereof is prohibited and not considered conducive to a business discussion
- 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
- Several states, as well as the [Department of Veterans Affairs \(VA\)](#) and the [Department of Defense \(DoD\)](#), impose meal limitations and reporting requirements that are stricter than the PhRMA Code and/or Pfizer policy
 - Before providing any meals or other items of value to HCPs, colleagues should refer to state laws and guidance for federal employees found in Section 9 of *The White Guide*
- Colleagues cannot provide any food or other support in connection with an accredited Continuing Medical Education (CME) activity, such as the Accreditation Council for CME (ACCME), Accreditation Council for Pharmacy Education (ACPE), or American Nurses Credentialing Center (ANCC)
 - Any type of financial support for accredited Continuing Education (CE), 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 office of Global Medical Grants (GMG)
 - Please note that "medical education" also includes education for HCPs that are not physicians, such as pharmacists

Furthermore, there are PhRMA Code restrictions on out-of-office meals that only apply to Sales Representatives and their immediate managers. Whether 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.

Section 3 of [The Orange Guide](#) provides a high-level summary of when Pfizer Colleagues are permitted to provide meals to HCPs based on each colleague's role.

As long as they follow the requirements reviewed later in this chapter, Pfizer Headquarters (HQ)-based Marketing and Medical Colleagues may host non-speaker program meals held in

- An HCP's office and/or a Hospital
 - These meals can be either face to face or virtual
- Restaurants

For information on non-speaker program meals, snacks, and beverages provided by sales representatives and their immediate managers, please refer to Section 3 of [The Orange Guide](#).

Exceptions to Restrictions Against Hosting Out-of-Office Meals

The PhRMA Code restrictions on out-of-office meals that apply to Sales Representatives and their immediate managers are not applicable to:

- Senior Sales Colleagues above Area Business Manager level
- HQ personnel, including Marketing, HQ Medical, and Senior Business Leadership Colleagues
- Account Management Colleagues when interacting 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.

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Legitimate Business Reasons for Out-of-Office Meals

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, 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.

Planning and Execution for Out-of-Office Meals



All out-of-office meals MUST follow the requirements below:

- 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 they will ensure there is a meaningful opportunity to engage with all attendees - for example, by including other colleagues who can support the interaction.
- The host must have a legitimate business objective for the interaction and consider having a list of topics and questions or another presentation to facilitate the legitimate business discussion
 - 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 consistent with RC-approved content, and discussed and reviewed, as needed, with their manager and the relevant GPC and/or Brand Medical before the meal, depending on their 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
- Any materials and questions to be used to facilitate the discussion must be on-label and consistent with overall brand strategy—unless the discussion is being led by a colleague who is permitted by Pfizer policy to engage with HCPs regarding an unapproved product/indication or disease states/therapeutic areas for which Pfizer has no product
 - Colleagues should consult their Product Attorney for any questions regarding whether the topics to be discussed at a proposed meal with an HCP are appropriate
- To the extent that one is aware that multiple Pfizer Colleagues—such as Regional Business Directors (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

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coordinate to ensure that the overall number of events and HCP attendees is appropriate to achieve the business need

- 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 used 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
 - Deliverables should clearly decipher between which content reflects HCP insights versus Pfizer Colleague conclusions

Attendance by Other Colleagues at Out-of-Office Meals Hosted by Permitted Pfizer Colleagues

When determining who may be in attendance for an out-of-office meal hosted by an appropriate colleague, colleagues must always ensure that the topics of discussion are appropriate for all colleagues in attendance and that the ratio of Pfizer Colleagues to HCPs is conducive to the business discussion.

- Senior Sales or HQ Colleagues should not discuss a proposed speaker agreement with an HCP in the presence of a Sales Representative or the Sales Representative's immediate 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 their immediate 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 considerations include:

- Their specific expertise relating to the customer, Account, or local dynamics—attendance should only be 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 their immediate manager at a meal with that same HCP would generally be unnecessary, and 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 their immediate managers
- Sales Representatives and their immediate managers may not attend out-of-office meals for the purpose of conducting promotional activities or discussions that they cannot host on their own, such as detailing at a restaurant, or to meet their own objectives of building a relationship with an HCP
- Sales Representatives should not be attendance where the agenda includes discussion regarding an unapproved product or indication, or disease states or therapeutic areas for which Pfizer has no product (led by a colleague who is permitted by Pfizer policy to engage on such topics)
- 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 manager in attendance

Any attendance by HQ or field-based Medical Colleagues should be consistent with guidance on joint commercial-medical activities in this guide and [The Green Guide: Governance for Medical Activities](#). Medical participation is subject to review and approval by the relevant Product Attorney.

For information about business meals provided by Sterile Injectable Colleagues and non-speaker programs provided by Patient Support Roles, please refer to Section 3 of [The Orange Guide](#).

Non-Speaker Program Meals Disclosure Requirements for Healthcare Professionals (HCPs)

Pfizer's disclosures include all meals provided to U.S.-licensed HCPs, regardless of value. This is because state laws may also impose meal limitations and reporting requirements that are stricter than the PhRMA Code or Pfizer policy.

Although not treated as "meals," snacks and refreshments of nominal value, defined as \$10 or less per attendee, must also be appropriately recorded in expense reports.

FAQ: Disclosure of Snacks and Refreshments Provided at Exhibit Booths	
	We are planning to have an exhibit booth at a state physicians' annual convention, at which we intend to make coffee and pastries of nominal value (\$10 per attendee or less) available. Do I need to track and report the refreshments provided to U.S.-licensed HCPs visiting the Pfizer booth?
	No. As a general rule, snacks and refreshments of nominal value do not need to be tracked at an exhibit booth when conducted in a large-scale convention or conference setting of greater than 50 attendees.

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.

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, such as 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.

	<p>Based on the minimum standards, Colleagues MUST ensure:</p> <ul style="list-style-type: none">• 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
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	<ul style="list-style-type: none"> • Appropriate materials and content • Appropriate program execution • Appropriate expenditures are made • Appropriate transparency of transfers of value
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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.

	<p>The SPNA MUST set forth:</p> <ul style="list-style-type: none"> • The educational goal(s) • The topics planned to support the educational goal(s) • The respective justification for each topic planned • The target audience • Any data/metrics that support the need for education in a peer-to-peer format
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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.

For more information on speaker programs with a consumer audience, see Section 4 of *The White Guide*. For more information regarding Global Speaker Program Policy minimum standards, please review the [Global Speaker Program Policy](#).

FAQ: 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.</p> <p>Generally, the Sales Colleague chooses an appropriate venue and presentation topic from the list of RC-approved topics in CentrisDirect™, selects an appropriate speaker, and contacts that speaker. Marketing Colleagues should partner with an appropriate Sales Colleague with CentrisDirect access to enter their program into the system.</p>

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	<p>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.</p> <p>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 CentrisDirect™. 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 CentrisDirect™ close-out process.</p> <p>For more information on program host responsibilities when conducting a speaker program, see Section 3 of The Orange Guide.</p>
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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 be aligned with the educational goals identified in the SPNA.

Examples of legitimate educational needs are:

- Raise awareness of a disease state
- Education on a new product within 24 months of FDA approval
- Education on a 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 a product or specific disease state

Brand Teams interested in conducting speaker programs outside these windows must obtain approval from a Business leadership-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, such as 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, such as detailing or Direct-To-Consumer (DTC) advertisements.

	<p>All speaker program content MUST:</p> <ul style="list-style-type: none">• Be reviewed by RC and approved by commercial• Be designed to meet the educational goal identified in the SPNA• Comply with Pfizer policies on advertising and promotion• Include a mandatory introductory compliance slide which notifies attendees of certain key Pfizer speaker program policies, including reminders such as:<ul style="list-style-type: none">– Speakers are presenting on Pfizer's behalf– Content is required to be consistent with FDA-approved labeling
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	<p>Speakers MUST:</p> <ul style="list-style-type: none">• Use only Pfizer-approved slides when speaking on behalf of Pfizer• Use slides that have been approved for the specific audience• Comply with Pfizer Promotional Speaker Compliance Guidelines Training annually and with the brand's Core Product or Topic Training Slide Kit as applicable• Engage attendees in line with the program duration requirements<ul style="list-style-type: none">– Programs held out-of-office: minimum of 45 minutes, inclusive of Questions and Answers (Q&A)– Programs held in-office or conducted virtually: minimum of 30 minutes
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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.

	<p>Speakers MUST NOT:</p> <ul style="list-style-type: none">• Modify slides or insert their own slides, including introductory, speaker bio, case study, and disease state slides<ul style="list-style-type: none">– 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, truthful, supported by substantiated and scientifically sound data, and appropriately balanced with information on both benefits and risks
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Speaker Programs Topics and Invitations

As part of the RC review 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 CentrisDirect™, 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—such as “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—such as in the case of a new product launch—please discuss the matter beforehand with the relevant GPC, Regulatory, and the Enterprise Travel, Meetings, and Healthcare Engagements Team (ETM&HE) Team to ensure that all legal, regulatory, and operational requirements are satisfied.

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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 Section 3 of [The Orange Guide](#).

Speaker Recruitment and Contracting

A list of active and appropriate Pfizer speakers for given products and topics is available in CentrisDirect™.

These are speakers that have:

- Been vetted by a third-party against an objective set of criteria that reflects evolving industry standards and accounts for reputational risks
- Been assessed based on their qualifications, license status, and presence on internal and exclusion lists
- Obtained a signed contract with Pfizer
- Completed compliance training
- Completed training on a core product or topic slide kit in-person, virtually, or online on-demand, as applicable
- Not yet reached Pfizer's annual promotional speaker payment cap or caps on frequency of utilization by individual sales representatives or sales district members

Contracted speakers are only approved to conduct programs if they have completed Pfizer's annual training requirements.

The two main analyses relevant to the speaker recruitment process are:

- Determination of the number of speakers reasonably required to execute the expected number of speaker programs
 - This helps determine if new speakers need to be recruited for the initiative in addition to the speakers that are already trained and active
- Identification of the qualifications and expertise of the speakers necessary to execute the planned programs

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 ETM&HE Team for more information on speaker nominations and validation.

	<p><i>Speakers MUST only be selected based on their:</i></p> <ul style="list-style-type: none">• Expertise• Credentials• Ability to communicate with the target audience
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	<p><i>Speakers MUST NOT be selected to:</i></p> <ul style="list-style-type: none">• Establish, maintain, or improve a relationship with the speaker• Gain or improve access to the speaker• Reward past prescribing or induce future prescribing<ul style="list-style-type: none">– Although the speaker should have experience with the product or disease state, prescribing volume may not specifically be considered when selecting a speaker
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Prior to providing any speaking services, all speakers must have a signed agreement in place with Pfizer that documents the speaker's 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 to the ETM&HE Team to obtain final Legal 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 Standard Operating Procedure \(SOP\)](#). For additional information, see the [U.S. HCP Payment Disclosure Information page](#) on Policy Xchange.

Speaker Training

Prior to engaging in any speaking engagements, all speakers are required to complete the following training:

- Pfizer Promotional Speaker Compliance Guidelines Training, annually
- 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.

A speaker may complete training either online via CentrisDirect™, 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. For further guidance on this scenario, consult the relevant GPC.

Live in-person speaker training sessions should be held in venues and locations that are appropriate and conducive to informational communication and training about medical information. Resorts are not appropriate venues.

Furthermore, 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, please reach out to the [Speaker Operations mailbox](#).

Program Execution

All Pfizer-sponsored speaker programs are conducted in accordance with PhRMA Code principles to address a bona fide educational need with appropriate attendees in a venue and manner conducive to informational exchange.

Regulatory guidance and enforcement actions also highlight the fact that there is some inherent risk associated with conducting speaker programs. Therefore, to mitigate risk while preserving the educational value of speaker programs, Pfizer policy:

- Prohibits providing or paying for alcohol in connection with speaker programs, including product theaters and promotional symposia at a conference or congress
- Does not permit “high-end” restaurants as venues
- Requires a company representative to be physically present with attendees if an accompanying meal is to be provided—however, the speaker may present virtually

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Regardless of whether it is a program led by Marketing or Sales program, all speaker programs must be executed consistent with the more detailed requirements outlined in Section 3 and Section 5 of [The Orange Guide](#).

Educational Items to HCPs

	<p>In accordance with the PhRMA Code and Pfizer policy, Pfizer Field Commercial Colleagues MUST:</p> <ul style="list-style-type: none">• Only provide RC-approved educational items valued at \$100 or less on occasion to HCPs or members of their staff if they are not otherwise prohibited under applicable state laws or VA/DoD restrictions• Refer to state laws and guidance for federal employees before providing any educational items to HCPs<ul style="list-style-type: none">– As with meals, several states and the VA/DoD also impose limitations that are stricter than the PhRMA Code or Pfizer policy on educational items, and other items of value, that may be provided to HCPs– Understand that 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
	<p>Pfizer Field Commercial Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Offer non-educational items, even if the items are practice-related and of minimal value, such as pens, pads, or mugs

If a question arises about whether a specific educational item is approved to be provided to HCPs, colleagues should consult the relevant product Legal or Regulatory Colleague, or submit the question to StateHealthcareLawCompliance@pfizer.com.

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 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, including:

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- 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
- 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 FMV of the opportunity.

For more information on promotional opportunities at third-party meetings and conventions, including funding and execution, please refer to Section 7 of *The White Guide*.

Furthermore, remember that 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. Please 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 used in symposia programs is typically customized for the event, delivered by a Pfizer-paid faculty speaker, and 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 either, attendance is controlled with logistic support provided by meeting planners on the ETM&HE Team.

Open-door symposia take place at third-party events, such as congresses or conventions, with logistical support provided by a Meeting Manager on the ETM&HE Team.

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 ETM&HE 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 because the intent is to foster unbranded disease awareness
- **Scientific-exchange Symposia** are symposia where non-promotional scientific or medical information about an unapproved product, such as 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 ETM&HE 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

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trained Pfizer Colleague—the “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, which is 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 any contracted content vendor are responsible for ensuring the symposium faculty follows Pfizer’s content requirements and processes. For symposia managed with the support of the ETM&HE Convention Housing and Logistics Team, the Meeting Managers are responsible for ensuring that all speakers have received compliance training.

Invitations, Logistics, and Meals

The Project Owner and the ETM&HE 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 [Global HCP/HCO Transparency 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 [Pfizer Transparency Repository System \(PTRS Tool\)](#) on Policy Xchange so as not to invite those holding a Minnesota or Vermont license. For additional information, see Section 9 of *The White Guide*.

Exhibit or Display and Other Digital Activities

Funding for an **exhibit or display** or other promotional opportunity at a congress or convention must not be greater than the FMV of the opportunity. Likewise, Brand Teams cannot bypass the grant process administered by **GMGs** 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 \(External Funding SOP\)](#), which is described in more detail in Section 7 of *The White Guide*. Applicable Foreign Corrupt Practices Act due diligence must also be conducted by the Funding Request Form (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/display opportunity.

Company Sponsored Programs (CSPs)

Company Sponsored Programs (CSPs) are Pfizer-sponsored programs that gain insight from, or provide information or support to, its customers and that allow for collection of patient-level data by Pfizer or Pfizer contracted resources.

Patient-level data may be collected via different channels including:

- Direct interaction, such as telephone or face-to-face
- E-mail or text messaging (SMS)
- Open text fields in digital media, such as internet sites or social media
- Paper-based surveys and enrollment forms

“Customers” include patients, consumers, caregivers, HCPs, or other external stakeholders.

CSPs can be categorized into four categories:

- Patient Support Programs
- Market Research Programs
- Social Media, Websites, and Mobile Applications
- Other Patient-Level Data Collection

[Corporate Policy 902, Company Sponsored Programs Policy](#) defines Pfizer’s guiding principles for the management of CSPs to ensure timely and accurate reporting of Product Safety Information and adherence to applicable privacy requirements.

	<p>CSP Owners MUST ensure that:</p> <ul style="list-style-type: none">• The design, review, approval, and conduct of CSPs comply with Corporate Policy 902, Company Sponsored Programs Policy and Corporate Policy 902a, Cross-Divisional Procedure Company Sponsored Programs Procedure<ul style="list-style-type: none">– These documents contain additional detail on the types of activities that may fall into scope of Corporate Policy 902, Company Sponsored Programs Policy• Reportable Safety Information is submitted within 24 hours of becoming aware of any such information concerning Pfizer products<ul style="list-style-type: none">– This is reviewed in Section 1 of <i>The White Guide</i>, Corporate Policy 903, Your Responsibility to Report Information about the Safety, Quality, and Performance of Pfizer Products, and associated training entitled Your Reporting Responsibilities (YRR) Training.
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Colleagues may visit the [Biopharma Quality \(BQ\) Resource Center](#) for tools and other information. Please note that Patient Support Programs may be subject to additional requirements as described in Section 4 of *The White Guide* and [Cross Divisional Policy: Management of Patient Support Programs](#).

Chapter 4: Guidance for Healthcare Professional (HCP) Consulting Engagements

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, HCPs are defined as members of the medical, dental, pharmacy, and nursing professions as well as anyone else who may in the course of their professional activities recommend, influence, manage or directly prescribe, supply, administer, or buy any medicines. It also includes researchers and investigators, and any other individuals engaged in healthcare-related practices or employed by a healthcare institution, as noted in the [HCP Engagements Standard Operating Procedure \(SOP\)](#) and [HCP/GO Engagements & Interactions \(R&D SOP 201\)](#).

For United States (U.S.)-based businesses, Corporate Affairs, and Medical Colleagues, the [HCP Engagements SOP](#) is applicable to most HCP, non-U.S. HCP, and non-U.S. GO consulting engagements. However, it does not apply to Marketing and Sales speaker programs, clinical services, and other activities subject to other policies. See the Scope section of the [HCP Engagements SOP](#) for more information.

For U.S.- based Worldwide Research, Development and Medical (WRDM) and Global Product Development (GPD) (collectively, R&D Colleagues), HCP engagements in support of Pfizer's R&D activities are subject to the policies and procedures set forth in the [HCP/GO Engagements & Interactions \(R&D SOP 201\)](#).

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 Party, in a [Restricted Market](#), or otherwise prohibited from being engaged by Pfizer
 - For more information on what constitutes a Restricted Party, see [Corporate Policy 206. Compliance with Global Trade Control Laws](#)
 - For more information on what constitutes a Restricted Market, see the [Global Trade Control \(GTC\) website](#).
 - Otherwise prohibited from being engaged by Pfizer means the consultant is not
 - on any applicable internal Pfizer exclusion lists
 - on any lists of HCPs/GOs subject to state disciplinary actions, state licensing suspension or revocation, Food and Drug Administration (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 their 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

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	<ul style="list-style-type: none">• 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• Any compensation does not exceed fair market value (FMV)
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	<p>Colleagues <i>MUST</i>:</p> <ul style="list-style-type: none">• Ensure that consultants provide an actual service<ul style="list-style-type: none">– For example, passive activities, such as time spent merely listening to a marketing presentation, are not considered Bona Fide Services and are not compensable• Select consultants who possess experience or expertise relevant to the engagement• Specify in the written consulting agreement that there is no connection between the compensation provided and the prescribing of Pfizer products
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	<p>Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Select consultants to influence or reward their prescribing or recommendation of Pfizer products or to provide Pfizer with any other improper benefit or advantage• Determine consulting fee payments in a manner that takes account of the past, present, or future volume or value of business generated by consultants for Pfizer• Enter into a consulting arrangement with an HCP with the objective of:<ul style="list-style-type: none">– Establishing or improving a relationship with the HCP– Gaining or improving access to the HCP– Rewarding past prescribing– Inducing future prescribing– Influencing formulary decision making– Gaining any other improper business advantage
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The [Global Policy Xchange on Biopharma Ops on Demand](#) contains job aids, guidelines, and other useful documents to help ensure a compliant consulting arrangement. Also, colleagues should consult the following SOPs, as applicable, to identify the specific steps that are necessary to plan and execute a compliant consulting engagement:

- [Corporate Policy 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 FMV 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 \(MAPP\)](#)
- For R&D Colleagues, the HCP engagements process is detailed in the [HCP/GO Engagements & Interactions \(R&D SOP 201\)](#)

Furthermore, the Pfizer Enterprise Travel, Meetings, and Healthcare Engagements (ETM&HE) Team is generally responsible and should always be consulted for managing the logistics for meetings that involve HCP consultants.

Consulting Engagement Controls Overview

Pfizer has developed, implemented, and continued to maintain controls to manage HCP consulting engagements. Review the controls in the following table.

Controls to Manage HCP Consulting Engagements	
Controls	Description
Annual Consultant Needs Assessment	<ul style="list-style-type: none"> For engagements subject to the HCP Engagements SOP, on an annual basis, U.S. business 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 HCP/GO Engagements & Interactions (R&D SOP 201) does not require completion of an ACNA
Business Rationale Form Requirements	<ul style="list-style-type: none"> Prior to each engagement under the HCP Engagements SOP, and certain engagements related to FDA-approved Pfizer products under HCP/GO Engagements & Interactions (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 <p>The BRF MUST:</p> <ul style="list-style-type: none"> Identify the legitimate business need for the services of the consultant <ul style="list-style-type: none"> For example, describing the gap in knowledge, understanding, or expertise that the consultant would be able to fill Provide specific details including qualifications of the consultant(s) to be engaged Identify the necessary and substantive scope of services that the consultant will provide Detail the expected work product/information that will be generated from the engagement Describe how the output or deliverable(s) of the proposed arrangement will benefit Pfizer <p>The relevant Global Product Counsel (GPC) will:</p> <ul style="list-style-type: none"> Review each BRF associated with any proposed consulting engagements prior to the retention of consultants Only review BRFs that meet BOTH of the following criteria: <ul style="list-style-type: none"> One or more US-Based HCPs will be engaged Some or all of the colleagues directly involved in the meeting have job responsibilities that include the U.S. market/territory <ul style="list-style-type: none"> This may be as part of a US-specific team or a team with a broader focus, such as a global team or a regional team that encompasses the US Review the BRF for consistency with Pfizer policy, and with the relevant ACNA if applicable <ul style="list-style-type: none"> This includes working with the team to ensure that any variance from the ACNA has been appropriately documented

Controls to Manage HCP Consulting Engagements	
	<ul style="list-style-type: none"> • Determine if the BRF is out of scope for GPC <ul style="list-style-type: none"> – If it is out of scope, the BRF would then be reviewed/approved by the Project Owner's Business reviewer
Contract Requirements	<ul style="list-style-type: none"> • Pfizer must execute written agreements with the consultants it engages prior to work beginning <p>The agreement MUST:</p> <ul style="list-style-type: none"> • Describe the scope of work to be performed as well as the consultant fees to be paid <ul style="list-style-type: none"> – Fees are determined based on a centrally managed rate structure that represents FMV • Describe the compliance obligations of the consultant, including consent to and cooperation with Pfizer's public disclosure of payment to the HCP • 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 GO, the MAPP process must be completed before the contract with MAPP required clauses for consultant engagements is executed, including any requirements set forth in the relevant market Country Annex Portal
Work Product	<ul style="list-style-type: none"> • 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

There are key compliance requirements pertaining to the process for engaging HCP consultants as outlined in the [HCP Engagements SOP](#) and the [HCP/GO Engagements & Interactions \(R&D SOP 201\)](#). Review the following content for an overview.

Legitimate Need for Services

A legitimate need for services must always be established and documented.

FAQ: 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 Marketing 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?
	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 Marketing 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.

	<p>For engagements subject to the HCP Engagements SOP, project managers <i>MUST</i>:</p> <ul style="list-style-type: none"> • Work with a Pfizer Medical Colleague to define the required qualifications and specifications for consultant selection <p>For engagements subject to the HCP Engagements SOP, and requiring a BRF, the following <i>MUST</i> be addressed:</p> <ul style="list-style-type: none"> • The number of consultants necessary for the project or meeting must be supported objectively • The qualifications of the consultants need to meet the identified business need
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	<p>Colleagues <i>MUST NOT</i> select an HCP:</p> <ul style="list-style-type: none"> • Because they are a “high prescriber” <ul style="list-style-type: none"> – Though a consultant’s experience with a particular class of drugs may be taken into consideration in determining whether they are qualified to provide the requested services, prescribing habits may not be the basis for selection • To influence their prescribing or recommendation of Pfizer products • To gain any other improper business advantage
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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 [Corporate Policy 206, Compliance with Global Trade Control Laws](#), 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, by the colleague wishing to engage the consultant, or someone else assigned to do so
 - For information on how to use RPS OnDemand, see the [GTC Center of Excellence \(CoE\) website](#)
- 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 Compliance
- **IOC Member List:** Per [Independent Oversight Committees \(CMCD CT22-GSOP\)](#), 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
 - Visit the [IOC Database](#) to review the IOC Member List
 - For additional information regarding permissible activities of IOC members, please consult [Independent Oversight Committees \(CMCD CT22-GSOP\)](#) and Section 8 of *The White Guide*.
- **Minnesota-Licensed Prescribers:** Per Pfizer policy, Minnesota-licensed prescribers may only be engaged as consultants in certain circumstances
 - For more information see Section 9 of *The White Guide*.

Restricted Markets

The United States imposes comprehensive economic sanctions programs, or embargoes, that prohibit dealings with certain countries and parties. The GTC CoE maintains a list of Restricted Markets based on these sanctions programs, which is available on the [GTC website](#) under the [Restricted Markets](#) section.



An engagement MUST NOT involve:

- Activities in a Restricted Market
- Organizations or Governmental Entities from a Restricted Market
- Individuals who ordinarily reside in a Restricted Market

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The only exception would be if required licenses or other authorizations have been obtained, the issuance of which is not guaranteed, and written approval is received from an attorney in the [GTC CoE](#).

Export Controlled Technology

Export controlled Technology can include information regarding

- Certain viruses, toxins, bacteria, or pathogens
- Medical countermeasures to treat nerve agent poisoning
- Certain military or defense related items, services, or projects
- Certain sensitive or sophisticated manufacturing or equipment processing information

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, as defined in [Corporate Policy 206, Compliance with Global Trade Control Laws](#), colleagues must contact the GTC CoE for further guidance prior to proceeding.

Fair Market Value Compensation

	<p>Colleagues MUST:</p> <ul style="list-style-type: none">• Only provide compensation that does not exceed FMV 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• Determine appropriate fees by:<ul style="list-style-type: none">– Using the US FMV Calculator for U.S. consultants– Using the “Consultancy/Service Arrangements” tab, “FMV” subsection, of the Country Annex Portal for non-U.S. HCPs and/or GOs– Going to the FMV webpage on Global Policy Xchange on Biopharma Ops on Demand• Make every effort to ensure consistency in FMV when engaging an HCP<ul style="list-style-type: none">– The rate should be generally consistent for a specific activity regardless of which business or function is engaging a particular HCP• Must receive legal and business approval prior to committing to a higher rate for U.S. consultancies if the proposed FMV for an HCP exceeds the high end of the system-generated range for a particular tier based on the unique and relevant credentials and attributes of that HCP• Ensure that the FMV rate is reflected in the written agreement• Pay all U.S. and International Consultant fees directly to all consultants/institutions<ul style="list-style-type: none">– Vendors may not make payments to consultants on behalf of Pfizer– The only exception is for market research that is blinded to Pfizer, where a vendor may pay the HCPs directly
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FAQ: Zero Fee Engagements	
	I would like to discuss a new marketing initiative with an HCP, and she does not wish to be paid for the meeting nor reimbursed for travel expenses. Do I still need to treat this as a consulting engagement, subject to the various required controls, such as a BRF or contract?
	<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. However, colleagues should consider whether a confidentiality agreement is appropriate in this scenario.</p> <p>When the activities are such that compensation would normally be provided but for an HCP's request not to be compensated—and/or if Pfizer will cover or reimburse an HCP's travel expenses, such as hotel, airfare, or taxi—the interaction should be processed as a formal consulting engagement.</p> <p>For further guidance, consult the relevant GPC.</p>

FAQ: Consulting Engagements with Non-Healthcare Professionals (HCPs)	
	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>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.</p> <p>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.</p> <p>Note that these requirements apply to interactions with any non-U.S. GOs.</p> <p>For engagements with patients, please see the following SOPs:</p> <ul style="list-style-type: none"> • U.S. Patient Organization Fair Market Value (FMV) SOP • U.S. Funded Patient-PO Engagement SOP • Patient Engagements & Interactions (R&D SOP 206)

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](#)—however, the requirements for engagements subject to [HCP/GO Engagements & Interactions \(R&D SOP 201\)](#) are similar.

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	<p>The written agreement MUST:</p> <ul style="list-style-type: none">• 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 and why their 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 the Global HCP/HCO Transparency Reporting SOP, and applicable laws• Require the consultant to disclose their relationship with Pfizer and to adhere to the disclosure requirements of any healthcare institution, medical committee, or other medical or scientific organization with which the consultant is affiliated• Contain the consultant's representation that they have not been, and are not, subject to government discipline or criminal sanction unknown to Pfizer• Include the Standard Anti-Corruption Contract Provisions for Consultancy
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With respect to the RPS and Restricted Market points noted earlier, 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 the [GTC site](#), under the [Guidance and Contract Language](#) tab.

Meeting Venue

	<p>Colleagues MUST:</p> <ul style="list-style-type: none">• Ensure that the venue for any consultant meeting, including a live speaker training meeting, is conducive to the business purpose of the meeting, commercially reasonable, and not susceptible to characterization by third parties as “resort-like” or “lavish”<ul style="list-style-type: none">– 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 Compliance as needed• Use the ETM&HE Team to organize meetings involving HCP consultants
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Output/Deliverables

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

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

Reimbursement of Expenses

Reimbursement of expenses will be done in a manner that is consistent with the [Pfizer U.S. Travel Policy](#).

	<p>Consultants <i>MAY</i> be reimbursed for, or Pfizer will directly arrange:</p> <ul style="list-style-type: none">• Reasonable travel, such as coach airfare for flights lasting less than 5 hours• Lodging expenses incurred in connection with the consulting services
	<p>Consultants <i>MAY NOT</i> be reimbursed for:</p> <ul style="list-style-type: none">• Extended or non-business-related stays at a hotel prior to or after a meeting• Travel or additional lodging costs for spouses or other guests

Types of Consulting Arrangements

All Pfizer HCP consulting arrangements must adhere to the guidelines mentioned earlier in this chapter. 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.

Advisory boards help Pfizer better understand factors, such as the:

- External environment
- Therapeutic areas
- Data
- Use of products, approved or in development
- Commercial, clinical, and medical asset strategies
- Payer landscape
- Unmet medical needs

	<p>When organizing an Advisory Board, Colleagues <i>MUST</i> ensure that:</p> <ul style="list-style-type: none">• The purpose is to gain needed feedback or advice
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	<ul style="list-style-type: none"> • Certain minimum standards applicable to the compliant execution of Advisory Board interactions are addressed <ul style="list-style-type: none"> – These global requirements are set forth in the Global Advisory Board Guidelines which must be adhered to in addition to local requirements and laws • Participants clearly understand that they are being retained to provide a service and not to passively receive promotional presentations • If off-label information is presented at an advisory board meeting, it must bear a direct relationship to the legitimate purpose of the meeting <ul style="list-style-type: none"> – 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 – For additional information, see Section 3 of <i>The White Guide</i> • They complete the necessary due diligence in compliance with MAPP If the meeting involves a non-U.S. HCP or GO
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	<p><i>An advisory board meeting MUST NOT be designed to:</i></p> <ul style="list-style-type: none"> • Provide a forum for product promotion or convey product information where Pfizer is not obtaining appropriate advice or information • 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 • Provide physicians with an opportunity to meet and mingle with their peers • Solicit confidential competitive information
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FAQ: Sales Assistance with Advisory Boards	
	<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 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—however, the ultimate decision rests with the Brand Team.</p> <p>Sales Colleagues, however, may not be involved with any communications with HCPs regarding the proposed advisory board, such as offering an invitation to participate, and may not participate in the advisory board itself. Sales Colleagues must also refrain from communicating to the HCP that they were involved with assisting the Brand Team in identifying potential attendees.</p>

Paid Speaker Training

Paid speaker training activities are treated as consulting arrangements. 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 they received speaker training.

	<p><i>Prior to participating in a Pfizer paid speaker training, the HCP MUST have:</i></p> <ul style="list-style-type: none">• A fully executed Speaker Contract• No outstanding speaker training obligations
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When a speaker program initiative requires speakers to be trained, colleagues should consult with their 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.

For more information on speaker recruitment, contracting, and training, see Section 3 of [The Orange Guide](#).

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 gain a better understanding of customer needs
- Assess how Pfizer and competitor products are perceived and used in clinical practice
- 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 used 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](#).

	<p><i>To help achieve compliance with Pfizer policies and procedures governing the conduct of market research, Pfizer Colleagues MUST:</i></p> <ul style="list-style-type: none">• Execute any market research activities through Business Analytics• Conduct all market research activities in accordance with the Insights Association Code of Standards• Ensure that no detailing or other dissemination of promotional information occurs, except for the purpose of legitimately testing a particular promotional message or strategy
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Preceptorships and Mentorships

A [preceptorship](#) is a training program for Pfizer Colleagues, usually provided and hosted or 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 or 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.

Mentorship programs are one-on-one observational teaching sessions where a Pfizer Colleague, usually a Sales Representative, observes or “shadows” an HCP, usually a physician, at their 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.

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 additional information, please see:

- The Mentorship Guidelines and Forms available on [MyPfieldNet](#)
- Section 1 of *The White Guide*
- [HCP/GO Engagements & Interactions \(R&D SOP 201\)](#)

Chapter 5: Additional Resources for More Information

Advertising and Promotional Labeling:

- Refer any advertising and promotional labeling questions to your team's Regulatory Colleague or Product Attorney
- For more information on Commercial Standards for Promotional Materials, please see [1.01 Global Content Policy: Commercial Standards for Promotional Materials](#) and [2.02 Global Content Policy Addendum](#)
- For more information on review and approval procedures, please see [Global Commercial Content: Review & Approval Procedure for Promotional Materials \(United States \[U.S.\] Addendum\)](#)
- For more information on Direct-to-Consumer Advertisements, please see [Pharmaceutical Research and Manufacturers of America \(PhRMA\) Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines](#) and [Pfizer's Guidance for the Implementation of the Updated PhRMA Direct To Consumer \(DTC\) Principles](#)
- For Questions and Answers (Q&A) on the PhRMA Code, see [Global Policy Xchange on Biopharma Ops on Demand](#)
- For more information on state Attorney General agreements, please see the [Compliance Division internal website](#)
- Please refer Global Trade Control (GTC), Restricted Party Screening (RPS), and Restricted Market questions to gtc@pfizer.com
- For Pfizer's policies for complying with The Prescription Drug Marketing Act of 1987 (PDMA), see the [Starter Compliance Manual](#)
- For more information on Pfizer Global Content policies and guidelines related to Review Committee (RC) Review and Approval, please see:
 - [1.01 Global Content Policy: Commercial Standards for Promotional Materials](#)
 - [1.04 Global Commercial Content: Review & Approval Procedure for Promotional Materials—Deviation](#)
 - [2.01 Global Commercial Content: Review & Endorsement Procedure for Global Promotional Materials Policy Addendum](#)
 - [2.02 Global Commercial Content: Review & Approval Procedure for Promotional Materials \(Global Policy Addendum\)](#)
 - [7.01 Global Commercial Content: Review & Approve Procedure for Promotional Materials \(Country Policy Addendum\) U.S. Policy Addendum](#)
- For more information on Pfizer's Guidelines for Advertising and Promotion, please see:
 - [Advertising and Promotion Guidelines on Pfizer Policy Xchange](#)
 - [Pfizer Policy Committee Communications on Pfizer Policy Xchange](#)

Common Engagements and Communications Involving Healthcare Professionals (HCPs)

- For more information regarding promotional interactions with Healthcare Professionals, please see
 - [The Orange Guide](#)
 - [The Green Guide: Governance for Medical Activities](#)
- For speaker programs, please consult the Enterprise Travel, Meetings, and Healthcare Engagements (ETM&HE) Team
- For conventions, congresses, and symposia, please consult the Global Congress Center of Excellence (CoE) Leads
- For more information on Speaker Programs for Healthcare Professionals (HCPs), see Section 3 of [The Orange Guide](#) and/or visit the [Speaker Programs tab](#) on Policy Xchange

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- For more information on HCP Consulting guidelines and resources, visit the [HCP Engagements](#) tabs on Policy Xchange
- For more information on digital activities, please visit the [Digital Review Team website](#) and review the Digital Review Team e-mail [Guidelines](#)
- For tools and information regarding Company Sponsored Programs (CSPs), please visit the [Biopharma Quality \(BQ\) Resource Center](#)

Healthcare Professional (HCP) and Government Official Consulting Engagements:

- For information regarding HCP and Government Official Consulting Engagements, please see
 - [Global Policy Xchange on Biopharma Ops on Demand](#)
 - [HCP Engagements Standard Operating Procedure \(SOP\)](#)
 - [HCP Consulting: U.S. Fair Market Value SOP](#)
 - [Corporate Policy 206, Compliance with Global Trade Control Laws](#)
 - [U.S. Consultant—Speaker Business Travel and Expense Standard Operating Procedure \(SOP\)](#)
 - [Corporate Policy 207, Global Policy on Interactions with Healthcare Professionals \(GPIHP\)](#)
 - [Corporate Policy 301, Travel, Entertainment and Other Business-Related Expenses](#)
 - [Corporate Policy 304, Global Meetings and Congresses Policy and Procedure](#)
 - [My Anti-Corruption Policy and Procedures \(MAPP\)](#)
 - Section 3 of [The Orange Guide](#)
 - [HCP/GO Engagements & Interactions \(R&D SOP 201\)](#)
 - [Global Advisory Board Guidelines](#)
- E-mail Contacts:
 - Refer Foreign Corrupt Practices Act (FCPA) questions to FCPAQuestions@pfizer.com
 - Refer GTC, RPS, and Restricted Market questions to gtc@pfizer.com



The White Guide

Section 3

Guidelines for Non-Promotional Activities and Communications

Section 3

Guidelines for Non-Promotional Activities and Communications

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[Click here to visit the Glossary and Acronyms.](#)

Chapter 1: Introduction

In the United States (U.S.), the [Food and Drug Administration \(FDA\)](#) regulates all advertising and promotional labeling that Pfizer disseminates for its products. 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. Therefore, manufacturers may distribute certain information, and make some communications, without being subject to FDA rules.

Non-promotional activities can generally be characterized as either:

- Communications related to service-based relationships
- Non-promotional communications

This section summarizes certain key Pfizer policies regarding key non-promotional activities, including publications and certain media activities. Promotional media activities are also reviewed in this section.

Chapter 2: Communications Related to Service-Based Relationships

Pfizer engages Healthcare Professionals (HCPs) and others, such as consumers and advocates, to perform services necessary for the operation of Pfizer business. When HCPs are engaged to provide Bona Fide Services, communications directly related to the service-based relationship are considered non-promotional.

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 \(FMV\)](#). 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.

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. Also, it must not be a pretext for a discussion that would otherwise be impermissible.

A non-disclosure agreement may be required before any such communication. Colleagues must consult Legal before sharing any potentially sensitive information without a non-disclosure agreement in place.

Furthermore, it is important to note that 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.

For more information on speaker requirements for speaker programs, see Section 2 of *The White Guide* or Section 3 of *The Orange Guide*.

Communications with a Bona Fide Consultant

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 Section 2 of *The White Guide*.

FAQ: Bona Fide Consulting Engagements	
	<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. 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 as well as follow relevant Pfizer guidelines.</p>

Chapter 3: Non-Promotional Engagements

The Food and Drug Administration (FDA) regulates [promotional labeling](#), including both printed and oral statements designed or intended to promote the use of a Pfizer product 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 as found in the [Review and Approval Procedure—United States \(U.S.\) Addendum](#).

In contrast, **non-promotional engagements** are those that are not designed or intended to promote the use of a Pfizer product to impact prescribing. Non-promotional engagements outside of service-based relationships are generally divided into several distinct categories:

- Responses to unsolicited medical requests (UMRs) from Healthcare Professionals (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
 - For the review and approval process, see the [Medical Material Review and Approval Work Instruction \(CMCD MA01-WI-USA01\)](#)
- Scientific Exchange, which is a 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
- Transactional Communications

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

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

Review the following for more information on each category of non-promotional engagements.

Responses to Unsolicited Requests for Medical Information

To help ensure that responses to unsolicited questions seeking unapproved information are considered non-promotional engagements, 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, where applicable, including any relevant safety data, and complete data which is not “cherry-picked”
- Narrowly tailored to answer the question asked
- Void of any promotional claims
- Documented in accordance with relevant Pfizer policy, such as [The Green Guide: Governance for External Medical Activities](#)

Section 4: Guidelines for Patient Support and Patient/Consumer Interactions

Please consult [The Green Guide](#) for policy on responding to requests for unapproved information and other non-promotional activities. *The Green Guide* is applicable to Field Medical, Therapeutic Area (FM, TA); Field Medical, Outcomes & Analytics (FM, O&A); and other field-based Medical Colleagues in the U.S.—as well as U.S. Business Medical Affairs colleagues—when interacting with HCPs.

Specified Roles with Respect to Non-Promotional Engagements

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 use the [Pfizer Triage App](#) if enabled or otherwise refer the HCP to Pfizer's Medical Information Department at 1-800-438-1985.

External Promotional Speakers

	<p><i>If a promotional speaker is asked an unsolicited question regarding unapproved information by an audience member, speakers MUST:</i></p> <ul style="list-style-type: none">• Only briefly respond to the specific question• Note that:<ul style="list-style-type: none">– The use or information under discussion is unapproved– They are answering the question based upon their own knowledge or experience– Their views may not represent the views of Pfizer
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	<p><i>HCPs retained as promotional speakers MUST NOT:</i></p> <ul style="list-style-type: none">• Solicit unapproved questions or initiate unapproved discussions of our products with other HCPs at Pfizer speaker programs
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A promotional speaker retained by Pfizer is “speaking for Pfizer” when they present, and failure to adhere to these guidelines could expose Pfizer—and the speaker—to possible legal enforcement.

Field-Based Medical Colleagues

FM, TA colleagues provide approved non-promotional medical and scientific information to HCPs regarding the safe and appropriate use of Pfizer medicines for approved indications through the [Medical Material Review and Approval Work Instruction \(CMCD MA01-WI-USA01\)](#) as documented in the Medical Global Content Management and Approval Program (GCMA).

FM, TAs may also provide support for Pfizer-sponsored research activities—such as facilitation of research site selection and study placement—and interact, where appropriate, with Investigator-Sponsored Research (ISR) investigators.

In general, FM, TA responsibilities include:



Section 4: Guidelines for Patient Support and Patient/Consumer Interactions

- Engaging in omnichannel medical communications, such as:
 - Proactive medical communications with identified HCPs using materials approved according to [Medical Review Committee \(MA01-WI-USA01 1.0\)](#)
 - Responding to UMRs received from HCPs, organized customers, or patient Organizations
- Handling inquiry escalations from the Medical Information department, including requests to meet with Pfizer Medical and from the Medical Portal, Medical on Demand, or the [Pfizer Triage App](#)
- Conducting medical presentations to decision makers, payers, health systems, and other organized customers—often in coordination with Field Medical Outcomes & Analytics (FM, O&A) colleagues—when there is a demonstrated legitimate need for support by a colleague with deep scientific and medical expertise
 - These presentations may be provided by FM, TA; Field Medical, Organized Customer (FM, OC); or hybrid role colleagues
- Gathering and communicating insights regarding HCP questions and information needs to appropriate internal stakeholders
- Responding to questions about ISR grant processes in accordance with the [Independent Medical Grants SOP \(GNT01-GSOP\)](#)
- Communicating Request for Proposals (RFPs) or competitive grant programs, if requested by the Global Medical Grants (GMG) Team
- Participating as appropriate in external research [collaborations](#) or evidence generation in accordance with relevant policies, such as the [Non-Interventional Studies SOP \(CT24-GSOP\)](#), [Interventional Studies with Minimal Risk SOP \(CT45-GSOP\)](#) and the [Research Collaborations SOP \(RC01-GSOP\)](#)
- Staffing Medical Information or Medical Affairs booths at congresses/conventions, with approval from Medical Affairs leadership
- Providing medical training on approved speaker decks for promotional speakers
- Providing investigator and site recommendations for Pfizer sponsored clinical site visits if/when requested by the Study Team/Global Product Development (GPD)

FM, O&A colleagues are a group within U.S. Medical Affairs that primarily work with organized customers such as payers, including formulary and Pharmacy and Therapeutics (P&T) committees, Integrated Delivery Networks, medical groups, and colleges of pharmacy.

In general, FM, O&A responsibilities include:

- Presenting disease-state, clinical, real-world data/evidence (RWD/RWE), and pharmacoeconomic/healthcare economic information (HCEI) related to Pfizer products and disease
- Providing medical outcomes support for large medical projects and formal engagements for collaborations with organized customers, as well as participation or leading evidence generation/external research, in accordance with the [Non-Interventional Studies SOP](#) and the [Interventional Studies with Minimal Risk SOP](#)
- Working with customers to identify provider or patient knowledge gaps or identify areas for quality improvement interventions
- Working with electronic clinical data, including extraction and management, information technology, and clinical content within electronic applications
- Providing the Pfizer Asset Teams with customer insights and clinical perspectives to inform development of customer-focused tools
- Designing and conducting customer-specific outcomes projects including performing data analytics

Section 4: Guidelines for Patient Support and Patient/Consumer Interactions

	<p>The FM, O&A group and other similar field-based medical groups MUST:</p> <ul style="list-style-type: none"> • Only respond to unsolicited requests for: <ul style="list-style-type: none"> – On-label data – Pharmacoeconomic information related to an approved indication, whether or not included in product labeling – Information that is consistent with the product label and medical GCMA-approved • Refer all unsolicited requests received for unapproved data, including those seeking information on the general safety or efficacy of Pfizer products, to Pfizer’s Medical Information Department • Adhere to The Green Guide: Governance for External Medical Activities
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	<p>The FM, O&A group and other similar field-based medical groups MUST NOT:</p> <ul style="list-style-type: none"> • Respond to unsolicited requests for unapproved data
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Other Pfizer Medical Colleagues

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 Legal.

FAQ: Unsolicited Request for Medical Information	
	<p>A physician contacts Pfizer seeking information regarding the unapproved use of a Pfizer product. Can the Pfizer Medical Colleague who supports the product provide this information?</p>
	<p>Yes. It is permissible for the Medical Colleague to provide the requested information if the information provided is:</p> <ul style="list-style-type: none"> • Truthful, accurate, balanced, and not misleading • Supported by relevant scientific data, where applicable, including any relevant safety data and complete data which is not “cherry-picked” • Narrowly tailored to answer the question asked • Void of any promotional claims • Documented in accordance with relevant Pfizer policy, such as The Green Guide

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 relevant Medical product/asset lead and Chief Legal Counsel in consultation with Medical Affairs Governance.

Key factors that the Medical product/asset lead, 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 must be limited, and HCPs/customers receiving the information must be narrowly selected on a need-to-know basis
- Proposed execution of the communication
 - Non-promotional engagements must not be promotional in tone, including being 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
- The context in which it is delivered
 - 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

All Pfizer Colleagues, including Medical Colleagues engaged in scientific exchange, are prohibited from making claims of safety or efficacy about an unapproved product, such as 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, which 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 following table 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.

Content/Context	More Likely to be Viewed As	
	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
Peer Review	Information which has not undergone formal peer review	Information which 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, colleagues should consult the relevant Product 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.

Section 4: Guidelines for Patient Support and Patient/Consumer Interactions

Examples of transactional communications are:

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

Any disease state or product related information contained within these Transactional Communications must be:

- non-promotional in content and tone
- the minimum necessary to meet the non-promotional purpose of the communication

Chapter 4: Publications

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.

The policies and procedures for managing Pfizer-supported publications in scope for the [Pfizer Scientific Publications \(CMCD PUB01-GSOP\)](#) are summarized here, 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 covered here 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 \(CRCs\)](#) as outlined in the [Registrational Clinical Research Collaborations SOP](#)
- Certain publications from Research Collaborations (RCs) as outlined in the [Research Collaborations SOP](#)
- Publications based on epidemiology analyses, surveillance studies, health economics and outcomes research, and real-world evidence (RWE) that are done in support of a Pfizer product, even if they do not mention a Pfizer product such as disease state/therapeutic area reviews
- Books and book chapters

Note that non-clinical publications are separately addressed by the [Non-clinical Publications SOP](#)

Pfizer Colleagues, external authors, and vendors—such as publications agencies and medical writers—who are involved with Pfizer-supported publications must understand and follow Pfizer's publications policies.

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 the results are favorable to Pfizer. They are not developed to encourage the use of a Pfizer product 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, such as 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 Healthcare Professionals (HCPs) or Healthcare Institutions (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 is not actually contributing or performing any author responsibilities, the government might

Section 4: Guidelines for Patient Support and Patient/Consumer Interactions

question whether the HCP was chosen and/or paid as an inducement for their 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 concerning whether any compensation received was based on fair market value (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 International Committee of Medical Journal Editors (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 **Scientific Publication Committee (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, a Biostatistician, and a Publications Specialist who is a member of the Publications Management Team.



Commercial, Marketing and Sales Colleagues MUST NOT:

- Be members of the SPC
- Attend SPC meetings or receive SPC 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
- 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](#).

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
- Drafting the publication or revising it critically with respect to important intellectual content

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- Final approval of the version to be published
- 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 four of the ICMJE criteria may 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 or 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 are responsible for obtaining and adhering 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.

The [Pfizer Scientific Publications SOP](#) 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 United States (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 such as errors in dosages or 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 [Contacting External Drug Compendia Guidance Document](#). Any other Pfizer

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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 HCI author is being paid for the development of a publication, Pfizer must contract with and make payments to the HCP/HCI directly and follow the requirements of [Corporate Policy 207, Global Policy on Interactions with Healthcare Professionals \(HCPs\)](#) and [Corporate Policy 102, Purchasing Policy and Procedure](#). In addition, [My Anti-Corruption Policy and Procedures \(MAPP\)](#) applies to all Pfizer Colleagues interacting with any non-U.S. 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 [Corporate Policy 304, 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. They must comply with [Global Content Policy: Commercial Standards for Promotional Materials](#).

Supplements are not in scope for the [Pfizer Scientific Publications SOP](#) and must not be managed by an SPC.

Publication of Investigator-Sponsored Research (ISR), Registrational Clinical Research Collaboration (R-CRC), and Research Collaboration (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 (ISR) study**,

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Research Collaboration (RC), or Registrational CRC (R-CRC), whether or not the results are favorable for a Pfizer product.

In ISR, R-CRC and RC 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 the [Pfizer Scientific Publications SOP](#) and the [Clinical Research Collaboration Local Manuscript Final Quality Control Check Form](#). Publications from ISRs are independent and out-of-scope for [Pfizer Scientific Publications SOP](#).

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 Section 8 of *The White Guide*.

Chapter 5: 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 such as Business Wire®; sent to print, broadcast, and online news sources; and posted on [Pfizer.com](https://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 channels, please see the [Social Media Guidelines for Non Promotional Communications](#) and [Corporate Policy 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 by means of a public disclosure.

What is Material Nonpublic Information?

Information is “material” if it is information that a reasonable investor would consider important in deciding whether to buy or sell a security. “Nonpublic” information is private, confidential, or has not been disclosed or disseminated to the general public.

Public Disclosure of Material Nonpublic Information

At the time of public disclosure, material nonpublic information must be disclosed to the entire investment community in:

- A press release
- A filing with the **United States (U.S.) Securities and Exchange Commission (SEC)**
- A webcast presentation to which the public has been invited in advance
- Another method reasonably designed to provide broad dissemination, as confirmed with Pfizer Legal

Press Releases

Pfizer 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 in a Pfizer press release regarding forward looking information.

Section 4: Guidelines for Patient Support and Patient/Consumer Interactions

No Selective Disclosure

Material nonpublic information may not be disclosed selectively, such as in nonpublic conversations, meetings, or written materials or other means. In general, such information should not be shared other than 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. 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 [Corporate Policy 604, Treatment of Material Nonpublic Information](#).

Considerations Related to Disclosure 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 contains “material” developments. An example is whether the press release discloses developments or 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, and, if a blackout notice is imposed, individuals must comply with the restrictions of the blackout notice until such blackout notice is lifted. Whether or not a blackout notice is imposed, pursuant to [Corporate Policy 604, Treatment of Material Nonpublic Information](#), 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 Food and Drug Administration (FDA) or regulatory authorities in other jurisdictions.

There must be no promotion of an unapproved use for a marketed product. As an example, a press release must not claim that a drug is safe and effective for an unapproved indication, and any unapproved uses must be described as “investigational” or made clear that they are subject to regulatory approval.

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, and the Legal, Regulatory, and Medical Colleagues responsible for the product/therapeutic area, if applicable.



Pfizer Colleagues MUST:

- Direct an inquiry or request from the media to Pfizer Global Media Relations at 212-573-1226
- Direct an inquiry from investors or investment analysts to Pfizer Investor Relations at 212-573-2668

Section 4: Guidelines for Patient Support and Patient/Consumer Interactions

The following is additional information regarding Corporate, New Data, and Promotional press releases, each of which must be assessed for materiality, blackout notice, and so forth 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**.

	<p>Corporate press releases MUST be:</p> <ul style="list-style-type: none">• 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
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	<p>Corporate Press Releases MUST NOT:</p> <ul style="list-style-type: none">• Contradict product labeling or promote an unapproved use<ul style="list-style-type: none">– If an unapproved use is discussed, it must be described as investigational in the press release or made clear that it is subject to regulatory approval• Claim that a product is safe
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FAQ: 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, which 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 must avoid claims about safety or efficacy as the regulators have not yet made determinations about those issues. They must also describe such uses as investigational or make clear that the product is subject to regulatory approval.</p>

New Data Press Releases

New Data Press Releases announce new clinical trial results and are initiated by Global Media Relations.

	<p>New Data Press Releases MUST:</p> <ul style="list-style-type: none">• Be approved by the Product Counsel in consultation with Clinical Development Legal, Regulatory, and Medical Colleagues responsible for the product/therapeutic area
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- Review should be conducted in consultation with Investor Relations and Corporate Governance
- Describe the size of the study, the study design, and the primary endpoints
- Meet the process steps and requirements of the Top-Line Report (TLR) Process and Communication Plan, which is set forth in the [Clinical Statistician Reference Guide](#) (associated with [Tables, Listings, Figures and Data Presentations, DMB09-GSOP](#))

For more information, see the [Clinical Statistician Reference Guide - Top Line Report](#).

New data press releases typically do not use promotional language or tone or disseminate study data previously released. Otherwise, the press release may be required to meet promotional standards and be approved by the Product Review Committee (RC) as a promotional press release.

Product-Specific Press Kits and Other Media Materials

Product-specific Press Kits are subject to the same FDA regulatory requirements as written promotional materials.



Product-specific Press Kits MUST:

- Meet promotional standards
 - Not misleading
 - Consistent with product labeling
 - Including appropriate safety information
- Be RC-approved
- Include the appropriate balance with any components that may be distributed further
- 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 the [Global Commercial Content: Review and Approval Procedure—U.S. Addendum](#) and Section 2 of *The White Guide*.

Contact Information & Disclaimer

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

If a press release could be seen as including any forward-looking information, such as information that describes or suggests future events or results, it must include a disclosure notice.

Colleagues must work with Legal and contact the Corporate Governance Team as early as possible 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.

Chapter 6: Non-Promotional and Media Opportunities for Pfizer Colleagues

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, and so forth, is truthful, accurate, complete, timely, and not proprietary or otherwise confidential. Further, such external communications must be consistent with Pfizer's publicly stated position on related issues.

When invited to speak at events—such as a third-party sponsored meeting, seminar, workshop, or conference—or when asked to author a document for publication, colleagues must obtain the approval of their manager. Their manager must determine whether it is appropriate for them to participate and should consult Legal if necessary. Additionally, if colleagues are unclear whether the content of their proposed activity is likely to be perceived as promotional, they should talk to their manager or consult Legal for further guidance.

Furthermore, in these situations, Pfizer Colleagues must ensure that their participation does not present a conflict of interest or create the appearance of one. For additional information, colleagues may consult [Corporate Policy 203, Conflicts of Interest](#).

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, and so forth—unless requested by the approving manager, but they must be sure not to disclose any confidential information or material non-public information and to include appropriate disclaimers in their presentations, including that they are an employee of Pfizer and that views expressed by them may not represent the views of Pfizer.

If colleagues 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, they should consult with their manager or Legal, as appropriate.

If colleagues are asserting any personal opinions in a talk or speaking engagement, they must clarify with the audience that the opinions expressed are theirs 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, they 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.

Section 4: Guidelines for Patient Support and Patient/Consumer Interactions



Pfizer Colleagues MUST:

- Direct an inquiry or request from the media to Pfizer Global Media Relations at 212-573-1226
 - This includes verbal or telephone, written or electronic requests
 - For more information, see [Corporate Policy 409, Relations with the News Media](#)
- Direct an inquiry from investors or investment analysts to Pfizer Investor Relations at 212-573-2668
- Promptly seek guidance from the Legal Division before responding to requests from any federal, state, or local government entity



Pfizer Colleagues MUST NOT:

- Answer any questions or supply any information directly to the media, or conduct interviews with the media, unless specifically directed by a member of Pfizer Global Media Relations

Chapter 7: Additional Resources for More Information

Non-Promotional Activities

- 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)
- For more information related to Field Medical Colleagues, please see [The Green Guide: Governance for Medical Activities](#)
- [Medical Review Committee \(MA01-WI-USA01 1.0\)](#)
- For more information on Independent Medical Grants, please see the [Independent Medical Grants Standard Operating Procedure \(SOP\)](#)
- For information on Speaker Programs for Healthcare Professionals (HCPs), see Section 3 of [The Orange Guide](#)
- For information on Advertising and Promotional Materials, see Section 1 of [The White Guide](#)
- For Information on Common Engagements and Communications Involving HCPs, see Section 2 of [The White Guide](#)
- For information on HCP and Government Official Consulting Engagements, see Section 6 of [The White Guide](#)
- For more information on Pfizer policies and guidelines related to Non-Promotional Activities and Communications, see:
 - [Public Disclosure of Pfizer Clinical Study Data and Authorship](#)
 - [Corporate Policy 407, Social Media Policy](#)
 - [Corporate Policy 409, Relations with the News Media](#)
 - [Corporate Policy 604, Treatment of Material Nonpublic Information](#)
 - [Social Media Guidelines for Non-Promotional Communication](#)
- Requests for medical information should be directed to Global Medical Information at 1-800-438-1985 or the [Pfizer Medical Information site](#)

Publications:

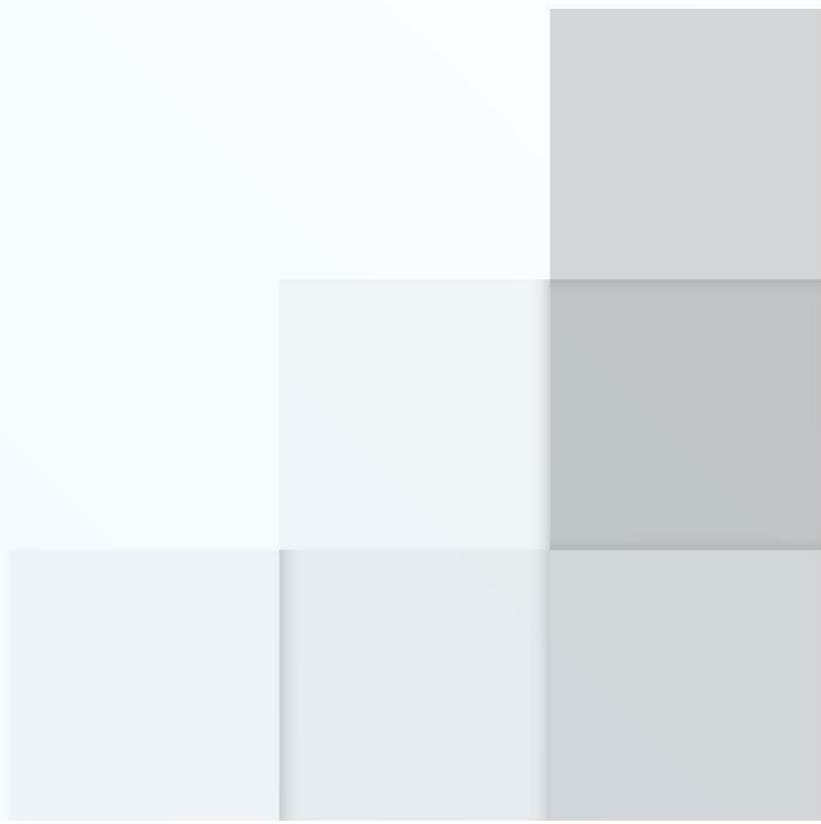
- For more information on Pfizer policies and guidelines related to Publications, please see:
 - [Corporate Policy 402, Scientific and Technical Publications and Presentations](#)
 - [Corporate Policy 207, Global Policy on Interactions with Healthcare Professionals \(HCPs\)](#)
 - [My Anti-Corruption Policy and Procedures \(MAPP\)](#)
 - [Public Disclosure of Pfizer Clinical Study Data and Authorship](#)
 - [Pfizer Scientific Publications SOP](#)
 - [Clinical Research Publications Checklist](#)
 - [Contacting External Drug Compendia Guidance Document](#)
- For more information on external guidance related to publications, please see:
 - [International Committee of Medical Journal Editors \(ICMJE\) Guidelines on Authorship and Contributorship](#)
 - [Pharmaceutical Research and Manufacturers of America \(PhRMA\) Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results](#)
- For more information on Pfizer-Sponsored and Non-Sponsored Clinical Research Including Investigator-Sponsored Research (ISR) Studies, please see Section 8 of [The White Guide](#)
- Refer any other questions or concerns to a member of [Pfizer's Publications Management Team](#)



The White Guide

Section 4

Guidelines for Patient Support and Patient/Consumer Interactions



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Guidelines for Patient Support and Patient/Consumer Interactions

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[Click here to visit the Glossary and Acronyms.](#)

Chapter 1: Introduction

In line with our purpose—breakthroughs that change patients' lives—Pfizer believes that all patients should have access to the medicines prescribed by their Healthcare Professionals (HCPs).

While Pfizer is built on a long history of innovation and a proven dedication to help patients live healthier lives, we recognize that our unique resources allow us to help patients, caregivers, and family members. In an effort to help patients, and aligned with our purpose and beliefs, Pfizer has created patient-centric roles and programs which are the focus of this section.

First, guidance related to Patient Support Roles (PSRs) and their activities will be reviewed. These roles and their associated activities fall into two general categories:

1. Facilitating patient access to Pfizer medicines and associated **Patient Support Programs (PSPs)** after a Pfizer medicine is prescribed by a patient's HCP
2. Providing non-promotional education on relevant disease states and/or products for patients, caregivers, and patient advocacy groups (PAGs)

Next, Pfizer's PSPs will be reviewed. These include Pfizer RxPathways® and Pfizer's product-specific or therapeutic-area-specific Patient Support Hubs ("hubs").

PSPs are Pfizer-sponsored programs for approved products or other general aspects of medical care that provide direct or indirect support to individual patients or caregivers.

Support can be either non-financial, financial, or both.

- Non-financial examples include disease self-management, home care including nurse and other HCP programs, patient compliance/adherence programs, support call centers focused on patients or caregivers, and product/disease education
- Financial examples include direct out of the pocket support, tiered pricing/income-based discounts, free goods, and microfinancing

When we interact with patients, we do so respectfully and in compliance with applicable laws, regulations, industry codes, ethical considerations, and Pfizer policies. Pfizer's [Cross-Divisional Policy: Management of Patient Support Programs \(PSP Policy\)](#) is specifically intended to provide guiding principles and requirements for the adequate design, management, and execution of PSPs.

PSP Owners must ensure that the design, review, approval, and conduct of PSPs comply with the PSP Policy and [Cross-Divisional Procedure Management of Patient Support Programs](#). These documents contain additional detail on the types of activities that may fall into scope of the PSP Policy.

If a PSP includes interaction between Pfizer, or a Pfizer Vendor acting on Pfizer's behalf and the individual patients or caregivers, then the PSP may also be in scope of [Corporate Policy 902, Company Sponsored Programs Policy](#). Refer to Section 2 for further information on Company Sponsored Programs (CSPs).

Furthermore, this section summarizes 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).

Pfizer policies regarding colleagues' interactions with patients and consumers will also be reviewed.

Section 4: Guidelines for Patient Support and Patient/Consumer Interactions

Lastly, this section provides additional information about Direct-to-Consumer (DTC) advertising, use of patient testimonials in promotion, and inclusion of animals in promotional communications. [Promotional labeling](#) and [advertisements](#) must be truthful, accurate, and not misleading. All promotional communications must also include a fairly balanced presentation between efficacy and risk information. For an overview of requirements for promotional labeling and advertising to consumers, refer to Section 1 of *The White Guide*.

It is important to understand that working with patients and other consumers, such as caregivers or PAGs, can present unique risks if not handled by Pfizer Colleagues in an appropriate manner. Therefore, specific guidance to ensure compliant interactions and activities with all types of patients and consumers is covered in this section.

Chapter 2: Patient Support Roles (PSRs)

Pfizer is committed to supporting patient access to the medicines prescribed by Healthcare Professionals (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 in Patient Support Roles (PSRs). These roles include:

- Access and Reimbursement Roles
 - Field Reimbursement Managers (FRMs)
 - Field Access Specialists (FASs)
 - Patient Access Coordinators (PACs)
- Advocacy and Patient Education Roles
 - Patient Affairs Liaisons (PALs)
 - Clinical Educators (CEs)

Generally, PSRs are field-based, external-facing roles that seek to appropriately support access to, reimbursement of, and/or education about Pfizer products and/or relevant disease states in a non-promotional and limited manner.

PSR activities are intended to facilitate patient access to Pfizer medicines and associated patient support programs (PSPs) after a Pfizer medicine is prescribed by a patient's HCP.

Although PSRs may fall under the commercial business and are externally facing roles, they are separate from the sales and marketing organization and are not intended to promote Pfizer products.

This chapter describes the different PSR roles and summarizes their responsibilities. For more information about PSRs, see Section 2 and Section 5 of [The Orange Guide](#).

Access and Reimbursement Role Descriptions

Field Reimbursement Managers (FRMs)

FRMs are subject-matter experts on reimbursement, access, and coverage issues affecting Pfizer products who primarily support HCPs and their staff. FRM responsibilities include educating 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 coordinate with Pfizer hubs with appropriate approvals.

Field Access Specialists (FASs)

The FAS role generally functions like the FRM. In addition to the direction above for FRMs, FASs may have additional approved permissions supported by considerations such as the uniqueness of the disease state, patient population, [therapeutic class](#), and current challenges to access. For example, FASs may proactively reach out to hubs and HCPs related to individual case support, whereas FRMs typically only provide reactive support.

Patient Access Coordinators (PACs)

PACs are colleagues who interface directly with patients and/or caregivers to provide limited reimbursement support. The rules governing those interactions are distinct from the rules that apply to interactions with HCPs.

Furthermore, PACs may communicate with the hub only in regard to patients with a signed PAC opt-in. For patients who have opted-in to receive PAC support, PACs may make a proactive welcome call to explain the hub enrollment process and timing and follow up on missing case information, as approved. They may also reactively address patient questions either by sharing information approved for inclusion in their Customer Relationship Management (CRM) platform or transferring patients to the hub.

In carrying out their activities, PACs may have the need to interact with FASs consistent with approved direction.

Advocacy and Patient Education Role Descriptions

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. Their primary functions are to develop strong working partnerships to help advance the needs of the patient community and to engage in proactive outreach with local advocacy and patient groups to understand their goals, objectives, and needs.

PALs may staff approved exhibits and displays at patient meetings and conferences. They may also educate patients and their caregivers on disease awareness and management.

PALs must not provide off-label information, proactively discuss specific treatment options, or act as a case manager or advocate for patients with respect to reimbursement, access, or affordability issues. Furthermore, PALs must not engage in patient interactions that are not specifically described in [The Orange Guide](#) without additional specific guidance.

For information about interactions between PALs and Sales Colleagues, see Section 2 of [The Orange Guide](#).

Clinical Educators (CEs)

Pfizer brands may have an appropriate business need to deploy either HCP-Facing CEs or Patient-Facing CEs.

HCP-Facing CEs educate HCPs and relevant office staff on topics such as relevant disease states, proper administration of Pfizer medicines, and safety and tolerability matters, including monitoring and management of adverse events. They also share contraindications, warnings, and other relevant product characteristics.

HCP-Facing CEs must provide education in a manner that is non-promotional, fair and balanced, and consistent with the relevant product's Prescribing Information. They must not make claims related to a product's efficacy.

Patient-Facing CEs are responsible for educating patients who have been prescribed a Pfizer product and their caregivers.

Patient-Facing CEs may educate on disease awareness and management as well as provide basic information on proper use and administration of Pfizer medicines and related devices. They may meet individually or in group settings, depending on the guidance developed by the Brand Team in partnership with Compliance. Patient-Facing CEs must not promote Pfizer products to patients or caregivers.



Section 4: Guidelines for Patient Support and Patient/Consumer Interactions

Please note that all CE roles must be approved by Pricing and Access Legal (P&A Legal), as there are execution considerations and potential enforcement risks with CE roles. For example, CE responsibilities should not include the delivery of programs, such as adherence programs, already being executed by Specialty Pharmacies.

Guiding Principles Related to Patient Support Roles (PSRs)

There are overarching guiding principles that apply to PSRs.

	<p>PSRs MUST:</p> <ul style="list-style-type: none">• Provide only limited support• Be non-promotional• Be independent from colleagues with Marketing or Sales responsibilities
	<p>PSRs MUST NOT:</p> <ul style="list-style-type: none">• Have promotional/off label discussions and must select their audiences accordingly• 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

Read below for more detail on each guiding principle.

Patient Support Roles (PSRs) Must Provide Only Limited Support

As discussed in Section 1 of *The White Guide*, 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.

PSRs may implicate anti-kickback laws if used to induce patients to request, or physicians to prescribe, Pfizer products. To mitigate this risk, PSRs 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.

PSRs 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 such as prior authorizations (PAs), submitting claims, coding records, processing bills, or compiling documentation for appeals and/or submitting written appeals
- PACs, PALs, and Patient-Facing CEs may not provide "on call" medical services and are prohibited from providing medical advice to patients or caregivers

Section 4: Guidelines for Patient Support and Patient/Consumer Interactions

- PACs, PALs, and Patient-Facing CEs must direct the patient to refer any treatment-related questions, including questions about side effect management and discontinuation of a Pfizer product, back to their treating HCP

Patient Support Roles (PSRs) Must Be Non-Promotional

PSRs, while externally-facing roles, are prohibited from promoting Pfizer products. To remain non-promotional, PSRs must ensure their activities and interactions with both external parties and internal colleagues are not, and do not appear, promotional.

As an example, FRMs, FASs, and PACs must not promote or detail any Pfizer product and must not discuss clinical product information with HCPs, their office staff, or patients/caregivers. Similarly, while PALs and 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.

	<p>Colleagues <i>MUST</i> ensure that:</p> <ul style="list-style-type: none">• PSR materials for use with HCPs, patients and caregivers are:<ul style="list-style-type: none">– Created by dedicated Market Access marketers– Reviewed and approved by the applicable Review Committee (RC)<ul style="list-style-type: none">▪ While these materials are not intended to promote Pfizer products, and must not contain promotional claims about Pfizer products, inclusion of certain information or formatting—such as the brand name or brand colors—may trigger the need to include product indication, important safety information, full prescribing information, and submission to the Food and Drug Administration (FDA) at first use.– Narrowly tailored to supporting patient access to, and education about, Pfizer products– On-label• PSR operating plans, tactical plans, and goals are consistent with their non-promotional nature and independent from commercial goals<ul style="list-style-type: none">– PSR activities must not have promotional tactics, goals, or objectives• PSR performance metrics and accountabilities are independent of commercial objectives and goals<ul style="list-style-type: none">– PSRs must not be measured by prescriptions, sales, or revenue generation– In no instance should a Return on Investment (ROI) calculation be done or the value of PSRs be determined by comparing pre- and post-PSR interaction prescribing patterns
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Patient Support Roles (PSRs) Must Be Independent from Colleagues with Marketing or Sales Responsibilities

The following general guidance is provided to ensure compliance of PSR activities with applicable laws:

	<p>Colleagues <i>MUST</i> ensure that:</p> <ul style="list-style-type: none">• PSR activities are<ul style="list-style-type: none">– Independent from promotional activities and influence
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Section 4: Guidelines for Patient Support and Patient/Consumer Interactions

- Made available in a non-discriminatory fashion to all appropriate HCPs and eligible patients
- Based only on the customer's or patient's need for the information the PSR provides
- Unrelated to the volume or value of business generated by any HCP or healthcare facility or to any decision by a patient to use a Pfizer medicine
- Not directed by Pfizer Colleagues with sales or brand marketing responsibilities
 - The PSR Team Lead and their managers should not have any direct sales or marketing responsibilities
 - PSRs must also limit their interactions with Field Commercial Colleagues
 - See Section 5 of [The Orange Guide](#) for more information



Colleagues *MUST* ensure that:

- PSR activities do not provide substantial, independent value to HCPs, HCP practices, patients, or their caregivers

For more information on PSR activities, please also see the [General Principles and Guidance for Patient Support Role Activities](#) on Policy Point.

Patient Support Roles (PSR) Interactions with Field Commercial Colleagues



Sales Colleagues and Account Managers *MAY*:

- Refer requests for inclusion on PSR call and contact lists to the applicable PSR Team Lead
- Provide the relevant PSR colleague's contact information to HCPs and offices who request it
- Use the [Pfizer Triage app](#) to refer unsolicited requests for PSR support related to an ongoing PSR engagement
 - For example, if an HCP asks a Sales Colleague about the status of an ongoing benefits investigation, the Sales Colleague may refer the issue to the PSR Team via the Pfizer Triage App
 - In such instances, the Sales Colleague should not collect or transmit any personal health information



Sales Colleagues and Account Managers *MUST NOT*:

- Direct or influence PSR to engage with certain audiences
- Refer requests for inclusion on PSR call and contact lists directly to the PSR colleague
- Solicit such queries from PSR audiences

Section 4: Guidelines for Patient Support and Patient/Consumer Interactions



PSR Team Leads MAY:

- Identify additional methods for Sales Colleagues and Account Managers to pass along HCP referrals, such as via iPad apps or e-mail templates
 - This must be done in consultation with Legal and also pertains to Brand Teams
- 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 PSR contact list
 - This must be done in consultation with Legal and Compliance
 - 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 PSR is permitted to share
 - Such data must not be used to reward high prescribing HCPs with PSR engagement or to target high prescribers of a competitor product for conversion of patients to a Pfizer product

Patient Support Roles (PSR) Creation Process and Approval

To ensure that Pfizer's PSR activities are appropriate, a team seeking to create a PSR or make a material change to an existing PSR must obtain approval from the Pfizer Legal Division. Legal's review and approval should include establishing an appropriate reporting line for the proposed role apart from Sales and Marketing. 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 PSR 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 PSR activities
- Whether, when viewed independently or in connection with other relevant Pfizer offerings, the proposed PSR activities could constitute independent value to an HCP, patient, or caregiver
- The need for and feasibility of any risk mitigation strategies and tactics

PSR 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. As with other field-based roles, PSR colleagues will be subject to ongoing monitoring, field rides, and audits.

Teams seeking information regarding the PSR approval process should refer to the [General Principles and Guidance for Patient Support Role Activities](#). Teams seeking to hire a vendor—such as a Contract Patient Support Organization, to carry out PSR activities—must work with Procurement and Legal for guidance on vendor selection and hiring. Contact the relevant Global Product Counsel (GPC) or P&A Legal for more information on the overall approval and renewal process.

Patient Support Roles (PSRs) and Privacy

Applicable privacy laws impose strict limitations on the use and disclosure by HCPs and insurers of information that may be used to identify patients, including [protected health information \(PHI\)](#). With certain exceptions—such as for

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purposes of treatment, payment, or healthcare operations—HCPs are generally permitted to use or disclose an individual’s PHI only if the individual has authorized that use or disclosure in writing in advance.

Most Pfizer Colleagues do not need access to PHI for any reason and should not request, collect, or retain any such information. PSRs should not collect or retain patient-specific information unless necessary to conduct an approved activity **and** the necessary patient authorization has been obtained.

While some PSRs, including PACs and PALs, are permitted to interact with patients, they are never permitted to meet with patients or caregivers at an HCP office or be present when a patient is receiving medical advice or treatment from an HCP. To learn more about privacy and individual patient support activities involving PSRs, please see Section 5 of [The Orange Guide](#).

To learn more about privacy laws, refer to Section 1 of *The White Guide*.

Individual Patient Support of Hub-Enrolled Patients

Patients enrolled in Pfizer hubs are required to sign an authorization that allows their HCP and insurer to share PHI with the hub, enabling the hub to assist individual patients. PSRs may provide individualized support for patients enrolled in a Pfizer hub only after confirming that the hub enrollment form, which contains the necessary authorization for the PSR activity, has been filled out and signed by the HCP for FRM or FAS engagement or the patient for PAC engagement. If such confirmation is not received, a new enrollment form and/or patient authorization must be submitted to the hub before the PSR can provide any individualized patient support.

Once the PSR has the necessary confirmation, they may conduct activities consistent with their specific role, the guidance provided in this Chapter, and any relevant brand guidance. Thereafter, PHI may be received from and provided to hub representatives, clinicians, case managers, or authorized individuals as required to coordinate and support reimbursement of or access to Pfizer products.

Individual Patient Support for Patients Not Seeking Hub Support

Some patients may opt not to receive hub support. In those circumstances, before receiving PHI, PSRs must obtain from the patient’s HCP a signed form attesting to the patient’s authorization for the patient support provided by the PSR. The Brand Team will provide PSRs with the approved form.

Educating Healthcare Professionals (HCPs) and Patients about Patient Support Roles (PSRs)

Communication about the availability of PSRs can raise significant legal concerns if such communication seeks to induce the prescription, purchase, or referral of Pfizer products.



Pfizer Colleagues MAY:

- Create materials for the purpose of educating HCPs and patients about PSRs, their availability, and how they can facilitate patient access to and education about Pfizer products
 - Materials must be reviewed and approved by the applicable RC

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- Discuss PSRs after a promotional detail as long as Sales Colleagues do not return to a promotional discussion



Pfizer Colleagues MUST NOT:

- Promote the availability of PSRs as a reason to prescribe Pfizer products
- Use PSRs to differentiate Pfizer products from competitor products
- Suggest that PSR activities provide substantial independent value to any HCP, patient, or caregiver
- Use PSRs as levers to gain access for Sales Colleagues or Account Managers
- Make the availability of PSR offerings contingent on providing access to other Pfizer Colleagues
- Create materials that promote, make claims about, or position PSRs as providing value to, or conducting services for, the HCP or staff

Chapter 3: Patient Support Programs (PSPs)

Pfizer is committed to encouraging patients to talk to their doctors about available treatment options and believes that all patients should have access to the medicines prescribed by their Healthcare Professionals (HCPs).

Aligned with the goal of supporting patient access to medicines, Pfizer has established Patient Support Programs (PSPs) so that eligible patients may access resources designed to help with:

- Benefits investigations
- Limited prior authorizations (PAs) and appeals assistance
- Drug delivery and administration assistance
- Co-pay support
- Financial assistance
- Patient education

To that end, this chapter describes the following PSPs in more detail:

- Pfizer RxPathways®
- Hubs
- Savings and Free Trial Programs

General Guidance for Pfizer Colleagues Regarding Pfizer Patient Support Programs (PSPs)

Even though PSPs 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, federal and state privacy laws, state contract law, and state pharmacy laws.

It is Pfizer’s policy to establish and implement Pfizer PSPs consistent with all applicable laws and regulations. To that end, Pfizer PSPs provide no more than limited reimbursement support to patients who are prescribed a Pfizer medicine. This limited support is in line with the applicable [U.S. Department of Health and Human Services \(HHS\) Office of Inspector General \(OIG\)](#) guidance.

Furthermore, third-party vendors acting on Pfizer’s behalf in administering PSPs must certify/warrant compliance with applicable state and federal healthcare laws and regulations as well as Pfizer policies and procedures.

PSPs are intended to support patient access to prescribed Pfizer medicines and are not intended to reward or induce an HCP for past, present, or future prescribing of products; to impact clinical decision-making; or to reduce economic or administrative burdens for an HCP or related practice or office staff.

Pfizer offers its patient support activities in a non-discriminatory fashion to all eligible patients after they are prescribed an applicable Pfizer product by their HCP. The availability of patient support through Pfizer PSPs 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 and Access Legal (P&A Legal) Team must review and provide guidance for PSPs operating in the United States. Additionally, Pfizer annually re-evaluates the need for specific patient support activities on a product-by-product basis to substantiate the need for their continued offering.

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	<p>Content that mentions PSPs MUST, at a minimum:</p> <ul style="list-style-type: none">• Accurately and transparently describe the program offerings• Clearly outline eligibility criteria
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	<p>Content that mentions PSPs MUST NOT:</p> <ul style="list-style-type: none">• Guarantee coverage• Include unsubstantiated claims comparing Pfizer and competitor programs• Position the program as an inducement or reward for prescribing the relevant medication
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Lastly, Pfizer Colleagues must follow the guidance summarized below when engaging HCP customers in discussions regarding Pfizer PSPs.

	<p>Pfizer Colleagues MUST:</p> <ul style="list-style-type: none">• Limit communications about the availability of PSPs and related activities to Review Committee (RC)-approved information• Refer all inquiries from their HCP customers regarding the status of a particular patient case to the applicable Patient Support Role (PSR) through the Pfizer Triage App or refer the HCP or office staff to RxPathways® or the applicable Pfizer hub
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	<p>Pfizer Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Promote Pfizer’s hub activities as a reason to prescribe a Pfizer medicine or as a means to reduce economic and administrative burdens for HCPs and staff<ul style="list-style-type: none">– Hubs operate to assist patients with accessing prescribed medicines, without any substantial or independent value• Promote Pfizer PSPs and activities to induce HCPs to prescribe products or discourage HCPs from prescribing alternative therapies
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Pfizer RxPathways®

[Pfizer RxPathways®](#) serves as a single point of access that connects patients, regardless of their insurance status, to available financial assistance and PSPs such as:

- Hubs
- Co-pay and savings offers
- Free trial programs
- The Pfizer Patient Assistance Program (PAP)
- Educational and other resources

Pfizer RxPathways® is not brand-specific and is run by the Pfizer Global Health and Social Impact (GH&SI) Team.



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Marketing materials, including implementation guides, that reference Pfizer RxPathways® MUST be created in line with the following requirements:

- The Pfizer RxPathways® Team will make available through PROMOs Prime a set of unbranded Pfizer RxPathways® materials that can be used by Marketing for purposes of discussing Pfizer RxPathways
 - The Pfizer RxPathways® Team will also make limited materials available on Pfizer PAPs
- Marketing Teams may include in their marketing materials the Pfizer RxPathways® logo and Pfizer RxPathways® pre-approved taglines and logo lock-ups without requiring the approval of the Pfizer RxPathways® 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 Pfizer RxPathways® to keep on file
- In addition to applicable brand, therapeutic area, or other relevant RC approvals, content that mentions services managed by GH&SI, such as PAPs and reimbursement support services, must be reviewed by a member of the Pfizer RxPathways® Team and Pfizer RxPathways® RC if the content deviates from standard language provided

Hubs

Hubs are administered by third-party vendors who are contracted by Pfizer to 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 activities.

Hub offerings vary by program, but they often include:

- Reimbursement support, such as benefits verification and limited PAs and appeals assistance
- Co-pay enrollment
- Specialty or retail pharmacy coordination
- Interim care (free drug) programs
- Product and disease state education
- Injection training

Hubs are jointly managed by the Specialty Access Solutions Center of Excellence (SAS CoE) and GH&SI Teams. The offerings that the hub provides, or to which the hub connects patients, are overseen by different teams depending on the offering.

For example:

- GH&SI is responsible for hub reimbursement support and Pfizer PAP services
- SAS CoE is responsible for the development, review, and implementation of hub-related fee-for-service arrangements, outside of Reimbursement Support and PAP, that meet the legitimate business needs of Pfizer and the patients who have been prescribed Pfizer medicines

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Pfizer Colleagues MUST ensure that:

- The [Patient Access Toolkit](#) is followed when creating Materials related to product-specific patient support hubs
- Brand RCs review and approve branded materials related to product or disease-state-specific hubs

Additional information is available in [The Patient and Reimbursement Support Hubs Standard Operating Procedure \(SOP\)](#).

Savings and Free Trial Programs

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 co-pay coupons/cards, discount programs, and direct purchase programs—and certain other programs that provide a limited supply of Product at no cost to the patient for the purpose of determining efficacy and tolerability, such as voucher programs and free trial programs. These programs are referred to collectively as “Savings and Free Trial Programs.”

The **OIG** of the U.S. Department of Health and Human Service has cautioned that programs that provide free or reduced-price product or savings on out-of-pocket costs to patients implicate the federal [Anti-Kickback Statute \(AKS\)](#) and raise substantial risks of fraud and abuse.

This Chapter provides a framework for the structure, operation, and implementation of Pfizer Savings and Free Trial Programs to help patients access or try their prescribed Pfizer medications and to facilitate compliance with applicable federal and state laws and guidance from the OIG.

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.

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
- GH&SI
- Legal
- 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.

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, such as a co-pay or co-insurance or reduced cash price. Program owners must consult with Biopharma Operations and P&A 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—such as third-party payers, [pharmacy benefit managers \(PBMs\)](#), or retail



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pharmacies—are not subject to this Chapter. However, Pfizer Colleagues interested in such third-party programs not operated by Pfizer must consult with P&A Legal and Compliance prior to entering into any such programs.

Pfizer Savings and Free Trial Programs include both commercial savings and discount programs offered by Brand Teams, which are centrally operated by Biopharma Operations. 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.

Read the following for detailed information regarding Savings Programs and Free Trial programs, and refer to the [Savings and Free Trial Programs SOP](#) for additional information.

Savings Programs

Co-pay Programs

Co-pay Programs help to reduce patients' out-of-pocket costs for a Pfizer drug. Co-pay Programs may be offered in many forms, including paper co-pay coupons, which may be distributed by Pfizer or downloadable from a product website; physical or virtual co-pay cards; electronic coupons, which are typically offered through the pharmacy adjudication system or prescriber's electronic medical records or e-prescribing system; debit cards; or customer rebates.

Co-pay/Cost Sharing Programs	
Co-pay Coupon/Card	<ul style="list-style-type: none">A program that reduces a patient's out-of-pocket costs immediately at the point of sale
Electronic Co-pay Savings Program	<ul style="list-style-type: none">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	<ul style="list-style-type: none">A preloaded card that may be used at the point of sale to pay the pharmacy/dispensing Healthcare Professional (HCP) for the patient's out-of-pocket costs
Customer Rebates	<ul style="list-style-type: none">An offer of post-purchase reimbursement from Pfizer directly to an eligible patient for their out-of-pocket cost, such as a co-pay 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

All proposals for Co-pay Programs must be reviewed by P&A Legal and may require additional controls to ensure compliance with applicable laws and OIG Guidance. In general, Co-pay Programs are available for commercially insured patients only and require P&A Legal review and approval. Pfizer may consider offering Co-pay Programs to uninsured or cash paying patients.

Co-pay 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. Brand Teams may consider offering Co-pay 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; however, P&A Legal review is required.



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FAQ: Co-pay Programs and Federal Beneficiaries	
	May Co-pay Program offers be used by patients using Medicare, Medicaid, or other federal health care program?
	No. Co-pay Program offers, such as co-pay cards or co-pay 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.

Discount and Direct Purchase Programs

Discount and Direct Purchase Programs allow uninsured and/or underinsured patients to either:

- Use a program card to purchase certain Pfizer medications at a reduced cash price, outside of any insurance benefit, through participating pharmacies
- 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 and if they then 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. 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.

	<p>Brand Teams MUST:</p> <ul style="list-style-type: none">• 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
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	<p>Vouchers and free trial programs MUST NOT be:</p> <ul style="list-style-type: none">• Provided for the purpose of financial assistance• Positioned to HCPs or provided for the purpose of addressing long term issues, such as patient access, insurance coverage, or financial assistance
	<p>Field Sales Colleagues MUST:</p> <ul style="list-style-type: none">• Only distribute both Starters and vouchers to the same HCP office in accordance with the following principles• Clearly indicate the appropriate use of these resources to HCPs, including that:<ul style="list-style-type: none">– Vouchers are not intended to address financial hardship and insurance delays– An individual patient should receive either a voucher or Starter but not both<ul style="list-style-type: none">▪ 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 (AKS)

The OIG broadly defines “co-payment 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 co-payment 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 co-payment coupons to obtain prescription drugs paid for by Medicare. The OIG concluded that manufacturers are responsible for operating their co-payment 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, such as 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 payers—including Federal Health Care Programs—for samples they receive for free from manufacturers.

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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 co-pay coupons, co-pay cards, vouchers, and other Savings and Free Trial Programs in those states. More information on State Laws can be found in Section 9 of *The White Guide*.

Development and Implementation of Savings and Free Trial Programs

Either Commercial Colleagues or colleagues in GH&SI 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 SOP](#). 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 P&A 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 P&A 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.

P&A Legal and Global Product Counsel (GPC) provide legal guidance to Brand Teams, GH&SI, and Biopharma Operations with respect to Savings and Free Trial Programs. Every Savings or Free Trial Program must be reviewed and approved by P&A 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.

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	<p><i>When developing a Savings or Free Trial Program, Pfizer Colleagues MUST:</i></p> <ul style="list-style-type: none">• Consult with Biopharma Operations on the development, approval, and implementation of all Pfizer Savings and Free Trial Programs• 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• Submit the Savings or Free Trial Program Design Form to Biopharma Operations and receive approval from P&A Legal prior to initiating a new Savings or Free Trial Program or making changes to existing programs
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	<p><i>When developing a Savings or Free Trial Program, Pfizer Colleagues MUST NOT</i></p> <ul style="list-style-type: none">• Engage a new Savings or Free Trial Program vendor or enter into a new or amended SOW without coordinating with Biopharma Operations• Design a program to address access issues or financial need• Contract with a new or different vendor without Legal and Biopharma Operations approval of the Savings or Free Trial Program Design Form
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Materials Describing Savings and Free Trial Programs

	<p><i>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:</i></p> <ul style="list-style-type: none">• Reviewed and approved by the applicable RC• Accurate and not misleading• Clear and transparent regarding the offering, patient eligibility, and program terms and conditions• Compliant with the requirements outlined in this Chapter and the Savings and Free Trial Programs SOP, Commercial Review and Approval Policies, U.S. Addendum and its associated work instructions, and all other relevant Pfizer policies, SOPs, and guidance
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Chapter 4: Patient Assistance Programs (PAPs)

The Pfizer Patient Assistance Program (PAP), the Pfizer Institutional Patient Assistance Program (IPAP), donations to Independent Charity Patient Assistance Programs (ICPAPs), and other Patient Support Programs (PSPs) play an important role in assisting patients with accessing medically necessary products that are prescribed by their Healthcare Professionals (HCPs).

However, several federal and state laws and other regulatory guidance are implicated in connection with the operation of these programs. These include federal and state anti-kickback statutes (AKSs), 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 (HHS) Office of Inspector General (OIG) guidance.

It is Pfizer's policy to establish and implement PSPs and activities consistent with all applicable laws, regulations, and guidance issued by the OIG.

These programs and activities are intended to support appropriate patient access to independently prescribed Pfizer medicines or other prescribed medicines in the case of ICPAP donations and are NOT intended to:

- Induce a patient to select a product
- Induce an HCP to prescribe or reward an HCP for prescribing products
- Reduce economic or administrative burdens for an HCP or related practice or office staff

Furthermore, Pfizer Colleagues are not permitted to promote Pfizer's patient support or assistance programs as a reason to prescribe a product.

Pfizer offers its programs in a non-discriminatory fashion to all eligible patients who are prescribed an applicable Pfizer medicine, and the availability of these offerings is unrelated to the volume or value of business generated by any HCP or healthcare facility.

To ensure that Pfizer meets these obligations, the Pfizer Pricing and Access Legal (P&A Legal) Team reviews and provides guidance regarding the programs and activities covered in this Chapter. In addition, the P&A Legal Team must review and approve the inclusion, removal, and exclusion of products from the Pfizer PAP and IPAP. In addition, the ICPAP Review Committee (RC) must approve all donations to ICPAPs.

Please consult the P&A Legal Team for additional information on the Pfizer PAP and interactions with ICPAPs.

Pfizer Patient Assistance Program (PAP)

As part of its commitment to improving patient access to medicines and vaccines, Pfizer has established a charitable internal free drug program that provides commercially available Pfizer drug products free of charge to financially eligible uninsured and underinsured patients with government insurance. Government insurance includes Medicare, Medicaid, Champus/TRICARE, Veterans Affairs (VA), and any other federal or state health care program. This program is referred to as the Pfizer PAP or the Free Drug Program.

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Overview

To receive products prescribed by their HCPs for free, patients must meet program-specific financial need criteria and other eligibility requirements.

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 its toll-free number (**844-989-PATH**). They may also contact the product-specific hub if one has been established.

The Pfizer Patient Assistance Foundation (PPAF)

The Pfizer PAP is operated by the Pfizer Patient Assistance Foundation (PPAF), which is a nonprofit 501(c)(3) private operating foundation.

The Global Health and Social Impact (GH&SI) Team, 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 and exclusion criteria.

Institutional Patient Assistance Program (IPAP)

The IPAP—which is part of the Pfizer PAP—provides select products to financially eligible, uninsured patients through federally qualified community health centers, disproportionate share hospitals (DSH), free clinics, and state pharmacy programs.

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.

External Communications Regarding the Pfizer Patient Assistance Program (PAP)

Communications with patients and/or HCPs regarding the Pfizer PAP must be factual and non-promotional.

Please note that the following 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, including IPAP.

Furthermore, if a colleague's role allows them to engage with HCPs or patients regarding the Pfizer PAP, the general guidance below must be followed. More specific guidance for colleagues in Patient Support Roles (PSRs) can be found in the [General Principles and Guidance for Patient Support Role Activities](#) on Policy Point.

General Guidance

	<p>Pfizer Colleagues MUST:</p> <ul style="list-style-type: none">• Be transparent regarding program eligibility criteria and other key terms and conditions• Use only marketing materials referencing the Pfizer PAP that have been approved through all applicable Pfizer materials review processes
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Pfizer Colleagues MUST NOT:

- Position the Pfizer PAP as a tool to promote products, differentiate products from competitor products, or influence HCP prescribing habits
- Describe the Pfizer PAP as a way to fill gaps in product coverage, such as the Medicare Part D donut hole
- Refer to the Pfizer PAP as a patient discounting program
- Make any statements about the potential outcome of an application or guarantee enrollment in, or provision of free product through, the Pfizer PAP
- Fill out or submit PAP applications on behalf of patients or HCPs

In addition to the general guidance described above, please consult Section 5 of [The Orange Guide](#) for role specific guidance for Field Commercial Colleagues, including PSRs.

Patient Assistant Program (PAP) Guidance for Pfizer Non-Field Colleagues

Pfizer's GH&SI Team is responsible for administering the Pfizer PAP on behalf of PPAF, a nonprofit 501(c)(3) private operating foundation. Except as described below or in the PAP/IPAP Standard Operating Procedure (SOP), or as otherwise approved in advance by P&A Legal. Pfizer Colleagues must not be involved in the development, operation, or management of the Pfizer PAP.

Patient Assistant Program (PAP) Guidance for Pfizer Non-Field Colleagues

<p>Budget</p>	<ul style="list-style-type: none"> • The Pfizer PAP budget is a component of the GH&SI budget within the Corporate Affairs budget • Brand Teams indirectly fund the Pfizer PAP operations through permanent budget transfers to GH&SI 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 GH&SI Colleagues to understand GH&SI's requests for budget transfers • As part of these communications, GH&SI may provide relevant Pfizer PAP data, such as PAP utilization or forecasting data and information about expected administrative costs
<p>Operations</p>	<ul style="list-style-type: none"> • With very limited exceptions, including those provided in the Pfizer PAP & IPAP SOP, Pfizer Colleagues must not seek to influence GH&SI'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 GH&SI 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 • At the request of GH&SI Team, relevant Pfizer Colleagues—including Commercial Colleagues—may provide information about Products, relevant diseases, and patient populations to allow GH&SI Team to develop the PAP budget and establish patient need
<p>PAP Data</p>	<ul style="list-style-type: none"> • Pfizer Colleagues may request reports containing Pfizer PAP data from the GH&SI Team • The GH&SI Team must consult with P&A Legal prior to distributing any new report type/data to anyone not working on behalf of PPAF

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Patient Assistant Program (PAP) Guidance for Pfizer Non-Field Colleagues	
	<ul style="list-style-type: none"> • Consult your Legal or Compliance 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, compliance monitoring, and program auditing • Pfizer Colleagues must not use Pfizer PAP data and reports to drive commercial objectives such as 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 P&A Legal • Pfizer Colleagues must never conduct Return on Investment (ROI) analyses on the provision of free drugs 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 803, Contributions to Independent Charity Patient Assistance Programs 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	<ul style="list-style-type: none"> • 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 Section 1 of <i>The White Guide</i> • 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 nonprofit 501(c)(3) private operating foundation, or Pfizer except as may be required for program auditing purposes
Use of Patient and HCP Personal and Contact Information	<ul style="list-style-type: none"> • 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, such as hub or PfizerPro enrollment, Pfizer may use that information for purposes consistent with other Pfizer policies and SOPs
Interactions with Pfizer Hubs	<ul style="list-style-type: none"> • Except where permitted for PSRs, colleagues may not communicate with hubs for any PAP-related reason • Any question or concern concerning hub operations of the PAP must be referred to GH&SI

Patient Assistant Program (PAP) Guidance for Pfizer Non-Field Colleagues	
	<p>Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none"> • Fill out or submit PAP applications • Proactively involve themselves in patient cases including acting as a contact for the HCP in lieu of the hub

Independent Charity Patient Assistance Programs (ICPAPs)

Overview

ICPAPs are independent, U.S. 501(c)(3) nonprofit organizations that operate PAPs to help patients with financial need access their medicines by assisting them with their out-of-pocket co-pay obligations.

Pfizer may make monetary [charitable contributions](#) to ICPAPs through GH&SI. Charitable contributions to ICPAPs can provide a means to help patients access their medicines by providing significant financial assistance for co-pay, deductible, and/or premium obligations for prescriptions. These are collectively referred to as “co-pay assistance.”

ICPAPs may focus financial assistance on costs associated with treatment for specific disease states and generally have disease-state funds that provide co-pay assistance for all branded and generic drugs or other treatments associated with the disease state.

ICPAPs must operate entirely independently from Pfizer and award patient assistance based on their independently developed eligibility criteria.

The OIG has issued guidance permitting ICPAPs to provide co-pay assistance to federal healthcare program beneficiaries using donations from manufacturers if sufficient safeguards exist. Pfizer’s policies and processes governing ICPAP donations are designed to comply with government guidance and laws and meet those safeguards.

For additional guidance on interactions with ICPAPs, please see [Corporate Policy 803, Contributions to Independent Charity Patient Assistance Programs](#).

Independent Charity Patient Assistance Program (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.

ICPAP Guidance for Pfizer Non-Field Colleagues	
Communications with ICPAPs	<ul style="list-style-type: none"> • Only the GH&SI Team, including Legal and Compliance Colleagues advising GH&SI, may communicate with—and receive information and data from—ICPAPs regarding donations to ICPAPs for co-payment assistance

ICPAP Guidance for Pfizer Non-Field Colleagues	
Communications with HCPs or Patients	<p>Colleagues MUST NOT discuss the following with HCPs or patients:</p> <ul style="list-style-type: none"> • Specific ICPAPs • The availability of funding in relevant disease states from ICPAPs • Suggestions that ICPAPs can overcome co-pay barriers • The only exception is for certain colleagues engaged in reimbursement support who have gained approval in advance by Legal, Commercial, and Medical Affairs <ul style="list-style-type: none"> – Approved reimbursement support colleagues may provide materials to HCPs that are approved by the relevant Brand RC and discuss in general terms the range of assistance options to which Pfizer RxPathways®—or the relevant product hub—connects patients, including information about ICPAPs
Data from Other Third Parties	<ul style="list-style-type: none"> • 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, such as 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: <ul style="list-style-type: none"> – Obtain information about other donors or other donations made to the ICPAP except for general information on total donations received or funding available – 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: <ul style="list-style-type: none"> – Disaggregated and/or patient-specific – Related to the identity or amount of subsidized drugs, even in the aggregate
Exception	<ul style="list-style-type: none"> • Vendors may provide certain patient-specific or disaggregated information to Pfizer Colleagues responsible for administering the Pfizer PAP 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 • These Pfizer Colleagues include <ul style="list-style-type: none"> – The GH&SI Team – Specialty Access Solutions Center of Excellence (SAS CoE) Colleagues – Colleagues engaged in reimbursement support, such as Field Reimbursement Managers (FRMs) • Other Pfizer Colleagues must not seek to obtain or be provided with such information
Independence of ICPAPs	<ul style="list-style-type: none"> • Pfizer Colleagues, including the GH&SI 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

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ICPAP Guidance for Pfizer Non-Field Colleagues	
Information Related to ICPAPs	<ul style="list-style-type: none"> The GH&SI Team must not share information related to donations to ICPAPs for co-pay assistance with any other Pfizer Colleagues except as specifically provided in Corporate Policy 803, Contributions to Independent Charity Patient Assistance Programs
ROI Analysis	<ul style="list-style-type: none"> Pfizer Colleagues are prohibited from undertaking any ROI 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	<ul style="list-style-type: none"> The GH&SI Team has sole responsibility for determining the allocation of the approved budget for donations to ICPAPs, subject to review and approval by the ICPAP RC Pfizer Colleagues are prohibited from discussing patient need, business interests, or funding decisions related to donations to ICPAPs for co-pay assistance with the GH&SI Team for purposes of influencing donations decisions
Co-Promote Agreements	<ul style="list-style-type: none"> If Pfizer collaborates with a third party in the marketing or promotion of a drug, it will be responsible, through the GH&SI Team, for making its own decisions regarding the provision of donations to ICPAPs for co-pay 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 co-pay 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 803, Contributions to Independent Charity Patient Assistance Programs and Legal

Chapter 5: Patient and Other Consumer Interactions

Pfizer interacts with consumers at various types of events including speaker programs, health fairs, public health screenings, and disease management programs. For purposes of this Chapter, the term “consumer” includes:

- Patients
- Potential patients
- Caregivers
- Patient Advocacy Groups (PAGs)
- Employees of PAGs or customer organizations, regardless as to whether they hold a professional healthcare degree
- All other non-Healthcare Professionals (HCPs) who could potentially use or benefit from information regarding a Pfizer product

A variety of laws and industry standards specifically govern interactions with consumers. These differ in some ways from the laws and standards governing promotional interactions and activities with HCPs.

Note the following examples:

- The U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) has warned that offering incentives, such as remuneration or free services, to consumers may implicate federal anti-kickback laws
- Some state attorneys general have interpreted state consumer protection laws to encompass off-label promotion
- The Food and Drug Administration (FDA) has established stringent requirements regarding direct-to-consumer (DTC) communications

Furthermore, Pharmaceutical Research and Manufacturers of America (PhRMA) has issued [Principles on Interactions with Patient Organizations](#) with the goal to help pharmaceutical companies and patient organizations have collaborative relationships to benefit public health while ensuring the independence of the patient organization and appropriate support of the organization’s mission. Pfizer has also implemented [Global Guidelines on Interactions with Patients and Patient Organizations](#) that provide guidance on these engagements. Colleagues should also refer to [U.S. Patient and Patient Organization Standard Operating Procedure \(SOP\)](#).

PhRMA has also published 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](#).

Pfizer’s goal when communicating with consumers is to provide useful and understandable information about conditions and treatment options that will help patients partner with their HCP to make more informed decisions about their treatment.

Guidelines for Patient and Consumer In-Person Interactions

Pfizer Colleagues are permitted to provide consumers with disease state and product information that is Review Committee (RC)-approved for consumers in the following circumstances:

- At consumer events
 - Includes community health fairs, health screenings, state fairs, and disease management events where Pfizer has the opportunity to set up a display or exhibit



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- At speaker programs or presentations organized by Pfizer specifically for consumers as well as presentations held in connection with third-party consumer events
 - Must use RC-approved consumer slide decks and contracted speakers or specific internal colleagues such as Patient Affairs Liaisons (PALs)
 - If asked to participate at a patient association event where there is no display or exhibit opportunity or compliant speaker program opportunity, please consult Compliance

Pfizer Colleagues must follow these general guidelines when interacting with patients and consumers.

	<p>Pfizer Colleagues MUST:</p> <ul style="list-style-type: none">• Use only RC-approved content, following relevant implementation materials intended for consumers, and limit discussion to the information contained in these materials• Provide fair and balanced information• Clearly identify themselves as a Pfizer employee, such as wearing their Pfizer name tag• Adhere to adverse event reporting and reporting product quality complaints set forth in Section 1 of <i>The White Guide</i>
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	<p>Pfizer Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Provide off-label information• Act as a case manager or advocate for consumers with respect to reimbursement, access, or affordability issues unless explicitly permitted within the scope of their role• Engage in consumer interactions that are not specifically described in <i>The White Guide</i> without additional approved guidance<ul style="list-style-type: none">– Before engaging in any consumer interaction other than those outlined here, Pfizer Colleagues must confer with their manager or Compliance• Collect or use Sensitive Personal Information (SPI) about consumers when they are interacting with them unless specifically approved by Legal<ul style="list-style-type: none">– In the event Pfizer Colleagues encounter SPI in the course of interacting with a consumer, they must not disclose or use such information for any purpose or in any manner without receiving approval from Legal– For a detailed discussion of privacy issues and the appropriate handling of Personal Information, refer to Section 1 of <i>The White Guide</i>• Offer any medical opinions, advice, or consultation, including but not limited to diagnosis or discussion of treatments for a patient, even if they have a license to practice medicine or are any other type of HCP
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Exhibits and Displays at Consumer Events

Pfizer is routinely offered to fund opportunities to display at PAG events and 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.



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Health fairs and public screenings are discussed in further detail later in this Chapter. Review the guidance below specific to exhibits and displays. For more information regarding exhibit and display opportunities with HCP audiences, see Section 2 of *The White Guide*.

Display spaces and exhibits are promotional environments and promotional standards apply.

	<p>Pfizer Colleagues MUST:</p> <ul style="list-style-type: none">• Ensure that the consumer event where the display occurs is located at a neutral venue that is open to the public<ul style="list-style-type: none">– For example, a community hospital would be considered open to the public, while a doctor’s office is not• Only discuss Pfizer products at an exhibit and display as long as the exhibit and display booth is physically separate and apart from any health screening area or education presentation area, such as by a partition or by being in separate locations• Only use materials that have been RC-approved for use with consumers<ul style="list-style-type: none">– Colleagues may not discuss or provide product information to consumers at the event if only unbranded, disease-state communications have been RC approved for use at the event with consumers• Follow any accompanying instructions on use of the materials, such as those found in implementation guides• Only provide modest snacks such as fruit, granola bars, non-alcoholic beverages, or pastries and only to those consumers with whom they interact<ul style="list-style-type: none">– Any snack provided to consumers should be consistent with the level of interaction that they will be having with them• Only provide items of nominal value to consumers at exhibits, displays, or public events that are approved by the relevant RC<ul style="list-style-type: none">– The OIG has defined “items of nominal value” provided to consumers as having a retail value of no more than \$15 per item or \$75 in the aggregate per recipient, on an annual basis– Examples of such items include mugs, water bottles, and stress balls
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	<p>Pfizer Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Pay more than fair market value (FMV) for exhibit and display space at a consumer event• Cover the costs of food items for all event attendees• Allow people who are not Pfizer employees, including HCPs, to work or host at the Pfizer booth• Provide items of value to consumers in a manner that might suggest or imply that the recipient is being bribed or improperly influenced
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Health Screenings

Screenings can promote the early detection of diseases and may offer patients a meaningful opportunity to manage a disease or condition.

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These screenings often take place as part of larger health fairs, and Pfizer Colleagues may be able to support or help Organized Customers who wish to support or hold health screenings to benefit the quality of patient health care.

Different types of health screenings may include:

- Screenings offered by an employer for its employees
- Screenings offered to the public that are organized by Pfizer
- Screenings organized by a hospital, nonprofit organization, managed care organization (MCO), or other third party

Please note, it is also possible for Pfizer's office of Global Medical Grants (GMG) to support a screening organized by a third party through an unrestricted educational grant, provided that the event meets Pfizer's requirements for unrestricted educational grants. Pfizer Colleagues may not lead or have a formal presence at health screenings funded by a GMG grant.

General Health Screening Guidelines

For employer-led or Pfizer-organized health screening events, there are some general guidelines to follow.

	<p>Pfizer Colleagues MUST:</p> <ul style="list-style-type: none">• Only support health screenings in accordance with the guidelines in this chapter• Offer approved health screenings without any expectation of return to Pfizer• Make health screenings widely available• Ensure the screening is conducted by an approved third-party vendor that routinely conducts customer disease screening programs• Use only approved documents and obtain necessary documentation:<ul style="list-style-type: none">– Pfizer Vendor Agreement– Pfizer Patient Privacy Release– An invoice from the vendor for the services• Only hand out materials approved by RC for use with consumers—in locations separate from the area where the screening is occurring• Wear their Pfizer name tag throughout the screening, which will help identify them to consumers as a Pfizer employee
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	<p>Pfizer Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Design and/or conduct their own screening program for a customer• Modify approved health screening tools• Alter or customize materials in any way for a customer• Condition the offer of a health screening on increased prescribing, as an inducement to place Pfizer products on formulary, or tie health screenings to the use of Pfizer products in any way• Tie a financial Return-On-Investment (ROI) or similar analyses to the screening event• Choose customers to receive screenings based on their likelihood to purchase, request, or take Pfizer products• Use a screening to drive or attempt to generate patient referrals to any HCP
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- Use Pfizer-sponsored health screenings to direct consumers to particular Pfizer products or to get people to ask their doctors about Pfizer products

If a colleague is approached with a health screening opportunity, or is interested in holding such an event, they should contact Pricing and Access (P&A) Legal.

Privacy Implications and Issues

Consumer health fairs and screenings may raise patient privacy concerns since Personal Information is often obtained in the presence of Commercial Field Colleagues or other Pfizer Colleagues attending the health fair.

Pfizer's ability to use any Personal Information that is collected is strictly limited by the terms in the Patient Authorization and Release form.

For example, a Pfizer representative cannot pass specific data about an individual's health status to an employer at an employee health fair unless the employee has specifically authorized the representative to provide that data to the employer.



Data may be shared with an employer or employer health plan ONLY if:

- The data is [aggregated](#) and [de-identified](#)
- All screening participants whose data is being shared have signed the Pfizer Patient Authorization and Release form

Furthermore, Pfizer Colleagues should not engage health fair attendees in discussions about their specific health status, symptoms, diagnosis, or treatment. These discussions should occur between the patient and an appropriate HCP.

Should a patient attempt to initiate such a discussion, the Pfizer Colleague must make clear that they are not an HCP and are not providing medical advice. They should then redirect the patient to an HCP at the fair or to their treating HCP.

The Pfizer Patient Authorization and Release form is available on [MyPfieldNet](#). For more information on the topics of patient authorization and de-identification of data, refer to Section 1 of *The White Guide*.

FAQ: Managed Care Customer Health Screening



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?



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

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	<p>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>
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FAQ: Health Screening Vendors	
	<p>Is there a list of approved vendors that can be used to conduct health screenings?</p>
	<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 Legal.</p>

FAQ: Healthcare Professional (HCP) Screener	
	<p>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?</p>
	<p>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.</p>

Consumer Speaker Programs

Speaker programs for consumer audiences are a promotional activity controlled by Pfizer. At these events, contracted external speakers such as HCPs or approved internal speakers, such as PALs or Medical Colleagues under certain circumstances, present an RC-approved slide deck intended for consumers.

As with speaker programs for HCPs, Pfizer is responsible for speaker conduct, what they say, and all content presented at Pfizer speaker programs for consumers whether branded or unbranded.



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	<p>Pfizer Colleagues MUST:</p> <ul style="list-style-type: none">• Ensure that the content is appropriate for a “lay” audience, consistent with Pfizer Principles for Clear Health Communication found on the Pfizer health literacy site<ul style="list-style-type: none">– When developing a consumer speaker program slide deck, Pfizer Colleagues must be mindful that many consumers have different educational backgrounds and their ability to understand medical information varies• Ensure that the consumer speaker program content is sufficient to last a minimum of 45 minutes, inclusive of Q&A, for venue programs and a minimum of 30 minutes for in-office or virtual programs• Recognize that virtual consumer speaker programs without the provision of a meal are preferred<ul style="list-style-type: none">– If a meal is provided, the cost of food, beverage, tax, and tip must not exceed \$50 per attendee
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	<p>Pfizer Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Share slide decks unless the relevant RC has specifically authorized dissemination of the slide deck in this manner<ul style="list-style-type: none">– Other RC-approved consumer materials may be handed out• Provide meals to solicit business, in a manner that might suggest that the recipient was being bribed or improperly influenced, or to steer consumers to a particular HCP or pharmacy
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For more information on speaker programs to consumer audiences, including additional host requirements regarding appropriate attendees, see Section 5 of [The Orange Guide](#).

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 the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Unbranded Communications

	<p>Pfizer MAY:</p> <ul style="list-style-type: none">• Only provide unbranded disease awareness health information to the MCO’s members, where the MCO intends to use Protected Health Information (PHI) in making the communication<ul style="list-style-type: none">– The only exception is if prior authorizations (PAs) are obtained from the MCO’s members
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Branded Communications

If Pfizer seeks to compensate an MCO for sending branded health information and PHI will be used by the MCO in making the communication, the following requirements must be met.

	<p>Requirements for Branded Communications:</p> <ul style="list-style-type: none">• 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 FMV 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• 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, or per-letter, basis• The proposed mailing must conspicuously disclose Pfizer's financial support• It is preferable, but not required, that a third-party mailing operation perform the services and receive the payment<ul style="list-style-type: none">– If a third-party is used, the third-party may only receive FMV 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
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	<p>Restrictions for Branded Communications:</p> <ul style="list-style-type: none">• 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• Disease management program customer mailings must not involve disclosure to Pfizer of patient names, addresses, or other Personal Information<ul style="list-style-type: none">– Because of privacy concerns, 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
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Please consult the relevant Product Attorney if you have questions on the permitted scope of communications with MCOs and their members.

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, such as an MCO or a pharmacy. These programs typically involve sending scheduled mailings or other communications, such as text messages, to patients to remind them to fill or refill a current prescription.

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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.

	<p><i>Requirements for arrangements that comply with the HIPAA refill reminder exception:</i></p> <ul style="list-style-type: none">• The communications must conspicuously disclose Pfizer’s support• 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<ul style="list-style-type: none">– 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 FMV of the services provided
	<p><i>The following activities are not permitted under the refill reminder exception:</i></p> <ul style="list-style-type: none">• 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• Communications encouraging an individual to switch from a currently prescribed drug or biologic
	<p><i>Requirements for arrangements that do not comply with the HIPAA refill reminder exception:</i></p> <ul style="list-style-type: none">• The customer must obtain HIPAA-compliant patient authorizations before disseminating the communications• Any medication compliance programs must be approved by RC• Any medication compliance programs must be documented in a Service Agreement that sets forth the basis for payment as well as the program materials• If the customer is an MCO, the Organized Customer Legal Team must review and approve the proposed arrangement

Finally, the use of confidential patient medical information to communicate with patients has privacy implications, even if patient-identifiable information is not disclosed. Therefore, for more information on privacy implications, please refer to Section 1 of *The White Guide*.

Chapter 6: Advertising and Promotion to Consumers

The overarching principles of advertising and promotion to consumers are similar to that for Healthcare Professionals (HCPs) in that promotional communications should be truthful, accurate, not misleading, and fairly balanced. For an overview of promotional labeling and advertising requirements, refer to Section 2 of *The White Guide*.

Direct-to-Consumer (DTC) Advertisements

Advertising to consumers refers to communications that include broadcast (television, telephone, radio) and print advertisements (magazines, newspapers), and it can also refer to online advertising (banner advertisements). Pfizer has adopted the [Pharmaceutical Research and Manufacturers of America \(PhRMA\) 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 Food and Drug Administration (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 HCPs. 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.

Furthermore, applicable DTC television (TV) advertisements should be submitted to the FDA Office of Prescription Drug Promotion (OPDP) for pre-dissemination review, consistent with [FDA's Guidance for Industry, Direct-to-Consumer Television Advertisements—FDAAA DTC Television Ad Pre-Dissemination Review Program](#). The guidance categorizes DTC TV advertisements subject to pre-dissemination review, summarizes the content to be included in the submission, and offers answers to frequently answered questions.

Please note that there are also opioid-specific requirements for DTC advertising. 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

Patient testimonials for use in promotional or disease-state communications can be obtained through patient engagements. Patient testimonials may include patient perspectives about their disease journey, their experience taking a Pfizer product, or their participation in a Patient Support Program (PSP). Like all other advertising and promotion, testimonials must follow the principles of advertising and promotion.

Pfizer's [Patient Testimonial Guidance](#) provides General Principles for patient engagements that include, and are not limited to, establishing mutual understanding between Pfizer and the patient about goals and expectations, sensitivity for the patient's time and privacy, meeting a specific brand need, and ensuring the patient has completed all necessary written forms and releases. Further, testimonials must be representative of the typical patient experience, be medically accurate, and reflect honest opinions, feelings, beliefs, and experiences of the patient.

Section 4: Guidelines for Patient Support and Patient/Consumer Interactions

Refer to Pfizer's [Patient Testimonial Guidance](#) for requirements, key considerations, and the vetting process for patient engagements for both disease-state, or unbranded, testimonials as well as for product-specific, or branded, testimonials. Also refer to the guidance for consideration for one-time engagements with patients, testimonials during external live media events, celebrity endorsers, testimonials related to PSPs, and compensation to patients.

	<p>Any testimonial used by Pfizer MUST:</p> <ul style="list-style-type: none">• Follow key considerations for compliantly obtaining and using patient testimonials as provided in Pfizer's Patient Testimonial Guidance• If branded, be consistent with the product label and must include and/or be accompanied by fair balance
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	<p>Any testimonial used by Pfizer MUST NOT:</p> <ul style="list-style-type: none">• Include any claims that Pfizer could not make directly• Overstate a product's efficacy or minimize a product's risks• 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
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Use of Animals in Advertising

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 print, digital, or TV advertisements 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, Animal Care and Use](#). Colleagues are responsible for referring to and following all applicable portions of the policy. Further, Pfizer's [Guidance on Using Animals in Promotion in Support of Corporate Policy 901](#) provides a summary of requirements for including animals in DTC TV advertising, print, and digital promotion and should be reviewed and followed.

Internet, Social Media, and Other Digital Promotion

Like other forms of advertising and promotion, the FDA regulates Pfizer's use of the internet, social media, and other digital tactics to promote its products. This includes product websites, social media platforms, banner and other internet advertisements such as sponsored search or search-engine marketing.

Detailed information on the requirements of digital promotion by tactic can be found under the [Advertising & Promotion Guidelines tab](#) on [Global Policy Xchange on Biopharma Ops on Demand](#). These guidance documents can also be found on the [Digital Review Team site](#).

Chapter 7: Additional Resources for More Information

Patient Support Roles (PSRs)

- For more information on Patient Support Roles (PSRs), see Section 2 and Section 5 of [The Orange Guide](#)
- Refer any questions to your manager, Legal, or Compliance

Patient Support Programs (PSPs)

- For more information about Pfizer RxPathways® or other PSPs, please contact The Pfizer RxPathways® Team at PfizerRxPathways@pfizer.com
- For more information on Global Commercial Content, please see the [Review and Approval Procedure—U.S. Addendum](#)
- For more information about hub programs, including guidance to govern the initiation, management, and execution of hubs/hub activities, please see the [Patient and Reimbursement Support hubs Standard Operating Procedure \(SOP\)](#)
- For more information on Savings and Free Trial Programs, please see the [Savings and Free Trial Programs SOP](#)

Patient Assistance Programs (PAPs)

- For more information about the Pfizer Patient Assistance Program (PAP) and Institutional Patient Assistance Program (IPAP), please contact The Pfizer RxPathways® Team at PfizerRxPathways@pfizer.com
- For Review Committee (RC)-approved FAQs and Talking Points regarding Pfizer PAPs, please visit [MyPfieldNet](#)
- If you have additional questions about The Pfizer PAP, IPAP, and Donations to Independent Charity Patient Assistance Programs (ICPAPs), please contact Legal

Privacy

- For more information on Pfizer policies and guidelines related to Privacy, please see:
 - [Corporate Policy 403, Acceptable Use of Information Systems](#)
 - [Corporate Policy 404, Protecting the Privacy of Personal Information](#)
 - [Corporate Policy 405, Records and Information Management Policy and Procedure](#)
 - [Corporate Policy 411, Information Incident Response Policy](#)
- For information regarding handling sensitive information, please see [Handling Sensitive Information \(HSI\) Guidelines – Procedures for Handling PI and Sensitive Personal Information \(SPI\) for Colleagues and Contractors](#)
 - For information on Investigational Site Management and Monitoring, please see the [Investigational Site Management and Monitoring \(CMCD INV04-GSOP\)](#)
- Refer any additional questions to the Enterprise Multi-Channel Marketing Team, Legal, or the Global Privacy Office at privacy.officer@pfizer.com

Promotional Interactions with Consumers

- For more information on Direct-to-Consumer (DTC) Advertisements, please see [Pharmaceutical Research and Manufacturers of America \(PhRMA\) Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines](#) and [Pfizer's Guidance for the Implementation of the Updated PhRMA DTC Principles](#)
- For more information on Pfizer Principles for Clear Health Communication, please see the [Pfizer Health Literacy site](#)



Section 4: Guidelines for Patient Support and Patient/Consumer Interactions

- For more information on Pfizer policies and guidelines related to Company Sponsored Programs (CSPs), please see:
 - [Corporate Policy 902, Company Sponsored Programs Policy](#)
 - [Corporate Policy 902a, Cross-Divisional Procedure Company Sponsored Programs Procedure](#)
- For more information on Guidelines for Patient Support and Consumer Interactions, see Section 5 of [The Orange Guide](#)
- Refer any other questions to Regulatory or your Legal or Compliance



The White Guide

Section 5

Guidelines for Organized Customer (OC)-Related Engagements

Section 5

Guidelines for Organized Customer (OC)-Related Engagements

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[Click here to visit the Glossary and Acronyms.](#)

Chapter 1: Introduction

There are many customer organizations that Pfizer Colleagues engage with as part of their roles and responsibilities. These range from large Integrated Delivery Networks (IDNs) to employers and even state and federal government organizations. Historically, these customers have generally been grouped as “Accounts.” However, to more accurately reflect the broad range of these types of customer organizations, we will refer to them as “Organized Customers” or “OCs” throughout *The White Guide*.

OCs include:

- IDNs
- Health Systems
- Hospital Systems
- Medical Groups
- Managed Care Organizations (MCOs)/Health Plans
- Retail Pharmacies
- Specialty Pharmacies (SPs)
- Long-Term Care Pharmacies
- Pharmacy Benefit Managers (PBMs)
- Group Purchasing Organizations (GPOs)
- Distributors
- Employers
- State and Federal Government Organizations

This section summarizes key Pfizer policies regarding Pfizer Colleagues’ interactions with OCs and provides guidance to colleagues who interact with decision-makers at some of these key OCs at an Account level rather than at the prescriber or individual Healthcare Professional (HCP) level.

Furthermore, this section reviews the key resources, programs, and initiatives for OCs supported by Pfizer as well as the guidelines around these.

It is important to understand that engaging with OCs and implementing contractual arrangements can present unique risks if not handled by Pfizer Colleagues in an appropriate manner. Therefore, specific guidance to ensure compliant interactions and activities with all types of OCs is covered in this section.

Chapter 2: Guidance for Engagements with Specialty Pharmacies (SPs)

Pfizer enters into Non-Discount Arrangements with Organized Customers (OCs) to procure goods or services on behalf of the Company. An example of a Non-Discount Arrangement is when Pfizer purchases data from a pharmacy for the purposes of calculating incentive compensation for Pfizer Sales Colleagues.

Frequent Non-Discount Arrangement types include:

- Purchase Agreements
 - Pfizer is purchasing some item of value
- Service Agreements
 - Pfizer is procuring a service
- Other Non-Discount Arrangements
 - Patient Education Programs, Medication Compliance Programs, Collaborations, Clinical Research Considerations, and Medical Affairs Involvement

Anti-Kickback Analysis for Non-Discount Arrangements

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. However, activities that fall entirely within a [safe harbor](#), such as legitimate service arrangements, do not violate the Anti-Kickback Statute.

The [Personal Services 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 \(FMV\)](#) basis. Where appropriate, Pfizer endeavors to make Service Agreements meet the Personal Services Safe Harbor requirements.

The Anti-Kickback Statute and its safe harbors are critical to consider when entering into Non-Discount Arrangements with any customer—and particularly OCs who are eligible to receive discounts on Pfizer products under a separate Discount Arrangement.

When Pfizer is making a payment—directly or indirectly—to an OC that may purchase, prescribe, endorse, or recommend Pfizer products, every Non-Discount Arrangement between Pfizer and that OC must undergo anti-kickback analysis.

Anti-kickback analysis 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 FMV.

Arrangements to influence the purchase, prescribing, or recommendation of a Pfizer product—or to improve the price or discount at which a customer can purchase Pfizer's products—may not be considered when evaluating a proposed Non-Discount Arrangement with an OC, as this may subject Pfizer to liability.

Section 5: Guidelines for Organized Customer-Related Engagements

	<p>To ensure compliance when entering into Non-Discount Arrangements with OCs, Pfizer Colleagues MUST:</p> <ul style="list-style-type: none">• Ensure the Non-Discount Arrangement serves a legitimate business purpose for Pfizer<ul style="list-style-type: none">– Only purchase those goods or services for which Pfizer has a bona fide need– Avoid paying for unneeded goods, services, or data which can increase the risk that the arrangement is viewed as an illegal kickback• Pay FMV for the goods, services, or data<ul style="list-style-type: none">– Paying above or below FMV increases the risk that the arrangement may be viewed as a kickback• Consult a member of the Pricing and Access (P&A) Legal Team for all arrangements with specialty pharmacies (SPs)<ul style="list-style-type: none">– P&A 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 Personal Services Safe Harbor
	<p>Pfizer Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Leverage Pfizer's ability to purchase goods or services from an OC to influence the purchase, prescribing, or recommendation of Pfizer products• Combine Non-Discount Arrangements with Discount Arrangements<ul style="list-style-type: none">– Do not discuss Discount Arrangements under which a customer may be eligible for a discount on Pfizer products in conjunction with Non-Discount Arrangements under which Pfizer seeks to procure an item of value or service from the OC• Attempt to procure a service from an OC that they are already legally obligated to provide whether by statute, regulation, or contract• Imply unstated performance requirements, including therapeutic conversion, in discount or Non-Discount Arrangements, such as distribution or services agreements• In the event that an SP makes a statement(s) regarding switching patients in exchange for discounts or service fees, a colleague must immediately refer such statement(s) to P&A Legal for appropriate follow up

Overview of Specialty Pharmacies (SPs)

There has been an increase in the development of specialty medications over the years. [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, such as the [Food and Drug Administration \(FDA\)](#)-mandated Risk Evaluation Mitigation Strategies (REMS) requirements.

Specialty drugs are generally dispensed by **SPs** which are distinct from traditional retail pharmacies in their more comprehensive coordination of many aspects of patient care, disease management, and patient access to therapy. SPs also have 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.



Section 5: Guidelines for Organized Customer-Related Engagements

SPs employ **Specialty Pharmacy Providers (SPPs)** which include pharmacists, nurses, physicians, and pharmacy technicians to 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 providing a number of services as part of their normal business operations or “Core Services,” such as:

- Performing prescription intake and dispensing
- Conducting benefits investigations
- Offering clinical support
- Supplying eligible patients with information about third party funding sources, such as out-of-pocket assistance with co-pay resources, and contact information for third party co-pay foundations
- Extending support for prior authorizations and appeals

Pfizer enters into a variety of contractual Non-Discount and Discount Arrangements with certain customers when it procures services. Pfizer enters into Non-Discount Arrangements with SPs to participate in Defined SP Networks and/or to provide Supplemental Services to patients who have been prescribed a Pfizer product dispensed by such SPs versus Core Services which the SP is expected/obligated to provide independently. 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 Specialty Pharmacies (SPs)

Non-Discount Arrangements with Specialty Pharmacies (SPs)

Defined Distribution Networks

Through distribution agreements, Pfizer contracts with certain SPs that meet pre-defined objective inclusion criteria, including traditional SPs and directly contracted Integrated Delivery Network (IDN) SPs, to dispense a particular Pfizer product as part of a Defined SP Network.

Defined SP Networks are designed to:

- Ensure consistent and high-quality patient care
 - Meet specific Pfizer requirements, such as, therapeutic area expertise, data reporting capabilities, or distribution capabilities
- Facilitate patient access across payers and geographic regions

Defined Distribution Network inclusion criteria are determined by the Specialty Access Solutions Center of Excellence (SAS CoE) and P&A Legal. All pharmacies seeking access to a Defined Distribution Network must be reviewed by the SAS CoE against such pre-defined objective inclusion criteria.

Supplemental Services Contracts

Through Service Agreements, Pfizer contracts with SPs, including traditional SPs and directly contracted IDN SPs, to provide specific services to help support patients prescribed a Pfizer product. These Supplemental Services are in addition to an SP's Core Services, which are services that the SP provides to its patients as part of its normal business practice.



Section 5: Guidelines for Organized Customer-Related Engagements

Supplemental Services may include, but are not limited to:

- SP's dissemination of Pfizer patient educational materials
- Product adherence counseling
- 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 FMV, and the services contracted are not part of an SP's Core Services.

	<p>Supplemental Services MUST be:</p> <ul style="list-style-type: none">• Non-promotional in nature• Limited to patients with a prescription for a Pfizer Product consistent with an FDA-approved indication and dosing regimen• Transparent as to Pfizer funding
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All Supplemental Service arrangements with SPs are developed by the SAS CoE and must be approved by P&A Legal.

Discount Arrangements with Specialty Pharmacies (SPs)

Separate from distribution or services agreements, Pfizer may engage in Discount Arrangements with SPs, such as channel discounts. Such Discount Arrangements are negotiated by Specialty National Account Directors (NADs).

	<p>Discount Arrangements MUST be:</p> <ul style="list-style-type: none">• Negotiated and contracted separately from distribution agreements or Service Agreements
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	<p>Discount Arrangements MUST NOT:</p> <ul style="list-style-type: none">• Be contingent upon the performance of Supplemental Services
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Furthermore, certain SAS CoE Team members, including Directors, Strategy and Innovation; Directors, Operations and Execution; and Directors, Analytics of the SAS CoE, are specifically firewalled from discussions concerning SP product discounts and must not participate in these discussions. Please consult your manager before having discount discussions.

Patient Materials Provided to Specialty Pharmacies (SPs)

Pfizer may provide certain Pfizer-approved materials to SPs for distribution to patients.

Development of SP-related patient education materials is managed by the SAS CoE. P&A Legal is responsible for the review of patient educational materials intended to be provided to and by the SP. These materials usually undergo further review outside of Pfizer by an SP's own Review Committee (RC) to ensure they are not promotional in nature and meet the SP's standards in maintaining the SPP-patient relationship.



Section 5: Guidelines for Organized Customer-Related Engagements

	<p>SP Patient Materials MUST be:</p> <ul style="list-style-type: none">• Educational in nature
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	<p>SP Patient Materials MUST NOT:</p> <ul style="list-style-type: none">• Contain Pfizer product brand names<ul style="list-style-type: none">– SP welcome kits/brochures are the exception
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Privacy Requirements and Specialty Pharmacy (SP) Data

Privacy laws also limit the scope of permissible activities for which Pfizer may contract when SPs are interacting with patients on Pfizer's behalf.

For example, the **Health Insurance Portability and Accountability Act of 1996 (HIPAA)** and some state privacy laws restrict certain activities in which SPs and OCs 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, SPs and Accounts may implement such programs without securing patient authorizations. However, in such cases Pfizer and the applicable SPs and OCs 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 Sections 1 and 9 of *The White Guide*.

Please consult a P&A attorney if you have questions on the permitted scope of SP interactions and communications involving patients or clinicians.

Any patient-level data procured through an SP Supplemental Services agreement must be [de-identified](#), consistent with applicable privacy laws and regulations.

Pfizer-sponsored SP communications transmitted over telephone systems—including any automatic dialing systems, artificial or prerecorded voice messages, Short Message Service (SMS) text messages, and fax communications—must comply with the **Telephone Consumer Protection Act (TCPA)**.

These programs must not be implemented at an SP 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 must not share any de-identified prescription data or other proprietary information such as Fingertip Formulary with SP personnel or prescribers.

Prohibitions on Return on Investment (ROI) Analysis

Pfizer prohibits colleagues from conducting any analysis of SP data or reports. These include **return on investment (ROI)** analyses that would violate applicable laws, regulations, and/or company policies and procedures.

To mitigate the risk of any impermissible analysis, no Pfizer Colleagues other than SAS CoE may calculate any measures of program impact on product utilization or financials or ROI.

Interactions with Specialty Pharmacies (SPs)

Because of the nature of the relationship and the influence that Healthcare Professionals (HCPs) employed by SPs often develop with patients, it is important to ensure that Pfizer's interactions with SPs are managed appropriately and Pfizer Colleagues do not interfere with the independent clinical judgment of the SP HCPs.



Pfizer Colleagues *MUST NOT* directly or indirectly:

- Interfere with the carefully defined contractual arrangements between Pfizer and the SP, including by providing any items of value to SP personnel other than as expressly stated in Pfizer's contract with the SP
- Interfere with the independent clinical judgment of HCPs, including both prescribers and SP clinicians
- Interfere with the relationship between the patient and their HCPs, including both prescribers and SP clinicians
- Encourage SP personnel to suggest to patients or a prescribing HCP that the patient should switch to a Pfizer product from their existing therapy
- **Steer** HCPs or patients to one particular SP to the exclusion of other SPs
- Use SP personnel, including SP 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

Specialty National Account Director (Specialty NAD) Interactions with Specialty Pharmacies (SPs)

SPs are sometimes owned by or affiliated with other healthcare organizations (HCOs).

Organized SP Customers are SPs that are aligned to payers, [Pharmacy Benefit Managers \(PBMs\)](#), and similar organizations. The Specialty National Account Directors (Specialty NADs) serve as the primary Pfizer contact for Organized SP Customers. They also manage relationships through aggregators that contract with the non-Organized SP Customers for Supplemental Services.

A listing of Organized SP Customers can be found on [MyPfieldNet](#).

Other Field Commercial Colleague Interactions with Specialty Pharmacies (SPs)

In addition to Organized SP Customers, certain SPs may operate independently or may be affiliated with IDNs or academic medical centers that are approved to dispense Pfizer brands. These institutions may be supported by Key Account Managers (KAMs) or similar Account Management roles.

Field Commercial Colleagues other than Specialty NADs—such as Sales, KAMs, other Account Management roles, and Patient Support Roles (PSRs)—must receive prior approval from their management, the relevant Global Product Counsel (GPC), P&A, and—for organized SPs—United States Market Access (USMA) before engaging with SP personnel.

Section 5: Guidelines for Organized Customer-Related Engagements

In addition to receiving approval, colleagues are also required to follow any brand or business specific guidance on appropriate engagement with SP personnel applicable to their role.

Approval Process for Field Commercial Colleague Specialty Pharmacy (SP) Interaction

To ensure that Commercial Colleagues' interactions and PSR interactions with SPs are consistent with these principles, a team seeking approval for such interactions must obtain approval from their GPC, P&A Legal, and—for organized SPs—the Payer Channel Access Team.

Among the factors to be considered are:

- The duration and frequency of these interactions
- The training requirements associated with the SP engagements
- The risk mitigation strategies and tactics associated with these interactions

Requests for approval 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. Please note that Field management, in consultation with the GPCs, must submit an approval form to P&A Legal.

As with other field-based roles, colleagues partaking in such activities may be subject to ongoing monitoring, field rides, and audits.

Sales Interactions with Specialty Pharmacy (SP) Healthcare Professionals (HCPs) and SP Office Staff

Subject to the approval identified above, Pfizer Sales Representatives may engage with HCPs and office staff at SPs, including SPs at IDNs, consistent with the requirements discussed in Section 4 of [The Orange Guide](#).

Any such interactions must arise from a need and be narrowly tailored to:

- Educate an SP HCP about the clinical profile of a Pfizer product
- Educate SP office staff about patient support programs available to patients
- Further an otherwise approved purpose

	<p>Sales Representatives <i>MUST</i>:</p> <ul style="list-style-type: none">• Ensure that interactions are for educational purposes only• Only use materials and messaging specifically approved for use with SPs during these interactions
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	<p>Sales Representatives <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Engage an SP that is part of a defined network without express approval• Attempt to influence the SP personnel's decision-making• Make any express or implied requests for the SP personnel to recommend Pfizer products either to patients or HCPs• Discuss product discounts, rebates, reimbursement details to SPs, participation in Pfizer's SP Defined Networks, or Purchase or Service Agreements with any personnel at an SP
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Section 5: Guidelines for Organized Customer-Related Engagements

	<ul style="list-style-type: none">– In the event that a Pfizer Sales Representative learns that the SP wishes to discuss such a contractual arrangement, the matter must be referred to the Specialty NAD covering the SP• Share complaints about SP performance issues that are relayed to them by customers, such as slow dispense times or inadequate inventory, to any SP personnel directly or indirectly<ul style="list-style-type: none">– The Pfizer Sales Representative must elevate potential SP performance issues that they learn about to their sales manager, who can share the information with the appropriate Specialty NAD
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Sales Interactions with Specialty Pharmacy (SP) Sales Representatives

SPs employ their own sales representatives to call on HCPs and promote the services of the SP to encourage referrals.

	<p>Subject to the approval process referenced above, Pfizer Sales Representatives MAY:</p> <ul style="list-style-type: none">• Have limited interactions with SP sales representatives on a periodic, infrequent basis and only when there is a legitimate business purpose to share appropriate information
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	<p>Pfizer Sales Representatives MUST NOT:</p> <ul style="list-style-type: none">• Leverage SP sales representatives to:<ul style="list-style-type: none">– Build relationships with the SP– Gain access to HCP offices– Gather general payer information regarding Pfizer products– Seek information about market shares of competitive products within the SP, top prescribers, product volumes, or utilization information on specific products<ul style="list-style-type: none">▪ This information may be subject to restrictions on further use by Pfizer or third parties• Share call or HCP target lists with SP sales representatives• Meet jointly with the SP representative and a prescriber or HCP office• Provide Pfizer materials to the SP sales representative<ul style="list-style-type: none">– In the event that an SP 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 SP sales representative to the SP's own clinical personnel to answer the product-related question• Share or discuss patient-specific information, even if de-identified—including information regarding the status of fulfillment of prescriptions at the SP or with a payer—when interacting with SP sales representatives• Share information about an HCP's prescribing patterns, or coordinating targeting of—or visits to—HCPs with the SP business representative, as such actions may be perceived as inappropriately steering business to a particular SP
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In addition, SP sales representatives generally should not attend educational presentations provided by Pfizer Sales Representatives or by Pfizer Medical Colleagues for SP HCPs.

Chapter 3: Guidance for Engagements with Employers

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.



When interacting with employers and employer representatives, Pfizer Colleagues MUST:

- Coordinate with **Director, Employers (DE)**
- Treat employer representatives as Healthcare Professionals (HCPs)
- Tailor discussion to the individual employer representative
- Treat employees as consumers

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 DE. DEs are Pfizer Colleagues in the **United States Market Access (USMA)** group who are dedicated to working with employers.

DEs work directly with national employers, brokers, employee benefit consultants, unions, and national associations and coalitions. 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 as Healthcare Professionals (HCPs)

Pfizer Colleagues may interact with medical and non-medical employer representatives who are the decision makers for the Organized Customer (OC). These roles include Chief Executive Officers (CEOs), Chief Financial Officers (CFOs), Chief Medical Directors (CMDs), and employer 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.

Section 5: Guidelines for Organized Customer-Related Engagements

	<p>When interacting with these employer representatives, Pfizer Colleagues MUST:</p> <ul style="list-style-type: none">• Always give a fair and balanced presentation• Include the proven benefits of the product along with relevant risk information• Refer all unsolicited inquiries requesting off-label information about unapproved products or uses to United States (U.S.) Medical 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
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	<p>When interacting with these employer representatives, Pfizer Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Modify approved resources in any way• 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
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FAQ: 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 the Individual Employer Representative

	<p>When interacting with individual employer representatives, Pfizer Colleagues MUST:</p> <ul style="list-style-type: none">• 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
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Employer Benefit Managers

Employer benefit managers may want to discuss the coverage offerings and access availability for Pfizer products.

Section 5: Guidelines for Organized Customer-Related Engagements

	<p>As with HCPs at medical groups or hospitals, when interacting with employer benefit managers, Pfizer Colleagues MAY:</p> <ul style="list-style-type: none">• Engage in discussions about coverage and access provided that their statements are truthful, accurate, and not misleading• Use materials approved for that purpose, such as Pfizer-approved access grids
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	<p>When interacting with employer benefit managers, Pfizer Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Direct employers to a specific Pharmacy Benefit Manager (PBM)/Health Maintenance Organization (HMO) or encourage an employer to switch to a different PBM/HMO• Discuss confidential information between Pfizer and a PBM/HMO, including whether 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
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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 Pfizer Colleagues to additional guidelines relevant to interacting with public employees, such as restrictions on gifts or meals or reporting obligations arising from [lobbying laws](#).

Pfizer Colleagues should consult with the Government Relations Director or Legal before interacting with a state or municipal employer.

For more information on interacting with Federal Employees, see Section 6 of *The White Guide* and for more information on interacting with State Employees, see Section 9 of *The White Guide*.

Unions

Certain interactions with unions are subject to federal reporting obligations and possibly other limitations. Pfizer Colleagues must 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.

	<p>Pfizer Colleagues MUST:</p> <ul style="list-style-type: none">• Consult with their DE before interacting with any broker or consultant to ensure that Pfizer presents a consistent message
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Pfizer Colleagues MUST NOT:

- Direct or influence employers to work with a specific broker or consultant

FAQ: Materials Used With Employers



What type of information may Pfizer provide to employer representatives?



Pfizer may only use Review Committee (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 it must include the proven benefits of the product along with relevant safety information.

Treat Employees as Consumers

Employers will often request that Pfizer Colleagues 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.



Pfizer Colleagues MUST:

- Treat employees as consumers and apply the guidance for interactions with consumers that is covered in Section 4 of *The White Guide*
- Ensure that their discussions comply with Food and Drug Administration (FDA) regulations
- Remember that additional considerations and limitations may apply to employees of healthcare providers or payers of healthcare items and services, including hospitals, medical practice groups, or Managed Care Organizations (MCOs) that seek reimbursement from the federal government

Chapter 4: Guidance for Resources, Programs, and Initiatives with Organized Customers (OCs)

Pfizer offers resources, programs, and initiatives that are specific to Organized Customers (OCs) based upon their unique needs.

This chapter will review the following:

- OC and Payer Tools and Resources (OCP Resources)
- Quality Programs
- Health Information Technology (HIT) Initiatives

For more information regarding compliant interactions with OCs, refer to Section 4 of [The Orange Guide](#).

Organized Customer and Payer Tools and Resources (OCP Resources)

Occasionally Pfizer offers certain educational, quality-based programs and resources to OCs. These Review Committee (RC)-approved resources are referred to as Organized Customer and Payer Tools and Resources (OCP Resources).

OCP Resources are designed to educate OCs, benefit patients, improve patient outcomes, and promote wellness, disease prevention, and patient awareness. Many of these resources or programs can be found on the Pfizer intranet site at [PROMOSprime](#).

	<p>The decision to provide an OCP Resource MUST be consistent with the RC approval and implementation guidance regarding:</p> <ul style="list-style-type: none">• Which Pfizer Colleague may use the resource with customers• Who the appropriate customers are• How it can be distributed
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	<p>Pfizer's reason to offer or provide OCP Resources MUST NEVER be to:</p> <ul style="list-style-type: none">• Reward past prescribing or induce future prescribing• Influence an upcoming formulary decision• Offer an implied discount on the price of our products• Offset a customer's operational expenses or relieve a customer of an obligation to a third party, such as a payer's contractual obligation to a governmental entity• Attempt to establish or improve Pfizer's relationship with an OC or Healthcare Professional (HCP)• Gain or improve access for Sales Colleagues• Help a customer satisfy any accreditation or credentialing requirements
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Read below for specific guidance on the appropriate use of OCP Resources.

Appropriate Recipients

OCP Resources are intended to be used with OCs as part of Pfizer's overall mission to support improvement of patient care. Generally, OCP Resources are not intended for use with individual HCPs or prescribers.

Furthermore, OCP Resources should be broadly offered to OCs. Restricting these resources to select customers could be perceived as providing items of value in order to increase prescribing or improve formulary status with those specific customers, potentially implicating the Anti-Kickback Statute or other healthcare laws described in Section 1 of *The White Guide*.

However, colleagues may consider the availability of Pfizer resources and prioritize the OCs for whom the resources will most positively impact patient care.

Types of Organized Customer and Payer Tools and Resources (OCP Resources)

Unbranded Customer OCP Resources support Pfizer's overall mission of improving patient care and are intended to foster effective engagement and highlight potential areas of alignment/mutual interest with OCs.

Unbranded Customer OCP Resources:

- Promote an understanding of healthcare disparities, disease education and prevention, patient diagnosis and monitoring, and adherence to evidence-based guidelines
- Focus on areas such as population health, quality, adherence, value-based models, and total cost of care
- May also be platforms of tools and resources that support the identification, screening, diagnosis, management, or appropriate treatment of specific patient populations aligned to a therapeutic area
- Have a sub-category known as **Skills-Based Learning (SBL) Resources**, which:
 - Support improved health outcomes, patient awareness, and customer awareness
 - Focus on enhancing healthcare delivery acumen
 - May be provided to all healthcare stakeholders, including both Accounts and individual HCPs
 - May require tracking and disclosure under transparency and disclosure laws
- Cannot be used in conjunction with branded materials, unless otherwise approved by RC

Product-Related OCP Resources are branded resources intended to educate OCs on the appropriate use of our products and support the access of appropriate patients to our products. They can also help OCs identify and address barriers that may prevent patients from being prescribed clinically appropriate treatments or accessing the treatment they were prescribed. Product-related OCP Resources are not intended to drive individual prescriber utilization/prescription of our products.

The following requirements apply to both Unbranded and Product-related OCP Resources.

	<p>Account-Facing Colleagues MUST ensure that the OCP Resource:</p> <ul style="list-style-type: none">• Is approved by the relevant brand RC• Has specific approval for use by their role• Clearly discloses Pfizer's participation in their creation and dissemination• Is being used with the appropriate recipient
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Section 5: Guidelines for Organized Customer-Related Engagements

	<ul style="list-style-type: none">– For example, if an OCP Resource is only approved for use with Health System Customers, specific RC approval would be required before the resource could be used with HCPs at an individual medical practice• Although individual prescribers are not typically the target customers for OCP Resources, there may be circumstances where a customer’s organizational structure—such as a medical group that is risk-bearing—may be appropriate for certain OCP Resources after receiving RC approval
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	<p>Account-Facing Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Modify approved resources in any way• Design their own or customize OCP Resources without explicit RC approval to do so• Provide OCP Resources with any contingencies or conditions such as increased prescribing or formulary placement or improvement• Claim, in a direct or implied way, that an OCP Resource can help an OC achieve quality standards or allow an OC to obtain financial incentives or otherwise satisfy a requirement imposed by a third party• Position OCP Resources as a means to offset operational expenses which the OC is obligated to pay on its own
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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 (HCOs), such as:

- Medical groups
- Long term care
- Health maintenance organizations (HMOs)
- [United States \(U.S.\) Department of Veterans Affairs \(VA\)](#)
- [U.S. Department of Defense \(DoD\)](#)
- Pharmacy Benefit Managers (PBMs)

Quality programs:

- Focus on addressing the overall quality of healthcare rather than promoting Pfizer products
- Improve patient care by providing customers with information about factors such as:
 - Quality accreditation standards
 - An HCP’s patient interaction skills
 - Management of medical conditions
- Must receive approval from the relevant RC before it is made available publicly

	<p><i>Under Pfizer standards, quality programs MAY be used to support the following objectives:</i></p> <ul style="list-style-type: none">• 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• Provide scientifically sound information
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	<p><i>Pfizer’s quality programs MUST NOT be offered to:</i></p> <ul style="list-style-type: none">• Establish or improve Pfizer’s relationship with an HCP or institution• Gain or improve access to an HCP or institution• Reward past prescribing or induce future prescribing<ul style="list-style-type: none">– 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• Influence an upcoming formulary decision• Offer an implied discount on the price of Pfizer products
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Guidance for Health Information Technology (HIT) Initiatives and Digital Medical Tools

Health Information Technology (HIT) Initiatives

The use of digital health care, including the use of HIT—particularly Electronic Health Record (EHR) systems—is increasing within U.S. healthcare systems.

Pfizer engages with customers in many ways involving HIT—including providing HIT education, digital technology resources, and associated messaging—with the intent to improve patient care and health outcomes in therapeutic areas in which Pfizer has a public health goal.

These will be referred to as “HIT Initiatives” throughout *The White Guide*. HIT Initiatives can pose legal risks to Pfizer if not designed and implemented in an appropriate manner.

To help mitigate potential risks, HIT Initiatives and use of HIT resources should follow the following general principles.

	<p><i>HIT Initiatives/Resources MUST be:</i></p> <ul style="list-style-type: none">• Implemented only by the specific Pfizer role for which they were approved and consistent with any approved implementation guidance for the resource<ul style="list-style-type: none">– Depending on the content, some HIT resources may require implementation by, or in conjunction with, appropriate Field Medical Colleagues• Focused on HIT education for improvement in patient care/health outcomes in a therapeutic area in which Pfizer has a public health goal• Generally unbranded
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Section 5: Guidelines for Organized Customer-Related Engagements

	<ul style="list-style-type: none">– Above-brand HIT resources may educate customers about improving patient outcomes and promoting quality health care without referring to particular Pfizer products• Developed by or with input from Medical, with support from roles with expertise in health technology and EHR systems, as appropriate• Technically, clinically, and scientifically sound
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	<p>HIT Initiatives/Resources <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Provide independent value beyond clinical or disease state and/or limited HIT/EHR functionality education to improve patient care or outcomes<ul style="list-style-type: none">– Limited education on HIT/EHR functionality is permissible but should not include conducting any programming, coding, or operation of a customer’s EHR system on behalf of the customer, as this provides independent value beyond general HIT education– The HIT Center of Excellence (HIT CoE), defined below, will determine the appropriate level of detail for “educational content relating to HIT/EHR functionality” to remain consistent with “no independent value”• Be offered or conditioned on increased prescribing, improved formulary status, or other benefits to Pfizer• Be examined with a return on investment (ROI) analysis or any other metrics/analyses linking the HIT Initiatives to the sale of a Pfizer product<ul style="list-style-type: none">– Examples of prohibited analytics include metrics tied to prescription rates, conversion rates, or similar performance measures
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Furthermore, payments to third party vendors must be based on fair market value (FMV) and must not be tied to the value of potential referrals. For example, there must be no payment based on conversion rates or “per-alert.”

Health Information Technology (HIT) Engagement by Pfizer Role

Field Commercial Colleagues may engage with customers differently regarding HIT activities, based on their role. HIT Account Directors are the primary Field Commercial Colleagues to implement HIT resources. However, others may be implemented by Account Managers, Account Directors, or Sales Representatives if appropriate, and according to approved implementation guidance.

HIT resources containing both clinical and technical EHR considerations may require joint presentation by the HIT Account Director and relevant Field Medical Colleague with clinical informatics expertise. Some more clinically complex HIT resources with increased data requirements or inclusion of coding, such as patient registries or EHR data extraction resources, would be considered Medical-only tools.

Commercial Account colleagues, including HIT Account Directors, should not participate in the delivery of Medical-only resources or HIT activities unless otherwise outlined in Medical Global Content Management and Approval Program (GCMA)-approved implementation guidance.

Pfizer Colleagues should use only HIT resources approved for their specific role. Refer to the implementation guidance associated with the resource for direction on the appropriate user and audience for the resource.

Please refer to Section 4 of [The Orange Guide](#) for additional guidance regarding HIT engagements for commercial roles.

Section 5: Guidelines for Organized Customer-Related Engagements

Health Information Technology Center of Excellence (HIT CoE)

Pfizer has established an HIT CoE to support colleagues and ensure that HIT Initiatives are designed and implemented in the most appropriate, patient-centric, and compliant manner.

The HIT CoE is a U.S. enterprise-level endorsement body that is required to review all Biopharma and Digital Initiatives or resources that involve digital health information that may impact a clinical decision and are intended for use in the U.S.

Following endorsement by the HIT CoE, HIT Initiatives and/or resources will go to the relevant RC or Medical GCMA review process for final review and approval before use with customers.

Please see the [HIT CoE website](#) for detailed information about the HIT CoE process and a toolkit to guide development of HIT Initiatives/resources.

Digital Medical Tools

Pfizer also may develop Digital Medical Tools for use with customers, such as digital tools, devices, apps, software, and/or algorithms with health or medical functions.

Digital Medical Tools include tools or products intended to be used by HCPs, HCOs, patients, and/or caregivers in the diagnosis, screening, prevention, prediction, prognosis, monitoring, treatment, or alleviation of disease, injury, impairment, health condition, or disability.

If the tool involves artificial intelligence (AI), algorithms or data analysis methods or techniques that perform tasks traditionally performed by humans, then [Corporate Policy 413, Artificial Intelligence Risk Management](#) applies.

Purely educational tools are out of scope and are subject to the [Pfizer U.S. Digital Companion Guidance](#) or the [Digital Review Team \(DRT\) review](#).

	<p>Digital Medical Tools MUST:</p> <ul style="list-style-type: none">• Have a valid medical purpose, determined by Medical/Clinical colleagues<ul style="list-style-type: none">– Examples of a valid medical purpose include improving patient outcomes, appropriately improving patient adherence to treatment plan, diagnosing under-diagnosed populations• Be evaluated for FMV to ensure compliance with applicable laws and requirements prior to being provided to a patient, HCP, HCO, or any customer
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	<p>Digital Medical Tools MUST NOT:</p> <ul style="list-style-type: none">– Be examined with an ROI analysis or any other metrics/analyses linking the Digital Medical Tool to the sale of another Pfizer product unless products are Food and Drug Administration (FDA) approved to be used together– Examples of prohibited analytics include metrics tied to prescription rates, conversion rates, or similar performance measures
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Section 5: Guidelines for Organized Customer-Related Engagements

Procedural Requirements for Digital Medical Tools: Medical Algorithms/AI Review Committee (MAARC) and Software as a Medical Device (SaMD) Processes

	<p>All Digital Medical Tools must:</p> <ul style="list-style-type: none">• Be submitted to the Medical Algorithm & AI Review Committee (MAARC) website prior to development to ensure necessary Subject Matter Expert (SME) involvement<ul style="list-style-type: none">– This is only necessary if the tool is intended to be deployed in the U.S.– The MAARC's role is to assess and guide colleagues on how to mitigate legal and regulatory risks as well as to create a project plan that will achieve the goals of the project and efficiently move Digital Medical Tools through to development• Undergo a Software as a Medical Device (SaMD) assessment<ul style="list-style-type: none">– Many Digital Medical Tools are regulated as a SaMD, and whether a Digital Medical Tool is a SaMD depends on various factors including the uses and functionality of the tool– For more information, see the SaMD Resource Center or Medical Software Triage Tool• Have implementation guidance available and developed by the relevant RCs prior to deployment
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Chapter 5: Additional Resources for More Information

Privacy

- For more information about the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the appropriate use of patient information, and Pfizer's policies for protecting patient privacy, see Section 1 of *The White Guide*

State Laws

- For information on relevant state law restrictions, see Section 9 of *The White Guide*

Organized Customer (OC)-Related Engagements

- For more information regarding Organized Customer (OC)-related engagements, see Section 4 of [The Orange Guide](#)

Non-Discount Arrangements with Specialty Pharmacies (SPs) and other Accounts

- General questions regarding specialty pharmacies (SPs) should be referred to your manager and/or a member of the Pricing and Access (P&A) Legal Team

Promotional Interactions with Employer Groups

- General questions regarding interactions with employer groups should be referred to your manager and/or a member of the Director, Employers (DE) Team or the P&A Legal Team

Organized Customer and Payer Tools and Resources (OCP Resources)

- General questions should be referred to your manager, appropriate Marketing Teams, and/or the P&A Legal Team
- Consult PROMOSprime for information and guidance on use for individual resources
- For more information on our disclosure obligations under the [Sunshine Act](#), see Section 1 of *The White Guide*

Health Information Technology (HIT)

- For more information about Health Information Technology (HIT), see the [HIT Center of Excellence \(CoE\) website](#)



The White Guide

Section 6

Guidelines Related to Participation in Government Healthcare Programs and Interactions with Federal Employees

Section 6

Guidelines Related to Participation in Government Healthcare Programs and Interactions with Federal Employees

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[Click here to visit the Glossary and Acronyms.](#)

Chapter 1: Introduction

Interactions with federal and state employees are now more commonplace as Pfizer's sales to the government have become more significant and certain colleagues have become more involved in efforts with legislators.

In order to ensure compliant interactions and activities in this evolving landscape, this section summarizes:

- Key Pfizer policies regarding government healthcare programs
- The important rules Pfizer Colleagues must understand and follow when engaging in promotional and non-promotional activities with United States (U.S.) federal government agencies and their employees, including the Department of Veterans Affairs (VA), the Department of Defense (DoD), and the U.S. Department of Health and Human Services (HHS)
- Certain key Pfizer policies regarding lobbying registration and disclosure

This section is relevant to all Pfizer Colleagues, and particularly those who:

- Interact with federal government employees, including Healthcare Professionals (HCPs) and formulary decision-makers
- Engage in lobbying activities with any elected or appointed state or federal government official (GO) or public employee, including state Medicaid agency employees and public hospital and government HCPs

It is important to understand that working with federal and state employees can present unique risks if not handled by Pfizer Colleagues in an appropriate manner. Therefore, specific guidance to ensure compliant interactions and activities is covered in this section.

Chapter 2: Participation in Government Healthcare Programs

Pfizer participates in several government healthcare programs including Medicaid and Medicare. As a result, Pfizer is subject to a number of regulations including the [Anti-Kickback Statute \(AKS\)](#); Food, Drug, and Cosmetic Act (FDCA); and the False Claims Act (FCA). Furthermore, Pfizer is subject to government pricing requirements including Average Manufacturer Price (AMP), Best Price, 340B, and so forth. For more details on these laws and programs, see Section 1 of *The White Guide*.

To comply with the requirements surrounding Pfizer's participation in government programs, including price reporting obligations, Pfizer has a rigorous contracting and reporting process. Colleagues must submit all contracts for review by Pricing & Access Legal prior to executing an arrangement with the government.

Medicare Part D Regulations

Medicare coverage includes outpatient prescription medicines purchased by eligible senior citizens through a pharmacy. The Medicare program provides an outpatient drug benefit to Medicare beneficiaries through [Medicare Part D](#). There are two ways to get Medicare prescription drug coverage. A "Medicare Advantage Prescription Drug" (MA-PD) plan provides both medical coverage for hospital and physician charges as well as drug coverage. Alternatively, a stand-alone "Prescription Drug Plan" (PDP) provides drug coverage only, but beneficiaries who enroll in a PDP 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.

Medicare Part D Risk Areas

Swapping

The government has expressed concern that Managed Care Customers may use access to Medicare Part D enrollees as leverage in negotiations with pharmaceutical companies to obtain preferential terms under their commercial agreements. This practice is known as "swapping," and it may lead to higher costs under Part D in exchange for more favorable terms for the Managed Care Customer's commercial agreement.

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

Section 6: Guidelines Related to Participation in Government Healthcare Programs and Interactions with Federal Employees

- 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 not have been afforded 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 was 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

Contract Negotiations

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 AKS—thus, Pfizer should ensure that all arrangements are properly structured.

FAQ: Contract Negotiations	
	May discussions regarding a commercial contract and a Part D contract occur in the same meeting with a Managed Care Customer?
	<p>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. In other words, the discussion regarding commercial agreements must be clearly separate and apart from the discussion of Part D arrangements.</p> <p>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.</p>

Section 6: Guidelines Related to Participation in Government Healthcare Programs and Interactions with Federal Employees

Pharmacy and Therapeutics (P&T) Committee Members

Many healthcare organizations and [Pharmacy Benefit Managers \(PBMs\)](#), including Managed Care Customers administering Part D drug plans, maintain lists of preferred drugs—commonly referred to as formularies—that healthcare professionals (HCPs) 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.

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. Consistent with the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Health Care 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 Sections 3 and 4 of [The Orange Guide](#) and [The Green Guide: Governance for External Medical Activities](#), addressing field activities.

Medication Therapy Management Programs (MTMPs)

The Medicare Prescription Drug, Improvement, and Modernization Act (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 those who are:

- Part D enrollees with multiple chronic diseases
- Taking multiple Part D drugs
- Likely to incur annual costs for Part D drugs that exceed a pre-established threshold

Pfizer customers often seek help in developing a MTMP. 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 AKS. 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.



Section 6: Guidelines Related to Participation in Government Healthcare Programs and Interactions with Federal Employees

FAQ: 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 Drug Rebate Program

For its outpatient drugs to be covered by the Medicaid program, a manufacturer must enter into a national rebate agreement with the Secretary of the [U.S. Department of Health and Human Services \(HHS\)](#). This agreement generally requires manufacturers to offer Medicaid agencies mandated discounts for covered prescription drugs. Pfizer maintains a rebate agreement for all appropriate labeler codes.

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.

The two primary price points under the Medicaid Drug Rebate Program are AMP and Best Price. Both terms are in statute and regulation.

Generally, if Pfizer provides any value to its customers in the sale of its products, such value must be considered for inclusion in or exclusion from Pfizer's reported price points. For example, when submitting government price reports to the government, Pfizer must take into consideration all cash discounts, free goods contingent upon a purchase requirement, volume discounts, and rebates other than rebates under the Medicaid Drug Rebate Program itself. In addition, free or reduced-price services, grants, other price concessions, or other benefits offered to induce a sale may also be considered pricing terms.

The Centers for Medicare and Medicaid Services (CMS) uses AMP and Best Price data to calculate the **Rebate Per Unit (RPU)**, also known as the **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.

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

Section 6: Guidelines Related to Participation in Government Healthcare Programs and Interactions with Federal Employees

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 information. Such information includes a product's classification as an innovator or non-innovator product, which directs the level of rebate required under the Medicaid Drug Rebate Program.

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 or misrepresent information to avoid paying higher Medicaid rebates. Reporting false or inaccurate information to the government could lead to significant liability under the federal False Claims Act (FCA) and the Medicaid Drug Rebate Agreement. Significantly, liability under any of these statutes could subject Pfizer to exclusion from federal healthcare programs.

Chapter 3: Interactions with Federal Employees

As Pfizer's sales to the federal government continue to increase, interactions with government officials (GOs) such as the Director of Medicaid, and government employees such as a physician at a federal institution or a federal prison, are becoming more commonplace.

There are important rules colleagues must understand and follow when engaging in promotional and non-promotional activities with United States (U.S.) federal government agencies.

Pfizer's customers include federal government agencies and institutions, including the

- [Department of Veterans Affairs \(VA\)](#) and its hospitals
- [Department of Defense \(DoD\)](#) and its medical facilities
 - [Defense Health Agency \(DHA\)](#)
- [U.S. Department of Health and Human Services \(HHS\)](#), including, but not limited to:
 - [Centers for Disease Control and Prevention \(CDC\)](#)
 - [Indian Health Service \(IHS\)](#)

Interactions with **federal employees** are governed by:

- Standards of Ethical Conduct established by the Office of Government Ethics (OGE)
- Other government-wide OGE regulations
- Agency-specific regulations and policies
- 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"

Pfizer Colleagues may interact with Healthcare Professionals (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.

Promotional Activities

There are important rules colleagues must understand and follow when engaging in promotional and non-promotional activities with U.S. federal government agencies and their employees.

Gifts to Federal Employees

In addition to the Pharmaceutical Research and Manufacturers of America (PhRMA) Code's guidelines on gifts to HCPs, the federal government places restrictions on the acceptance of gifts by its employees, including those who are HCPs.

Section 6: Guidelines Related to Participation in Government Healthcare Programs and Interactions with Federal Employees



As a general rule, **a federal government employee MAY NOT:**

- Accept any single gift—including anything of value such as meals, travel, lodging, entertainment—that has a retail or market value of more than \$20
- Accept gifts with an aggregate value of more than \$50 annually from a single source, such as a single company, like Pfizer

To help ensure that Pfizer maintains compliance with the federal rules, the only gifts that colleagues may provide to federal government employees including those who are HCPs are Pfizer-approved educational items and modest refreshments, excluding alcoholic beverages, under the circumstances outlined in this Section.

In addition:

- Any gifts, including meals and refreshments, provided to federal government employees will be subject to Pfizer's [Global HCP/HCO Transparency Reporting SOP](#)
- All HCPs, including those employed by the VA and DoD, may opt out of receiving these items by notifying a Pfizer Colleague or by contacting PTI@Pfizer.com

Educational Items

Notwithstanding the general gift restrictions mentioned above, federal government employees may accept unsolicited educational items with a value of \$100 or less from a single source in a calendar year.



To qualify as an educational item, **the materials MUST:**

- Be educational or instructive in nature
- Contain information that relates in whole or in part to the following categories:
 - The employee's official duties or position, profession, or field of study
 - A general subject matter area, industry, or economic sector affected by or involved in the programs or operations of the agency
- Another topic of interest to the agency or its mission



The materials MUST NOT:

- Have been primarily created for entertainment, display, or decoration

A federal government employee may only exceed the \$100 limit with prior written authorization from their Designated Agency Ethics Official (DAEO). Before providing educational items to a federal government employee, colleagues must contact their Product Attorney for prior approval.

Section 6: Guidelines Related to Participation in Government Healthcare Programs and Interactions with Federal Employees

FAQ: Leaving Educational Items with federal government employees	
	If I leave educational items that are Review Committee (RC)-approved, nominally priced, and compliant with the PhRMA Code with an HCP at a federal prison, do I have to track it? What about a state prison system?
	Yes. Under Pfizer's Global HCP/HCO Transparency Reporting SOP , all educational 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 Product Attorney before leaving any item with an HCP at a state prison.

Meals and Refreshments

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.

Meals at VA facilities are prohibited. This includes meals to volunteers or non-VA staff while on-site at a VA facility, such as a hospital, office, or other agency offices. Other federal government agencies, including DoD and IHS, have their own rules concerning interactions on-site at their facilities and these should be followed.

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

- Colleagues must obtain confirmation from the federal employee that they are permitted to accept the in-office or in-hospital meal under all applicable laws and rules, including any local site rules
- Colleagues 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
- The meal must take place at the HCP's office or hospital when hosted by a Pfizer Colleague

Modest refreshments, such as coffee and donuts, can be offered to federal government employees in some cases 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." Offering even modest refreshments on a regular, repeated, or routine basis is not allowed, and alcohol is always prohibited.

FAQ: Compliance Responsibility	
	If an HCP at a VA facility asks me to provide them with something that would be considered a gift, isn't it the HCP's responsibility to make sure that they are in compliance with applicable gift rules? How can Pfizer get in trouble?
	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. Finally, providing

Section 6: Guidelines Related to Participation in Government Healthcare Programs and Interactions with Federal Employees

	<p>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 Section, 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 they were a government employee and follow the applicable rules herein and at the HCP's local facility.</p>
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Additional Promotional Activities with Federal Employees

Please refer to Section 7 of [The Orange Guide](#) for more information regarding:

- Impact of Formulary Status on Ability to Promote
- Site Visits, Promotional Materials, and Educational Materials
- Starters
- Inviting Government Employees to Speak or Present at Events
- Inviting Government Employees to Attend Events

Supporting Independent Medical Education (IME)

Federal government agencies and institutions often ask Pfizer to support their Independent Medical Education (IME) 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 IME.

For more information on Pfizer's educational grant process, refer to the [Independent Medical Grants Standard Operating Procedure \(SOP\) \(SOP GNT01\)](#).

Chapter 4: Government Official (GO) Consulting Engagements

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. This chapter reviews the guidance around retaining government employees as speakers or consultants. For information around HCP Consulting Engagements more broadly, please see Section 2 of *The White Guide*.

Retaining Federal 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 their 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 Federal Government Employees Outside of Their Official Duties

At times, Pfizer may retain a federal employee to perform services in their individual capacity outside of their official duties.

Services that may not relate to an employee's official duties should conform to the following parameters:

	<p>Employee is:</p> <ul style="list-style-type: none">• Advising on matters about which they are a subject matter expert and is not being engaged because of their official position but rather based on that expertise• Taking personal time to participate rather than participating during employer/government time (in which case they must be acting in an official capacity)
	<p>Employee is NOT:</p> <ul style="list-style-type: none">• Advising in relation to a matter pending before their government agency• 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 the federal employee can accept a fee from Pfizer.

If Pfizer engages a federal employee outside of their official duties, the federal employee may not use their official title or position to identify themselves in connection with the services, including teaching, speaking, or writing on behalf of

Section 6: Guidelines Related to Participation in Government Healthcare Programs and Interactions with Federal Employees

Pfizer or in conjunction with Pfizer Colleagues. An employee's title or position may, however, be included as part of their 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 U.S.

United States (U.S.) State and Federal Government Officials (GOs)

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 HCP 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.

FAQ: 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 they have 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.

FAQ: Using a Federal Employee as a Speaker	
	Can an employee of the Department of Veterans Affairs (VA) employee be a speaker for Pfizer?
	<p>Yes, with appropriate approvals from the VA entity that employs the individual and if Pfizer complies with the entity's requirements pertaining to its employees.</p> <p>Every consultant agreement with a government employee must include the representation that they have 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>

Non-United States (U.S.) Healthcare Professionals (HCPs) and Government Officials (GOs)

The **Foreign Corrupt Practices Act (FCPA)** is a U.S. law that prohibits corrupt or improper payments to non-U.S. government Officials (GOs). The FCPA prohibits 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 U.S., 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 GOs under the FCPA.

If Pfizer Colleagues 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—they must follow all applicable Pfizer procedures as outlined in the [U.S. Regional My Anti-Corruption Policy and Procedures \(MAPP\) Standard Operating Procedure \(SOP\)](#).

Pfizer Colleagues must also note that in addition to the FCPA, other anti-bribery or anti-corruption laws govern interactions with both U.S. and non-U.S. GOs, including the United Kingdom (UK) Bribery Act. It is critical that colleagues fully comply with all applicable Pfizer policies and procedures on interactions with GOs. Colleagues must consult the [Country Annex](#) for the HCP’s country of employment for local law and restrictions.

Colleagues must also comply with [Corporate Policy 206, Compliance with Global Trade Control Laws](#) when engaging Non-U.S. HCPs and GOs in consulting or other engagements, including confirming that the consultant is not a Restricted Party or in a Restricted Market. Colleagues must follow the Screening Requirements in Section 2 of *The White Guide* when engaging Non-U.S. HCPs and GOs.

Chapter 5: Federal and State Lobbying Engagements

In addition to the laws related to interactions with federal employees, the government also has laws that regulate lobbying activity, which are summarized in this chapter.

Please note that, before interacting with any federal or state government official (GO) or public employee, colleagues should seek guidance from a Government Relations Director (GRD); the Pfizer Washington, D.C. office; or their Product Attorney.

Lobbying

Federal and state lobbying laws regulate oral as well as written interactions with GOs 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](#) activity and related expenditures on a regular basis.

Federal Lobbying Law

The Federal Lobbying Disclosure Act (LDA), as amended by the Honest Leadership and Open Government Act (HLOGA), requires Pfizer to file quarterly reports that detail all its federal lobbying activities as well as any expenses incurred in carrying out its 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 any Pfizer Colleague who supports Pfizer's federal lobbying efforts during the reporting period.

Like the rules that govern interactions with Healthcare Professionals (HCPs), rules around lobbying, ethics, and gifts regulate specific interactions with federal GOs and employees.

In addition to becoming familiar with the information in this chapter, colleagues should check with their GRD or Product Attorney about the relevant laws in their region, since the specific state or local laws applicable may vary depending upon the state in which the colleague works.

Federal law defines lobbying activities as [lobbying contacts](#) with covered federal officials and any efforts in support of these contacts, including preparation and planning activities, research, and other background work intended for use in lobbying contacts.

Examples of supporting activities that would need to be reported include:

- Developing talking points or white papers if they are used for lobbying purposes
- Attending internal meetings or discussions regarding lobbying strategies
- Paying fees to outside consultants for analyses, studies, or reports if they are used for lobbying
- Providing educational information or materials to influence government formulary decisions

Reportable expenses include time spent by Pfizer Colleagues in meetings with covered federal officials for the purpose of influencing federal laws, regulations, or policies; time spent on any work done in support of a meeting with a covered federal official regardless of whether the colleague attends; and any expenses incurred in connection with any lobbying contact or supporting activity, such as travel, lodging, and meals.

Section 6: Guidelines Related to Participation in Government Healthcare Programs and Interactions with Federal Employees

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 proceedings
- Preparing for and providing on-the-record testimony in a congressional or agency hearing
- Communicating with GOs from one's home state as part of Pfizer's Grassroots advocacy program
 - Pfizer's Grassroots advocacy program works to inform and educate colleagues on public policy issues that impact Pfizer's ability to develop and deliver treatments to patients, and it provides colleagues the opportunity to engage with elected officials from their home state about those policies
- Requesting a meeting with a congressional or government agency official or their staff, if the request does not include an attempt to influence the official or staff
- Responding to a request from a congressional or government agency official for reports, information, statistics, subpoenas, or similar documents

Federal Lobbying Do's and Don'ts	
Do	Don't
Provide only Review Committee (RC)-approved educational materials or materials that have been approved by Legal to GOs	Discuss Pfizer products or specific Pfizer activities
Coordinate any lobbying activities with GOs through the Pfizer Washington, D.C. office or your state's 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 the Pfizer Washington, D.C. office; GRD; or a Product Attorney

Reporting Federal Lobbying Time and Expense

If a colleague has been engaged in federal lobbying activities, they must track and report the following on the form available at the [Lobbying Disclosure Reporting site](#).

- 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
- Any expenses associated with these efforts

Colleagues should fill out the form only when they have engaged in federal lobbying activity. They should not fill it out when they have engaged in state lobbying activity. See the subsection on state-specific laws below for more information on state lobbying activity.

The information from the online form is collected for the Company's quarterly federal LDA reports which are filed on April 20th (covering 1/1 through 3/31), July 20th (covering 4/1 through 6/30), October 20th (covering 7/1 through 9/30), and January 20th (covering 10/1 through 12/31) each year with both the United States (U.S.) House of Representatives and the U.S. Senate. If a colleague has engaged in federal lobbying activity during a reporting period, they should make sure to 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.

If ever in doubt, colleagues should consult with a GRD; the Pfizer Washington, D.C. office; or their Product Attorney to verify whether their activities subject them to registration or reporting requirements.



Section 6: Guidelines Related to Participation in Government Healthcare Programs and Interactions with Federal Employees

State-Specific Lobbying Disclosure Laws

There are two types of lobbying disclosure laws enacted by states that may require colleagues to record and report certain information. The first category requires Pfizer to report its state lobbying activities on a regular basis much like the federal lobbying law described above. 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.

If a colleague has questions regarding whether their participation in state lobbying activities triggers disclosure requirements, they should consult with the GRD responsible for the state. If the GRD determines that the colleague is required to disclose their activities, they will receive a compliance form or timesheet to complete.

States' Lobbying Laws Impacting Sales Colleagues

Certain 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, some state laws define attempts to influence state formulary decisions as lobbying.

For example, in Louisiana, pharmaceutical representatives who engage with members of the Pharmacy and Therapeutics (P&T) Committee in an effort to get the Committee to include a product on the state's formulary must register with the Board of Ethics and file semi-annual reports detailing their expenditures as they relate to these activities. In Miami-Dade County, registration and ethics training is required for pharmaceutical representatives who engage with employees of Jackson Memorial Hospital or the Public Health Trust to encourage the purchase of products or seek approval for clinical trials of new products and services.

State procurement or contract lobbying laws may also apply to colleagues if they 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 as well as disclosing lobbyist compensation and lobbying expenses incurred, such as meals (food and beverage), travel, and lodging. To ensure appropriate tracking and disclosure, colleagues should check with a GRD or their Product Attorney before engaging in these or related activities.

State Restrictions on Gifts to Legislators

Many states place restrictions on gifts to legislators. These range from a general prohibition to specific dollar limits. Colleagues can find additional information on these restrictions at the [National Conference of State Legislatures website](#).

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.



Chapter 6: Additional Resources for More Information

Healthcare Professional (HCP) and Government Official (GO) Consulting Engagements:

- For information regarding Healthcare Professional (HCP) and Government Official (GO) Consulting Engagements, please see
 - [Global Policy Xchange on Biopharma Ops on Demand](#)
 - [HCP Engagements Standard Operating Procedure \(SOP\)](#)
 - [HCP Consulting: United States \(U.S.\) Fair Market Value SOP](#)
 - [Corporate Policy 206, Compliance with Global Trade Control \(GTC\) Laws](#)
 - [U.S. Consultant—Speaker Business Travel and Expense Standard Operating Procedure \(SOP\)](#)
 - [Corporate Policy 207, Global Policy on Interactions with Healthcare Professionals \(GPIHP\)](#)
 - [Corporate Policy 301, Travel, Entertainment and Other Business-Related Expenses](#)
 - [Corporate Policy 304, Global Meetings and Congresses Policy and Procedure](#)
 - [My Anti-Corruption Policy and Procedures \(MAPP\)](#)
 - Section 3 of [The Orange Guide](#)
 - [HCP/GO Engagements & Interactions \(R&D SOP 201\)](#)
 - [Global Advisory Board Guidelines](#)
- E-mail Contacts:
 - Refer Foreign Corrupt Practices Act (FCPA) questions to FCPAQuestions@pfizer.com
 - Refer GTC, Restricted Party Screening (RPS), and Restricted Market questions to gtc@pfizer.com

Field Medical Colleague Roles

- For more information on Field Medical Colleague responsibilities, please see [The Green Guide: Governance for Medical Activities](#)

Interactions with Members of the Pharmacy and Therapeutics (P&T) Committee

- For questions regarding interactions with member of the Pharmacy and Therapeutics (P&T) Committee, please see:
 - Section 3 and Section 4 of [The Orange Guide](#)
 - [The Green Guide: Governance for External Medical Activities](#)
- Refer any additional questions related to P&T interactions to your manager, Legal, or Compliance
- For medical inquiries, contact Pfizer Medical Information at **800-438-1985**

Federal Employee Interactions and Lobbying

- Lobbying questions may be referred to the relevant Government Relations Director (GRD), the Pfizer Washington, D.C. office, or Compliance
- Federal Employee Interaction questions may be referred to your lead National Account Manager or Compliance
- Take the online training module on how to complete the federal Lobbying Disclosure form



The White Guide

Section 7

Guidelines for Funding and Other Support of External Organizations

Section 7

Guidelines for Funding and Other Support of External Organizations

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[Click here to visit the Glossary and Acronyms.](#)

Chapter 1: Introduction

Pfizer is often asked to provide funding or other support to external organizations, including both not-for-profit and for-profit entities.

As a demonstration of our commitment towards programs and initiatives that have broad public benefit, advance medical care, and improve patient outcomes, Pfizer, when permitted:

- Provides external funding through sponsorships and charitable contributions
- Supports joint collaborations with external organizations to advance shared objectives
- Sponsors awards, scholarships, fellowships, and similar funding in support or recognition of the education and professional accomplishments of Healthcare Professionals (HCPs) and students

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.

Therefore, 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
- External organizations' independence is preserved

All promotional materials, and certain other materials provided by colleagues through collaborations with external organizations, must be reviewed and approved by the applicable Review Committee (RC). Pfizer also must comply with certain reporting and disclosure requirements of Open Payments and State Laws, including the reporting of any payments or transfers of value that are made directly or indirectly to a Covered Recipient.

This section summarizes key Pfizer policies regarding specific types of funding and support of external organizations, mainly found in the [Funding Requests For Not-for-Profit Organizations Standard Operating Procedure \(SOP\) \(External Funding SOP\)](#). General information related to funding and support is reviewed below, while each chapter provides more details for each type of support opportunity.

In particular, this section does not comprehensively address the activities that may be funded by Commercial Leadership and the Medical Lead for each Business. Those activities are also addressed in the *External Funding SOP*.

Funding to external organizations by U.S.-based colleagues in Worldwide Research, Development and Medical (WRDM), excluding Worldwide Medical & Safety (WMS), and Global Product Development (GPD) (collectively, "Research and Development (R&D) colleagues") must follow the [R&D Charitable and NonProfit Funding Requests \(R&D SOP 202\)](#).

For detailed guidelines on supporting Independent Medical Education (IME) activities or research activities such as Investigator-Sponsored Research (ISR), colleagues should consult the [Independent Medical Grants SOP \(SOP GNT01\)](#). Research Collaborations are not covered in this selection.

Not-for-Profit and For-profit Organizations Defined

A **not-for-profit** or nonprofit organization is an organization that does not distribute its profits to its owners and is typically organized for educational, charitable, or scientific purposes.

Section 7: Guidelines for Funding and Other Support of External Organizations

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:

- Certain charities and patient advocacy groups designated by a 501(c)(3) status
- Professional medical associations or chambers of commerce designated by a 501(c)(6) status
- Cultural and civic organizations designated by a 501(c)(4) status

A **for-profit** entity, on the other hand, is an entity whose primary goal is to earn income.

It is important to note that requests for funding from for-profit entities are not covered by the [External Funding SOP](#) but are evaluated under similar standards.

General Requirements for Financial Support of External Organizations

The following provide general requirements for financial support of external organizations. It is critically important that Pfizer Colleagues do not make any sort of commitment until the funding request is fully approved.

	<p>Pfizer Colleagues MUST:</p> <ul style="list-style-type: none">• Understand the types of activities their role and group are permitted to fund as outlined in this section• Follow the policy and procedures described in the External Funding SOP<ul style="list-style-type: none">– Additional resources that can help colleagues determine whether a proposed funding activity is permissible to support are available at Policy Xchange<ul style="list-style-type: none">▪ 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 also direct any questions about the process to the U.S. External Funding Team at USFundingRequest@Pfizer.com
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	<p>Pfizer Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Make a verbal or written commitment until the funding request is fully approved• Offer or provide funding as a quid pro quo to inappropriately influence the formulary positioning, recommendation, or increased prescribing of a Pfizer product or to gain improper favor with an HCP, government official, or any other individual or organization• Provide individual HCPs or group practices with grant funding or donations unless approved in advance by Legal• Link charitable funding to a commercial transaction or interaction• Provide funding to an organization in a manner that undermines the organization's independence or mission, or for capital support or start-up costs• 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
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Chapter 2: Financial Support of Sponsorships

Organizations often offer Pfizer the opportunity to provide funding for sponsorships. When this occurs, colleagues must follow the review, approval, and documentation requirements applicable to their division. The requirements for Pfizer Colleagues are described below.

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 Pfizer Colleagues in accordance with the processes and requirements described in the *External Funding Standard Operating Procedure (SOP)*.

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. A tangible benefit must provide the opportunity to truly advertise or advance Pfizer business interests, such as educating customers and/or prescribers about the specific attributes of our products and services.

Fair recognition, defined as the receipt of general recognition or incidental goods or services that do not directly promote Pfizer business goals, does not constitute a tangible benefit.

Please see the table below for specific examples of fair recognition and tangible benefit.

Fair Recognition vs. Tangible Benefit		
Examples	Tangible Benefit As long as it meets all relevant Review Committee (RC) approval requirements	Fair Recognition NOT considered a tangible benefit
Promotional placement of product logos on a podium or in literature aimed at Healthcare Professionals (HCPs) or patients	x	
Placement of a Pfizer corporate logo by itself on a podium, in literature, on social media, or on a purchased table at an event		x
Opportunity to promote Pfizer products, such as via branded materials or a booth at an exhibition	x	
Tickets to an event		x
Opportunity to educate on Pfizer’s programs or services, such as Pfizer RxPathways®	x	
Ability of Pfizer Colleagues to welcome attendees		x
Honorable mentions and announcements of thanks, written or verbal		x
Providing or selecting a speaker, including for a policy topic	x	
Opportunity to promote Pfizer unbranded programs, such as the importance of vaccination, which may have related branded or unbranded materials	x	

Section 7: Guidelines for Funding and Other Support of External Organizations

Fair Recognition vs. Tangible Benefit		
Examples	Tangible Benefit As long as it meets all relevant Review Committee (RC) approval requirements	Fair Recognition NOT considered a tangible benefit
Playing a video that is on Pfizer's public website		x
Opportunity to promote specific businesses, portfolios, or franchises within Pfizer provided that such promotion involves relevant activities, such as the ability to distribute related materials or information	x	
Opportunity for a Pfizer Colleague to speak at a meeting regarding Pfizer products or unbranded programs	x	
Recognition in conference brochure/program, such as listing as Gold Sponsor		x
Opportunity for Pfizer to provide input for the agenda to a meeting or participate in a workshop in a pipeline disease state	x	
Distribution of branded materials or dissemination of information on specific products	x	

In cases when a not-for-profit sponsorship opportunity satisfies the key characteristics of an appropriate sponsorship:

	<p>Pfizer Colleagues MAY:</p> <ul style="list-style-type: none"> • Submit a funding request using the appropriate form in Ariba <ul style="list-style-type: none"> – Before submitting any requests using the form, colleagues must complete the Funding Request training module in order to gain access to the form in Ariba <ul style="list-style-type: none"> ▪ E-mail the U.S. External Funding Team at USFundingRequest@pfizer.com for further information – If colleagues receive requests from a for-profit organization, they should submit the funding request using the appropriate form in Ariba with a note clearly indicating the organization is for-profit for the reviewer's attention • All funding requests are subject to review and approval by the designated reviewers aligned to each Business/Division/Function, unless otherwise noted
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	<p>Pfizer Colleagues MUST NOT:</p> <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> – A funding request characterized as a sponsorship that does not include a tangible benefit in return for funding will be treated as a charitable contribution – To help determine whether a funding opportunity is a sponsorship or a charitable contribution, refer to the table in Chapter 3 below or contact Legal • Make a verbal or written commitment until the funding request is fully approved
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FAQ: Evaluating the Substantive Nature of Funding Request	
	<p>Can a colleague in a Business, Worldwide Medical & Safety (WMS), Chief Business Innovation Office (CBIO), or Corporate Affairs fund a sponsorship as long as the tangible benefit criteria is met?</p>
	<p>Not necessarily. When evaluating a sponsorship, colleagues must assess it holistically, beyond the tangible benefit, to determine if they are permitted to fund the activity or event.</p> <p>For example, an organization may offer exhibit space in return for providing support for a medical education conference. While the exhibit space is considered a tangible benefit, only Global Medical Grants (GMG) is permitted to support the medical education conference through an Independent Medical Education (IME) grant. Therefore, in order to fund a sponsorship for the exhibit space ONLY, the funding request must clearly outline that support is being provided for the exhibit space and not for the medical education conference.</p>

Chapter 3: Financial Support of Charitable Contributions

Organizations may also offer Pfizer the opportunity to provide funding for charitable contributions.

Generally, [charitable contributions](#) are expenditures that are intended to fund a qualified 501(c)(3) organization in the U.S. for its broad charitable purpose or mission. These charitable contributions may also fund non-U.S.-based not-for-profit entities equivalently recognized by the respective country's local government.

Any funding opportunity that does not include a direct tangible benefit to Pfizer will be treated as a charitable contribution. 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.

The *External Funding Standard Operating Procedure (SOP)* further distinguishes between four categories of charitable contribution:

- Non-Healthcare
- Healthcare (Non-Policy Focused)
- Policy-Focused Healthcare
- Special Events

Generally, charitable contributions are not permitted to be funded by Commercial Colleagues. If approached with an opportunity to fund a charitable contribution, Commercial Colleagues should immediately escalate the request to management who can triage the request to the appropriate colleague who will follow the *External Funding SOP* approval process.

Furthermore, please note that due to limited funding, not all charitable contribution requests will be approved. Therefore, never make a verbal or written commitment that funding will be forthcoming.

Please consult the [External Funding SOP](#) for full definitions and additional details. 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. Research and Development (R&D) Colleagues should refer to [R&D Charitable and NonProfit Funding Requests \(R&D SOP 202\)](#).

FAQ: Funding Request from For-Profit Organizations	
	Does the External Funding SOP apply to funding requests from for-profit organizations?
	No. These requests are evaluated under similar standards but are not covered by the External Funding SOP. 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. Please consult Legal for additional guidance.

Key Characteristics: Sponsorships vs. Charitable Contributions

The following table lists key characteristics that can be used to help determine whether a funding opportunity can be classified as a sponsorship or charitable contribution.

Sponsorship vs. Charitable Contribution		
Characteristic	Sponsorship	Charitable Contribution
Is this activity promotional in nature?	Yes	No
Will payment be made to an individual Healthcare Professional (HCP) or private practice group?	No	No
Will Pfizer receive a tangible benefit?	Yes	No
Can tickets or invitations received as a result of this support be offered to HCPs?	No	No
Is there an agreement documenting terms and conditions of Pfizer funding?	Yes	Yes

FAQ: Information on Pfizer’s External Funding Standard Operating Procedure (SOP)

	Where can Pfizer Colleagues in the Businesses, Worldwide Medical & Safety (WMS), CBIO, and Corporate Affairs get help and information on Pfizer’s policy regarding funding to not-for-profit organizations?
	Resources are available at Policy Xchange 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 . Once the appropriate category is determined, funding requests must be initiated in Ariba. Users should go to the Create menu and select “Funding Request Project.”

FAQ: Appropriate Pfizer Foundation Referrals	
	Can a customer's request for a charitable contribution be forwarded to the Pfizer Foundation for consideration?
	No. The Pfizer Foundation is an independent, tax-exempt organization established by Pfizer Inc. and does not accept unsolicited funding requests. The Pfizer Foundation provides funding through targeted initiatives focused primarily on healthcare and science education, such as the Pfizer Foundation Matching Gifts Program or the Pfizer Foundation Healthy Families, Healthy Futures program.

FAQ: Funding Virtual Activities	
	Can virtual activities be funded?
	<p>The tangible benefit requirements remain in effect when supporting sponsorships for 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. In addition, 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 (for example, 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.</p> <p>For additional guidance regarding cancellation/postponement of supported activities, reach out to the U.S. External Funding Team at USFundingRequest@Pfizer.com.</p>

Chapter 4: Financial Support of Collaborations and Coalitions

Another way that Pfizer supports external organizations is by participating in collaborations or joining coalitions to advance shared objectives.

Colleagues must follow the review, approval, and documentation requirements applicable to their division. The requirements for Businesses, Worldwide Medical & Safety (WMS), CBIO, and Corporate Affairs are described below.

Furthermore, for information regarding Clinical Research Studies or the steps that must be followed when evaluating a potential study, please see Section 8 of *The White Guide*.

Collaboration

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, such as 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 Commercial Colleagues, all materials developed for distribution must go through a Pfizer Review Committee (RC) evaluation to check the content for factual accuracy and compliance with applicable laws, regulations, and Pfizer policies.

Examples:

- A Brand Team may collaborate with cancer survivor organizations on a pamphlet about effective patient-physician dialogue
- A Brand Team may collaborate with the American Academy of Family Physicians to jointly conduct a campaign to address vaccine hesitancy

Colleagues Who May Provide Funding:

- U.S.-based (and non-U.S. based when charged to U.S. cost centers) colleagues in the Business
- WMS
- CBIO
- 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
 - These are subject to formal review and approval by designated reviewers aligned to each Business/Division/Function

Additional Requirements:

- Given the nature of Pfizer's involvement, including the provision of strategic input and often the rights to use the output of the activities, collaborations 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
 - As an example, the disclosure statement should read "Developed in collaboration with Pfizer" or "Developed in partnership with Pfizer" rather than "Funding support provided by Pfizer"

Coalition

One type of collaboration involves Pfizer working with two or more separate entities to achieve a common objective, such as 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. They also 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.

Chapter 5: Financial Support of Awards, Scholarships, and Fellowships

Another way that Pfizer supports external organizations is by sponsoring awards, scholarships, fellowships, and similar funding in support or recognition of Healthcare Professionals (HCPs) and students.

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
- An outstanding commitment to public health or patient care

Fellowships are generally funds to support junior faculty or emerging leaders in medical science for one or more years of research or study that are paid to

- Medical schools
- Academic medical centers
- Teaching hospitals
- Schools of nursing, pharmacy, or public health
- Other healthcare-related organizations

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:

- Permit medical students, residents, fellows, and other HCPs in training to attend carefully selected educational conferences
- Support clinical or research fellowships

The requirements and process related to funding awards, fellowships, and scholarships are described below.

Colleagues Who May Provide Funding:

- Awards, scholarships, and fellowships are permitted to be funded only by Worldwide Medical & Safety (WMS) and Medical Colleagues
- Global Access & Value (GAV) colleagues involved in designing and conducting research related to health economics and real-world data are permitted to fund fellowships

Approval Process:

- All such funding requests are subject to review and approval by designated reviewers aligned to each Business/Division/Function. Please consult the [External Funding Standard Operating Procedure \(SOP\)](#) for more details.

	<p>Fellowship funding MUST BE:</p> <ul style="list-style-type: none">• Considered only as a result of Pfizer receiving 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• Paid directly to the awardee's institution
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Section 7: Guidelines for Funding and Other Support of External Organizations

- Pro-rated based on the amount of time the awardee will devote to non-billable teaching and research if a position includes both billable services and research or teaching



Fellowship funding MUST NOT BE:

- Paid directly to the awardee
- Used to cover a salary for a position that bills services or for that portion of a position that bills services
- Used to cover the salaries of other individuals assisting the awardee

Chapter 6: Independent Medical Grants (IMGs)

Independent Medical Grants (IMGs) must only be used to support bona fide independent initiatives such as research, quality improvement (QI), or education that are scientifically and ethically sound and aligned with Pfizer's medical and/or scientific strategies. IMGs are not permitted to be funded by Pfizer Commercial Colleagues. If approached with an opportunity to fund an IMG, Pfizer Commercial Colleagues should refer organizations to the externally facing [Independent Medical Grant \(IMG\) page](#) on the Pfizer website.

IMG types include:

- Investigator-Sponsored Research (ISR) Grants
- General Research Grants
- Independent Medical Education (IME) Grants
- QI Grants

IMG requests are managed by the Global Medical Grants (GMG) group in Pfizer's Worldwide Medical & Safety (WMS) organization. These grant types are covered by the [Independent Medical Grants Standard Operating Procedure \(SOP\)](#).

Each request is evaluated based on objective criteria including the Healthcare Professional (HCP) or institution's ability to properly oversee and conduct the study/project/education in compliance with applicable regulations and guidelines, design, budget, and scientific rationale. To ensure Pfizer receives all necessary information, Pfizer requires the Grant Applicant to submit requests through [GMG website](#).

IMGs must be conducted in accordance with all applicable local laws and regulations, applicable Pfizer policies and SOPs, as well as applicable country or region-specific industry and professional standards. They must also be aligned with Pfizer's medical and/or scientific areas of program scope. 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 IMG.

Pfizer Non-Commercial Medical and Research Teams may also choose to implement a Competitive Grant Program, such as for Request for Proposals, to seek proposals focusing on specific gaps in research, practice, or care. These programs typically have a defined set of criteria and are limited to a certain timeframe. They are publicized broadly to a specific audience via professional journals or websites.

Commercial Colleagues may not attend strategy development meetings or otherwise influence or participate in the decision to fund a grant request.

When considering a Grant Request, it should be understood that Pfizer does not own the data and therefore cannot use study/project results for promotion.

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—[Clinical and Research Collaborations SOP](#) applies.



Commercial Colleagues MUST:

- Refer all inquiries regarding IMGs to the [GMG website](#)
- Ensure that requests for IMG support are initiated by an external organization and not solicited by Pfizer

Section 7: Guidelines for Funding and Other Support of External Organizations

	<ul style="list-style-type: none">– Pfizer's Competitive Grant Program is the only exception• Recognize that all decisions to support an IMG are made only by authorized colleagues in a medical, clinical, or scientific function• Refer requests for study product or pure substance for pre-clinical studies to support legitimate medical research to the GMG website
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	<p>Commercial Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Write, suggest, or comment on submissions to Pfizer for IMG support• Seek to be involved in any aspect of the review and approval of the project, project design, set-up, recruitment, or execution• Attempt to influence a decision by Medical or Clinical Colleagues to award grants based on the potential impact to Pfizer sales, as funding of an IMG may never be provided to:<ul style="list-style-type: none">– Establish, maintain, or improve Pfizer's relationship with an HCP or Account– Gain or improve access to an HCP or Account– Reward past or present, or induce future, prescribing or purchasing– Influence an upcoming formulary decision or reward a past formulary decision• Provide any funding directly from a commercial budget• Provide starters/samples to HCPs for use in ISR studies• Offer suggestions regarding topics, content, or speakers to a continuing medical education/continuing education (CME/CE) provider, program sponsor, or speaker at a CME/CE activity<ul style="list-style-type: none">– Even if colleagues are asked to provide input on topics or speakers, colleagues must decline because if a provider or speaker were to implement Pfizer suggestions, the independence of that medical education program could be compromised• Provide any logistical support or resources, including presentation materials• 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• Serve as faculty for any independent CME/CE activity supported by Pfizer
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Investigator-Sponsored Research (ISR) Grants

ISR grants are grants that support research involving a Pfizer asset. Either the grant includes investigational product—such as drug, vaccine, or medical device—and/or the intent of the research is to study a Pfizer therapy.

	<p>ISR Grants <i>MUST</i>:</p> <ul style="list-style-type: none">• Only be provided to support specified, prospectively approved research projects• Represent fair market value (FMV) 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• Only be provided once an ISR agreement has been fully executed and Pfizer has received all of the required documents outlined in the agreement
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X **ISR Grants MUST 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
- 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 [Independent Medical Grants SOP](#) and the [Clinical and Research Collaborations SOP](#) for additional details
- Be provided to reward or influence the prescribing practices of the investigator or institution
- 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

FAQ: Investigator-Sponsored Research (ISR) Support	
	Can a Pfizer Colleague provide information on how to request an ISR grant?
	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.
	Can Pfizer support an ISR grant request involving an off-label use of a Pfizer product?
	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.

Section 7: Guidelines for Funding and Other Support of External Organizations

	Could Pfizer clinical personnel help an ISR applicant with a proposed protocol?
	No, Pfizer must not be involved in any aspect of study protocol or project development nor the conduct or monitoring of the research/QI 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 QI areas of interest, track study progress, and require, minimally, a study status report twice per year.

Independence and Investigator Responsibilities

All ISRs must follow the requirements of the [Independent Medical Grants SOP](#). 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.

	<p>Pfizer MAY:</p> <ul style="list-style-type: none">• Provide feedback on an ISR proposal solely for the purposes of<ul style="list-style-type: none">– Safety assessments and safety reporting, including study drug dosing and handling– Describing why a specific ISR proposal was denied• Discuss research areas of interest• Track study progress• Require, minimally, a study status report twice a year
	<p>Pfizer MAY NOT be involved in:</p> <ul style="list-style-type: none">• Any aspect of study protocol development• The conduct or monitoring of the research

Pfizer's Role in Grant Funded Activities

	<p>Pfizer Colleagues MAY:</p> <ul style="list-style-type: none"> • Accept opportunities in connection with an IME or QI activity, such as exhibit space or time to conduct a speaker program only under strictly limited conditions • For information on promotional opportunities at CME/CE activities, see details later in this chapter
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	<p>Pfizer Colleagues MUST NOT:</p> <ul style="list-style-type: none"> • Influence Grant Funded Activities • Offer suggestions regarding topics, content, or speakers to a CME/CE provider, program sponsor, or speaker at a CME/CE medical education activity <ul style="list-style-type: none"> – Even if colleagues are asked to provide input on topics or speakers, colleagues must decline because if a provider or speaker were to implement Pfizer suggestions, the independence of that medical education program could be compromised • Provide logistical support at an IME or QI activity
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FAQ: 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.
	May a Pfizer Colleague serve as faculty if they are solicited by an external organization?

Section 7: Guidelines for Funding and Other Support of External Organizations



Before committing to the external organization, 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. However, if Pfizer did not provide funding, the colleague may serve as faculty if approved by their manager.

Promotional Opportunities at Medical Education Conferences

On occasion, Pfizer may be offered promotional opportunities in connection with an IME or QI activity, including exhibit space or time to conduct a speaker program, such as in a Product Theater.



If Pfizer is offered the opportunity to conduct a speaker program in connection with an accredited medical education activity, **Pfizer Colleagues MUST:**

- Ensure the Pfizer program is conducted in a room physically separated from the space where CME/CE content is being provided
- Ensure that at the start of the program, the speaker clearly communicates to attendees that it is a separate Pfizer promotional presentation which is not certified for CME/CE credit



If Pfizer is offered the opportunity to conduct a speaker program in connection with an accredited medical education activity, **Pfizer Colleagues MUST NOT:**

- 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
- Provide advice or guidance regarding the content of the medical education activity
- Provide financial or other support—including payment for event expenses or meals, setting up logistics, or handling non-Pfizer speaker arrangements—in connection with the Pfizer program, as these may only be funded by an IME grant approved by GMG



If Pfizer is offered the opportunity to exhibit at an event, regardless of whether CME/CE credit is being offered, **Pfizer Colleagues MAY:**

- Pay for placement of an exhibit or display at [FMV](#)
- Accept complimentary exhibit space that is offered by event organizers and tied to a GMG-approved grant only when it is offered to all potential exhibitors equally

Chapter 7: Permitted Funding by Group

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 such as "charitable contributions," "grants," and "sponsorships" interchangeably and inconsistently.

Colleagues must identify the substantive nature of each request, based on Pfizer's standard definitions summarized in this section, to ensure that a request represents the type of opportunity that they can appropriately fund.

Review the table below, which summarizes permitted funding by group.

Permitted Funding by Group								
		Field Commercial Colleagues						
	Type of Funding	Sales	Non-Sales (including Business Unit (BU) and U.S. Market Access (USMA) Account Management Colleagues) ¹	Corporate Affairs	BU Medical and Worldwide Medical & Safety (WMS)	Chief Business Innovation Office (CBIO)	Global Medical Grants (GMG)	Research and Development (R&D)
	Sponsorship	Yes, but Area Business Manager (ABM) and above only	Yes	Yes	Yes	Yes	Yes	Yes
Charitable Contributions	Healthcare Charitable Contribution (CC) (non-policy focused)						Yes	Yes
	Policy-Focused Healthcare CC			Yes				
	Non-Healthcare CC		Yes ²	Yes	Yes	Yes		Yes
	Special Event			Yes				

Section 7: Guidelines for Funding and Other Support of External Organizations

Permitted Funding by Group								
		Field Commercial Colleagues						
Type of Funding	Sales	Non-Sales (including Business Unit (BU) and U.S. Market Access (USMA) Account Management Colleagues) ¹	Corporate Affairs	BU Medical and Worldwide Medical & Safety (WMS)	Chief Business Innovation Office (CBIO)	Global Medical Grants (GMG)	Research and Development (R&D)	
Collaborations	Yes, but ABM and above only	Yes	Yes	Yes	Yes	Yes	Yes	
Awards				Yes			Yes	
Scholarships				Yes				
Fellowships				Yes	Yes ³		Yes	
Independent Medical Grants (IMGs)			Yes	Yes		Yes		

1. To remain consistent with the [External Funding Standard Operating Procedure \(SOP\)](#), “Business Unit (BU) and U.S. Market Access (USMA) Account Management Colleagues” includes all Account Management roles such as Account Directors, Key Account Managers (KAMs), Health Information Technology (HIT) Account Directors, and Vaccine Account Management roles

2. BU and USMA Account Management Colleagues must consult Legal before proceeding to support a Non-Healthcare Charitable Contribution (CC)

3. Global Access & Value (GAV) colleagues involved in designing and conducting research related to health economics and real-world data are the only Chief Business Innovation Office (CBIO) colleagues permitted to fund Fellowships

As the above table depicts, Field Commercial Colleagues generally have permissions regarding the ability to fund Sponsorships and collaborations and should take the time to be especially familiar with the *External Funding SOP*'s provisions regarding these funding types. Furthermore, colleagues should note that virtual sponsorship opportunities have considerations in addition to the *External Funding SOP*, and that guidance can be found on the [U.S. Funding Requests Page](#) on Policy Point. Remember, the *External Funding SOP* focuses on funding requests from not-for-profit entities, and Pfizer Colleagues should not commit to or provide funding to any such entity until the SOP's provisions are followed and the funding request is fully approved. Funding requests from for-profit entities are not technically covered under the SOP, so Colleagues should consult with Legal before committing to or providing funding for these entities. Furthermore, colleagues should note that virtual sponsorship opportunities have considerations in addition to the *External Funding SOP*, and that guidance can be found on the [U.S. Funding Requests Page](#) on Policy Point.

Chapter 8: Volunteerism and External Organization Memberships

Pfizer may also support external organizations in additional ways, such as through volunteering or board membership.

Colleagues must follow the applicable policies, which are summarized below.

Personal Volunteering

Personal volunteering activities by Pfizer Colleagues must be done during a colleague's personal time with the exception of manager-approved team building activities or site-led hands-on volunteer activities.

Personal volunteering should not be linked to commercial goals or objectives or otherwise be part of promotional activities or business plans. Please review [Corporate Policy 801, Global Charitable Contributions Policy](#) for additional guidance on volunteering.

Please note that this prohibition, however, does not apply to activities approved by the relevant Business 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.

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, or an advisory board or committee—may present a conflict of interest in some situations.



Pfizer Colleagues MUST:

- Ensure their participation in external organizations does not present a conflict of interest or create the appearance of one
 - For additional information, consult [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
- Recuse themselves from joining in any decisions or activities relating to Pfizer, Pfizer products, or competitor products if they are participating as officers or board members
- Inform their manager before accepting a role with an outside organization to determine if any specific review or approvals are required
 - In some situations, consultation with Legal and Compliance may be appropriate and additional approvals may be required

Section 7: Guidelines for Funding and Other Support of External Organizations

	<p>– Limited exceptions to the requirement are described in Corporate Policy 203, Conflicts of Interest</p>
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	<p>Furthermore, 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:</p> <ul style="list-style-type: none">• Indicate their affiliation to the requesting organization when submitting the funding request for approval, as this will ensure Global Health & Social Impact (GH&SI) is inserted into the approval workflow• Make appropriate disclosures to the reviewer responsible for reviewing the funding request that identifies their role in the organization and involvement in the activity for which funding is being solicited, such as participation on the event planning committee• Disclose to the organization, prior to the submission of a funding request, that they are not participating in Pfizer's review or approval of the request
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Chapter 9: Additional Resources for More Information

General Funding Request Information

- For more information regarding the majority of information in this section, please refer to the [External Funding Standard Operating Procedure \(SOP\)](#), which applies to U.S.-based (and non-U.S.-based when using U.S. cost centers) colleagues in the Business Units (BUs), Worldwide Medical & Safety (WMS), Chief Business Innovation Office (CBIO), and Corporate Affairs
- For questions relating to the *External Funding SOP*, e-mail the U.S. External Funding Team at USFundingRequest@pfizer.com
- Funding to external organizations by U.S.-based colleagues in Worldwide Research, Development and Medical (WRDM), excluding WMS; and Global Product Development (GPD) (collectively, “Research and Development (R&D) Colleagues”) must follow [R&D SOP \(SOP 202\)](#)
- For other general information and training materials regarding Funding Requests, consult the [Funding Requests tab](#) on Policy Xchange
- Refer other questions to your Legal support

Funding Exhibits and Displays

- Colleagues who need information about policies for funding exhibit and display opportunities can refer to
 - Section 3 of [The Orange Guide](#)
 - [Exhibits and Displays Standard Operating Procedure \(ED SOP2-01\)](#) available in Policy Xchange under “Funding Requests”

Charitable Contributions

- For questions regarding non-policy-focused healthcare charitable contributions, please visit the [Charitable Contributions](#) page of the Pfizer website or e-mail healthcharitables@pfizer.com
- For more information on the Pfizer Foundation, please refer to [The Pfizer Foundation](#) page of the Pfizer website

Independent Medical Education (IME)

- For more information on Independent Medical Grants (IMGs), please refer to the [GMG website](#) or e-mail the GMG Team at GMG@pfizer.com
- For more information on Investigator-Sponsored Research (ISR), please visit the [Investigator Sponsored Research SOP](#)
- For more information on [Clinical Research Collaborations \(CRCs\)](#), please visit [The Clinical Research Collaborations SOP](#)

Funding Disclosure

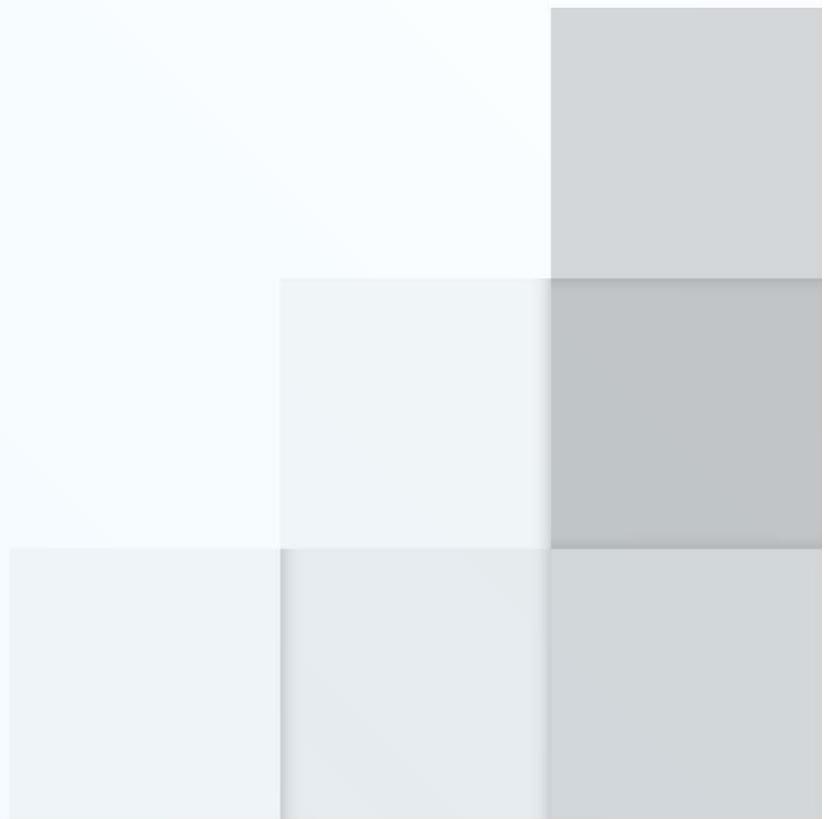
- For more information on our funding disclosure obligations under Open Payments and State Laws, please refer to Sections 1 and 9 of *The White Guide*
- For information about Pfizer’s disclosure of external funding activities, please visit the [Transparency in Grants](#) page of the Pfizer website



The White Guide

Section 8

Guidelines for Clinical Collaborations



Section 8

Guidelines for Clinical Collaborations

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[Click here to visit the Glossary and Acronyms.](#)

Chapter 1: 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 for discovery; in vivo studies, which are preclinical animal and human clinical studies; and consultancies and services related to these areas.

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 postmarketing 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.

The various types of Pfizer-sponsored clinical trials are covered by different Standard Operating Procedures (SOPs), including:

- [Protocol Development for Interventional Studies \(CMCD CT02-GSOP\)](#)
- [Non-Interventional Studies \(CMCD CT24-GSOP\)](#)
- [Interventional Studies With Minimal Risk \(CMCD CT45-GSOP\)](#)

Contact the **Business Process Owners (BPOs)** for information about these SOPs.

Clinical Research Collaborations (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—referred to as “Collaborators”—to conduct research of potential scientific value to patients, physicians, and the greater scientific community. Pfizer may provide Collaborators 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, and so forth. Unlike Pfizer-sponsored research studies, Pfizer is not responsible for any regulatory obligations when engaged in a CRC. Instead, the Collaborator assumes this role.

CRCs are covered by two different SOPs:

- [Research Collaborations \(RC01-GSOP\)](#)
- [Registrational Clinical Research Collaborations \(CMCD CT44-GSOP\)](#)

Contact the BPOs for information about these SOPs.

This section is relevant to all Pfizer Colleagues who have responsibility for Pfizer-sponsored clinical studies and CRCs.

Chapter 2: Clinical Research Requirements

Both Pfizer-sponsored research and Clinical Research Collaborations (CRCs) follow a standard set of requirements that ensure all ethical and scientific conditions are met. Please review the following table for a summary of these requirements.

Clinical Research Requirements	
Controls	Description
Investigational New Drug (IND) Requirements	<ul style="list-style-type: none"> • Clinical studies of drugs and biological products in the United States (U.S.) must be conducted under an Investigational New Drug (IND) application unless an exemption applies <ul style="list-style-type: none"> – An IND is required for clinical studies involving an unapproved compound and, generally, for those studies that involve a Food and Drug Administration (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 as seen in the Code of Federal Regulations, Title 21 • The Study Team must secure approval from the appropriate Regulatory Colleagues to proceed without an IND
Privacy Rules	<ul style="list-style-type: none"> • 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 valid privacy authorization from study participants or a relevant exemption 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 U.S. <ul style="list-style-type: none"> – 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 (PHI) collected in studies – It is important to note that many countries have their own privacy laws which could also apply to activities in the U.S. with a global reach, such as the European Union privacy law called the General Data Protection Regulation (GDPR) • Pfizer personnel must always ensure that appropriate measures are taken to protect any study participant information that they access to or review in accordance with Corporate Policy 404, Protecting the Privacy of Personal Information • For a more detailed discussion of Protected Health Information, please see Sections 1 and 4 of <i>The White Guide</i>

Clinical Research Requirements	
Controls	Description
Good Clinical Practice (GCP)	<ul style="list-style-type: none"> All clinical trials 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 Global Standards for Interventional Studies (CMCD CT19-POL) 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
Institutional Review Board (IRB) or Independent Ethics Committee (IEC)	<ul style="list-style-type: none"> Unless an exemption applies, all 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 their legally authorized representative
Scientific Validity and Value to Pfizer	<ul style="list-style-type: none"> All clinical studies must be a bona fide research project <ul style="list-style-type: none"> This means that 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, such as study data or 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 <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> As the study sponsor, Pfizer or our Collaborator must select only those investigators who possess the necessary professional qualifications, training, experience, time, and resources to conduct the study adequately Investigators must also be evaluated to ensure that they are duly 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 or our collaborator 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, defined as those exceeding \$25,000 to the investigator or institution that are in addition to the costs of conducting the clinical study, must also be disclosed

Clinical Research Requirements	
Controls	Description
<p>Public Disclosure and Access to Study Data</p>	<ul style="list-style-type: none"> • 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 and our Collaborators publicly share 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, 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 • Pfizer posts results of studies on ClinicalTrials.gov and on EudraCT within the timeframes specified in Public Disclosure of Pfizer-Sponsored Studies (CMCD CT28-GSOP) <ul style="list-style-type: none"> – ClinicalTrials.gov is a publicly available study registry provided as a service by the U.S. National Institutes of Health – EudraCT is a publicly available portal managed by the European Medicines Agency

Chapter 3: 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. Expanded Access requests are reviewed by our medical experts inside the company, and they strive to respond within five business days.

[Expanded Access Programs \(CMCD CT16-GSOP\)](#) identifies the criteria that must be met for Pfizer to consider a "Expanded Access" request. 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 [Expanded Access Programs \(CMCD CT16-GSOP\)](#) for more information, or email PfizerCAREs@pfizer.com with any questions.

Chapter 4: Additional Resources for More Information

Pfizer Guidelines for Clinical Collaborations

- For more information on Pfizer guidelines for clinical collaborations, please see:
 - [My Anti-Corruption Policy and Procedures \(MAPP\)](#)
 - [Corporate Policy 207, Global Policy on Interactions with Healthcare Professionals \(GPIHP\)](#)
 - [Corporate Policy 301, Travel, Entertainment and Other Business-Related Expenses](#)
 - [Corporate Policy 404, Protecting the Privacy of Personal Information](#)
 - [Pfizer Scientific Publications \(PUB01-GSOP\)](#)
 - [Clinical Research Publications Checklist \(PUB01-GSOP-RF04\)](#)
 - [Pharmaceutical Research and Manufacturers of America \(PhRMA's\) Principles for Conduct of Clinical Trials and Communication of Clinical Trial Results](#)

Clinical and Medical Controlled Documents (CMCD)

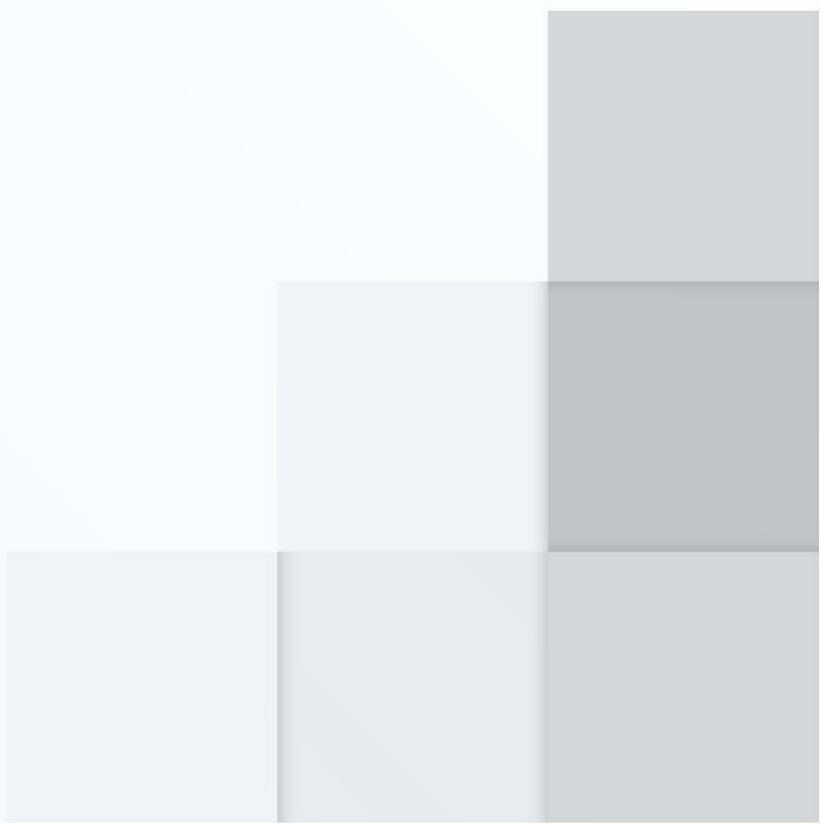
- For more information on Clinical and Medical Controlled Documents (CMCD) Policies and Standard Operating Procedures (SOPs), please see:
 - [Adverse Event Monitoring \(AEM\) System \(CMCD AEM01-POL\)](#)
 - [Global Standards for Interventional Clinical Studies \(CMCD CT19-POL\)](#)
 - [Independent Oversight Committees \(CMCD CT22-GSOP\)](#)
 - [Public Disclosure of Pfizer-Sponsored Studies \(CMCD CT28-GSOP\)](#)
 - [Pfizer Scientific Publications \(CMCD PUB01-GSOP\)](#)
 - [Registrational Clinical Research Collaborations \(CMCD CT44-GSOP\)](#)
 - [Research Collaborations \(RC01-GSOP\)](#)
 - [Independent Medical Grants \(CMCD GNT01-GSOP\)](#)
 - [Investigational Site Selection Preparation and Initiation \(CMCD INV02-GSOP\)](#)
 - [Investigational Site Management and Monitoring \(CMCD INV04-GSOP\)](#)
 - [Clinical Study Agreement and Investigator Site Payments \(CMCD INV02-INV04-CT24-WI-GL01\)](#)
 - [Reporting and Management of Quality Events \(CMCD QMS01-GSOP\)](#)



The White Guide

Section 9

State Healthcare Laws and Interactions With State Employees



Section 9

State Healthcare Laws and Interactions with State Employees

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[Click here to visit the Glossary and Acronyms.](#)

Chapter 1: Introduction

Interactions with federal and state employees are now more commonplace as Pfizer's sales to the government have become more significant and certain colleagues have become more involved in efforts with legislators. In addition, at the state level, laws and regulations are being enacted that impact our business and restrict our activities, including colleagues' interactions with healthcare professionals (HCPs) and state employees.

In order to ensure compliant interactions and activities in this evolving landscape, this section summarizes:

- Key state and city HCP-related healthcare compliance laws and restrictions
- The most significant restrictions on interactions with state employees in key states

This section is relevant to all Pfizer Colleagues and particularly to those who:

- Interact with federal government employees, including HCPs and formulary decision-makers
- Engage 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
- Interact with HCPs with an active license in the states discussed in this section and with state employees

It is important to understand that working with federal and state employees, as well as HCPs in certain states, can present unique risks if not handled by Pfizer Colleagues in an appropriate manner. Therefore, specific guidance to ensure compliant interactions and activities is covered in this section.

Chapter 2: Key State/City Healthcare Professional (HCP)-Related Healthcare Compliance Laws

States are increasingly enacting laws and regulations that impact our business and restrict our activities, including colleagues' interactions with HCPs and state employees. Many of these state laws are more restrictive than federal law and the generally applicable Pfizer policies reviewed in this Guide.

Even with the increasing state laws, Pfizer will continue reporting to the federal government all meals and other transfers of value required under the [Sunshine Act](#) and [SUPPORT Act](#) under the Open Payments provisions. All colleagues must ensure that their records on these expenditures are accurate and complete. For more information on the Sunshine Act and the SUPPORT Act, please see Section 1 of *The White Guide*.

Beyond that, 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.



Furthermore, **Colleagues MUST:**

- Understand the laws and policies of the states in which they work and the states where the HCPs with whom they interact hold licenses
- Remember that several state laws may apply regardless of where an interaction occurs, and if an HCP is licensed in multiple states, the most restrictive state's rules will apply
- Know where the HCP is licensed and follow any applicable state restrictions before providing a meal or educational item to an HCP
 - Regardless of where the interaction takes place, significant restrictions apply to HCPs with active Vermont, Massachusetts, Minnesota, and New Jersey licenses
- Conduct their activities in accordance with the relevant state laws described in this Chapter as well as general Pfizer policy found in *The White Guide*
- Ensure they are familiar with any state representative licensure laws for promoting or marketing products to HCPs in that state
 - Colleagues are responsible for registering with the state(s) and completing any other requirements, such as Continuing Education (CE)
- Be aware of and abide by all spending limits and restrictions
- Recall that federal government employees, such as those working for the Department of Veterans Affairs (VA) or Department of Defense (DoD), must follow federal gift restrictions, which include restrictions on meals
- Remember that almost all states impose restrictions on what may be provided to state and local employees, including HCPs employed by state institutions

If a colleague has questions about state healthcare compliance laws and HCP-related restrictions, they may:

- Consult the State Healthcare Law Compliance section on [Policy Xchange](#) or the Compliance tab in [MyPfieldNet](#)
- Direct any specific questions on state laws that are not addressed in *The White Guide* to Compliance or to StateHealthcareLawCompliance@pfizer.com
- For information about state employee restrictions, colleagues can consult with their Government Relations Director (GRD)

Summary of Key State/City Healthcare Professional (HCP)- Related Healthcare Compliance Laws

Here is a summary of the key State/City HCP-related healthcare compliance laws. Review the information following the table for more in-depth details for each State/City.

State/City	Important Provisions of the State Law	Requirements
California	<ul style="list-style-type: none"> Companies shall adopt a comprehensive compliance program which sets specific dollar limits on gifts, promotional materials, and activities 	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Individuals who market or promote prescription drugs to HCPs in Chicago must obtain a license <ul style="list-style-type: none"> 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 Chicago Department of Public Health (CDPH) website will need to provide a disclosure report 	<ul style="list-style-type: none"> Colleagues responsible for Chicago and who promote Pfizer products in Chicago for 15 days or more per calendar year must obtain a license Licenses must be renewed every year and CE requirements must be satisfied
Colorado	<ul style="list-style-type: none"> Colorado passed a Price Transparency law 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 As a result of this new law, Pfizer is putting the WAC price for each product and any generic information on the Pfizer website for it to be available publicly 	<ul style="list-style-type: none"> Show Colorado Prescribers the landing page of the website at first contact and at every detail <ul style="list-style-type: none"> Advise Colorado Prescribers that this is the landing page where they can get information on WAC prices and any generic information relating to Pfizer products
Connecticut	<ul style="list-style-type: none"> The Connecticut Compliance Program Law requires companies to adopt a marketing code of conduct—the Pharmaceutical Research and Manufacturers of America (PhRMA) Code is acceptable Companies must track payments or other transfers of value provided to Advanced Practice Registered Nurses (APRN) authorized to practice independently (not in collaboration with a physician) for reporting Starting in October 2023, manufacturers are required to provide Connecticut licensed prescribers and pharmacists the Wholesale Acquisition Cost (WAC) price of their products As a result of this new law, Pfizer is putting the WAC price for each promoted product on the Pfizer website for it to be available publicly 	<ul style="list-style-type: none"> Follow all Pfizer policies and procedures and the PhRMA Code Accurately and completely record all expenditures to all HCPs, including APRNs For in-person details, hand a hard copy of the Connecticut price form at first contact and keep copies to hand out, if requested. Show Connecticut Prescribers the landing page of the website at first contact and at every detail <ul style="list-style-type: none"> Advise Connecticut Prescribers that this is the landing page where they can get information on WAC prices relating to Pfizer products

**Section 9: State Healthcare Laws and Interactions
with State Employees**

State/City	Important Provisions of the State Law	Requirements
	<ul style="list-style-type: none"> This law also requires that manufacturers provide to Connecticut a list of pharmaceutical Sales Representatives who market prescription drugs on behalf of the manufacturer to healthcare providers 	
<p>District of Columbia (D.C.)</p>	<ul style="list-style-type: none"> Individuals engaged in the practice of “pharmaceutical detailing” must secure a license to detail in person in the District of Columbia (D.C.) <ul style="list-style-type: none"> Individuals who practice pharmaceutical detailing in D.C. less than 30 days per calendar year are exempt from this requirement Companies must report certain marketing costs Members of the D.C. Medication Advisory Committee (DCMAC) must not receive gifts, including meals or remuneration for speaking or consulting 	<ul style="list-style-type: none"> 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 CE courses 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 Do not provide any gift or meal to any member of the Medication Advisory Committee, no matter how nominal the value
<p>Massachusetts</p>	<ul style="list-style-type: none"> Adopt a marketing code of conduct consistent with Massachusetts regulations Companies may not provide meals, including snacks or other refreshments to Massachusetts (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 <ul style="list-style-type: none"> There is a limited exception for MA HCPs under Bona Fide Service contracts with Pfizer, in connection with job interviews, or at exhibit booths at large-scale conferences Pfizer must give HCPs the opportunity to withhold prescriber data Pfizer must annually report certain HCP expenditures to MA 	<ul style="list-style-type: none"> In-office or in-hospital meals are permissible during educational presentations Out-of-office “snacks,” as defined in Section 3 of The Orange Guide, are prohibited 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 Pfizer may provide modest meals to MA-licensed HCPs in connection with Bona Fide Service contracts or in connection with a job interview for prospective employment 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 <ul style="list-style-type: none"> You can also check Veeva Customer Relationship Management (CRM), which flags most, but not all, MA HCPs You must make a good faith effort to determine if an HCP is licensed in MA
<p>Michigan</p>	<ul style="list-style-type: none"> Michigan state healthcare regulations require pharmaceutical manufacturers to link mid-level practitioners to a supervising physician when requesting starters 	<ul style="list-style-type: none"> All starter requests recorded for Michigan Registered Nurses (RNs) and Advanced Practice Registered Nurses (APRNs)—including Nurse Practitioners (NPs), Clinical Nurse Specialists (CNSs), Certified Registered Nurse Anesthetists (CRNAs), and Certified Nurse Midwives (CNMs)—must include the supervising physician’s name in the transaction’s call notes in Veeva CRM <ul style="list-style-type: none"> Veeva CRM does not allow Pfizer to distinguish between APRNs and RNs in Michigan—therefore, we must record the supervising physician’s name for all nurses that request starters

**Section 9: State Healthcare Laws and Interactions
with State Employees**

State/City	Important Provisions of the State Law	Requirements
		<ul style="list-style-type: none"> • When starters for controlled substances are included, the supervising physician's name and their Drug Enforcement Administration (DEA) registration number must also be added to the transaction's call notes in Veeva • Michigan state law now permits a Physician Assistant (PA) to order and receive starters directly, without recording a supervising physician's name or DEA registration number
Minnesota	<ul style="list-style-type: none"> • Gifts to practitioners are prohibited • Pfizer policy prohibits HCP meals to Minnesota (MN) practitioners, including nominal meals and snacks <ul style="list-style-type: none"> – There is a limited exception for MN HCPs under Bona Fide Service contracts with Pfizer or at exhibit booths at large-scale conferences • Pfizer policy prohibits providing anatomical models, textbooks, journal subscriptions, and online subscription services such as Epocrates to MN practitioners • Pfizer policy also prohibits engaging MN practitioners as paid consultants except for the following type of projects: <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 	<ul style="list-style-type: none"> • Do not invite MN practitioners to any speaker programs that provide meals—even if the program is outside of MN • Unless an exception applies, do not provide MN practitioners meals or snacks • Do not provide MN practitioners anatomical models, textbooks, journal subscriptions, or online subscription services, such as Epocrates, including trial memberships • Do not engage MN HCPs as commercial consultants • Accurately and completely record all practitioner expenditures • If you are unsure of whether an HCP is a MN licensed practitioner, you can check the HCP Lookup Tool <ul style="list-style-type: none"> – Also, Veeva CRM flags most, but not all, practitioners with MN licenses • You must make a good faith effort to determine whether a practitioner is licensed in Minnesota
Nevada	<ul style="list-style-type: none"> • Nevada Marketing Code of Conduct requires companies to adopt a marketing code of conduct—the PhRMA Code is acceptable • Manufacturers must provide to the Nevada Department of Health and Human Services (HHS) a list of pharmaceutical Sales Representatives who market prescription drugs on behalf of the manufacturer to licensed, certified, or registered health care providers; pharmacies and pharmacy employees; and operators or employees of medical facilities in the state <ul style="list-style-type: none"> – The license registry applies to individuals who physically reside in or visit Nevada 5 days or more annually in order to communicate with HCPs • Manufacturers must annually report to Nevada HHS information about transfers of value and samples provided to Nevada covered recipients by registered pharmaceutical Sales Representatives 	<ul style="list-style-type: none"> • Follow all Pfizer policies and procedures and the PhRMA Code • Accurately and completely record all expenditures, as well as samples to Nevada HCPs

**Section 9: State Healthcare Laws and Interactions
with State Employees**

State/City	Important Provisions of the State Law	Requirements
<p>New Jersey</p>	<ul style="list-style-type: none"> • Meals to a New Jersey (NJ) prescriber must not exceed \$17 for breakfast or lunch promotional meetings and \$35 for dinner promotional meetings <ul style="list-style-type: none"> – The meal limit excludes delivery costs, service fees, and tax – The restriction applies to Prescribers practicing from an NJ location – There is a limited exception for Speaker Programs, Symposia, Bona Fide Service contracts, refreshments or other snacks at a convention/congress exhibit booth, and in connection with a job interview for prospective employment • An NJ prescriber shall not accept more than \$10,000 in the aggregate from all pharmaceutical manufacturers in a calendar year for certain Bona Fide Services <ul style="list-style-type: none"> – Bona Fide Services impacted by the cap include promotional activities (does not include Speaker Programs), participation on advisory boards, and 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 	<ul style="list-style-type: none"> • Do not provide NJ prescribers with meals over \$17 for breakfast and lunch and \$35 for dinner unless on occasions otherwise exempted • You must make a good faith effort to determine whether a prescriber is licensed in NJ and practices in NJ <ul style="list-style-type: none"> – 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, practitioners with NJ licenses • You must submit receipts in Concur/Pfizer Travel & Entertainment (PT&E) regardless of the total meal amount
<p>Oregon</p>	<ul style="list-style-type: none"> • Individuals, regardless of location, who market or promote prescription drugs to HCPs based in Oregon must obtain a license <ul style="list-style-type: none"> – Individuals who promote prescription drugs to HCPs in Oregon for fewer than 15 days per calendar year are exempt from the licensing requirement 	<ul style="list-style-type: none"> • Colleagues responsible for Oregon and who promote Pfizer products to HCPs located in Oregon for 15 days or more per calendar year must obtain a license • Licenses are required starting January 1, 2022 • Licenses must be renewed every calendar year and CE requirements must be satisfied • Licensees will also be required to record certain information about their interactions with HCPs
<p>Vermont</p>	<ul style="list-style-type: none"> • Vermont (VT) prohibits all HCP meals, including in-office meals and meals of nominal value <ul style="list-style-type: none"> – There is a limited exception for Bona Fide Service contracts, refreshments, or other snacks at a convention/congress exhibit booth as well as in connection with a job interview for prospective employment • VT also prohibits paid market research surveys involving VT-licensed HCPs <ul style="list-style-type: none"> – The restriction applies whether the survey is conducted directly by Pfizer or through an independent third-party survey research organization 	<ul style="list-style-type: none"> • Do not invite VT HCPs to any speaker programs that provide meals or snacks, even if the program is conducted outside of VT • Do not provide VT HCPs with meals or snacks— with limited exceptions <ul style="list-style-type: none"> – Pfizer may provide modest meals to VT HCPs in connection with Bona Fide Service contracts or in connection with a job interview for prospective employment – Refreshments or snacks at conference exhibit booths are permissible • Do not engage VT HCPs as part of any paid marketing research surveys

Section 9: State Healthcare Laws and Interactions with State Employees

State/City	Important Provisions of the State Law	Requirements
	<ul style="list-style-type: none"> • Pfizer must report certain HCP expenditures—as well as samples, copay cards, coupons, and vouchers—to VT • Price Disclosure Forms must be provided to HCPs when detailing and posted on Pfizer’s website 	<ul style="list-style-type: none"> • Accurately and completely record all HCP expenditures—as well as samples, copay cards, coupons, and vouchers—provided to VT-licensed HCPs • Provide VT Price Disclosure Forms, available on Statutory Price Disclosure for Vermont Prescribers, to HCPs as appropriate • If you are unsure of whether an HCP has a VT license, you can check the HCP Lookup Tool <ul style="list-style-type: none"> – Also, Veeva CRM flags most, but not all, VT HCPs • You must make a good faith effort to determine whether an HCP is licensed in VT

Details of Key State/City Healthcare Professional (HCP)-Related Healthcare Compliance Laws

Here is a more in-depth review of the key State/City HCP-related healthcare compliance laws that are summarized in the table above.

California

Definition of a Healthcare Professional (HCP)

Covered HCPs include any California-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.

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 [Office of Inspector General’s \(OIG’s\) Compliance Program Guidance for Pharmaceutical Manufacturers](#) and the PhRMA 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
- Declare annually, on its public website, that it is in compliance with California Law

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 California-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



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- Pfizer Review Committee (RC)-approved educational items, such as textbooks, anatomical models and so forth

The value of the following items is NOT included when calculating the annual aggregate limit:

- Starters
- **Fair Market Value (FMV)** 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 CE forums)
- Financial support for educational scholarships
- 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 a colleague has any questions concerning the California Drug Marketing Practices Law, they should contact Compliance.

City of Chicago

The Law: Pharmaceutical Representative License Ordinance

The Chicago Pharmaceutical Representative License 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.

For example, if a Sales Representative is calling on a Chicago HCP via telephone while physically in Chicago, then they should apply for a license if they are 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 CE requirements. The initial professional education course and application are available on the [CDPH website](#).

Licensees will be required to abide by a code of ethics and 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
- A \$750 licensing fee

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 HCPs regarding those drugs for potential disclosure, including:

- A list of HCPs within Chicago contacted
- The dates the HCPs were contacted
- The location and duration of contact

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- The pharmaceuticals promoted
- Whether product samples were provided to the HCP and the quantity provided
- Whether promotional materials, such as brochures or demo models, were provided to the HCP and the value of those materials
- The value of meals provided to the HCP

As of July 2017, the disclosure list includes only the category of Schedule II medications. The Pfizer Global HCP Transparency Reporting Team will submit any required disclosures on behalf of the Sales Representative. Sales Representatives should continue to track all HCP interactions in accordance with Pfizer policy.

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 a colleague has any questions concerning the Chicago Pharmaceutical Representative Licensing Ordinance, they should contact Compliance.

Colorado

The Law: Price Transparency Law

Colorado passed a Price Transparency law, effective August 2, 2019, requiring manufacturers to provide Colorado Licensed Prescribers, the 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, Pfizer is putting the WAC price for each product and any generic information on the Pfizer website for it to be available publicly. The information can be found at [Statutory Price Disclosure For Colorado Prescribers](#).

How the Law Impacts Pfizer Colleague Activities

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
- Advise Colorado Prescribers that this is the landing page where they can get information on WAC prices and any generic information relating to Pfizer products

If a colleague has any questions, they should contact Compliance.

Connecticut

The Law: Connecticut Compliance Program Law & Advanced Practice Registered Nurse (APRN) Disclosure Law

The 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
- The Connecticut Department of Consumer Protection 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

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- Manufacturers to disclose payments and transfers of value provided to Connecticut-licensed APRNs who practice not in collaboration with a physician—that is, independently
 - The definition of APRN below, for purposes of the Connecticut disclosure law, is defined as: an APRN who practices “not in collaboration with a physician”—that is, an APRN who practices independently
 - Who appears in the Connecticut Department of Public Health annual APRN list is available at the [Connecticut State Department of Consumer Protection website](#)

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. They must ensure that transfers of value, including their reporting of attendees at speaker programs, is accurate and complete.

The Law: Connecticut Pharmaceutical Marketing Firm Registration and Marketing Price Disclosure

Connecticut passed a Price Transparency law, effective October 1, 2023, requiring manufacturers to provide Connecticut Licensed Prescribers the WAC price of their products. As a result of this new law, Pfizer is putting the WAC price for each product on the Pfizer website for it to be available publicly. The information can be found at [Statutory Price Disclosure For Connecticut Prescribers](#).

In addition, Pfizer is required to submit an annual list of all pharmaceutical Sales Representatives who market prescription drugs on their behalf to healthcare providers in Connecticut.

How the Law Impacts Pfizer Colleague Activities

Sales Representatives in Connecticut are required to do the following:

- Show Connecticut Prescribers the landing page of the website at first contact and at every detail
- Advise Connecticut Prescribers that this is the landing page where they can get information on WAC prices relating to Pfizer products

If a colleague has any questions, they should contact Compliance.

District of Columbia (D.C.)

Definition of a Healthcare Professional (HCP)

The D.C. definition of an HCP is broad. The law applies to expenditures provided to persons and entities who are licensed to provide health care in D.C., including HCPs and persons employed by them who work in D.C., licensed insurance carriers, health plans and benefit managers, pharmacies, hospitals, nursing facilities, clinics, and other entities licensed to provide health care in D.C.

The Law: Prescription Drug Marketing Costs Disclosure Law

The 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:



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- Direct-to-consumer [advertisements](#) targeting D.C. residents
- Educational or informational programs, materials, or seminars provided to HCPs, pharmacies, clinics, health plans, and other HCPs
- 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
- 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
- Payments to D.C.-licensed HCPs for participating in blinded market research, if:
 - The research is conducted by an independent survey research organization
 - The pharmaceutical client does not know the identity of the practitioners participating in the research
 - The payments are determined and made by the survey research organization

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, PT&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.

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 the colleague's responsibility to apply for their license, and application costs will be reimbursed by Pfizer.

The license application materials are available online at the [D.C. SafeRx Pharmaceutical Detailers Licensing 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 their application prior to the deadline. As part of the license renewal application, colleagues will need to attest that they have completed a minimum of 15 hours of CE during the 2-year period preceding the date the license expires. They must register for a *SafeRx Pharmaceutical Detail Licensing CE Program* through Power to

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Learn (P2L). Once registered, colleagues will receive a list of Certified Medical Representative (CMR) training courses that are approved for CE under the *SafeRx Pharmaceutical Detail Licensing Program*. It can take up to 2 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 a colleague has completed a CMR Certification or CMR Flex course post-receipt of their pharmaceutical detailer's license, they should contact CMR by telephone at **800-328-2615** or via e-mail at program@cmrinstitute.org to determine if they already received renewal credit.

D.C. 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 a colleague has any questions concerning the D.C. Prescription Drug Marketing Costs Disclosure Law or SafeRx, they should contact Compliance.

The Pharmaceutical Detailer Licensing Law also requires that any speaker Pfizer engages to speak in D.C. obtain a Pharmaceutical Detailer License if they plan to speak more than once in D.C. in a calendar year.

Gifts to District of Columbia (D.C.) Medication Advisory Committee (DCMAC) Prohibited

D.C. law also prohibits offering a gift or remuneration of any kind to a member of the 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
- Educational items, such as 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 Frequently Asked Questions \(FAQs\)](#).

Massachusetts

Definition of a Healthcare Professional (HCP)

The Massachusetts definition of an HCP is broad. It includes any person who prescribes prescription drugs and is licensed to provide health care in Massachusetts, including a partnership or corporation comprised of such persons, as well as employees and agents of such persons, such as nurses and office staff.

Examples of Massachusetts HCPs include:

- Physicians
- Physician Assistants (PAs)
- Certified Nurse Midwives (CNMs)
- Psychiatric nurse mental health specialists
- Nurse Practitioners (NPs)
- Employees and agents of such persons, such as nurses and office staff

Massachusetts HCPs do not include hospitals, nursing homes, pharmacists, health benefit plan administrators, HCPs not licensed in Massachusetts, and other entities if they are not agents, employees, and so forth of a Massachusetts-

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licensed HCP. However, such entities and individuals *are* considered Covered Recipients for Massachusetts disclosure, as described below.

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. The law also requires Pfizer to disclose payments and items provided to "[Covered Recipients](#)," further defined below, that have a value of \$50 or more.

These Massachusetts 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
- 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.

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 of these expenditures are accurate and complete.

Colleagues must make a good faith effort to determine whether an HCP is licensed in Massachusetts. To help determine whether an HCP holds a Massachusetts license, colleagues 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 Massachusetts HCPs in certain limited situations that are specifically identified in the following guidance:

- In-office or in-hospital meals are permissible during educational presentations
 - Remember, Pfizer policy has a \$40 restriction on in-office or in-hospital meals which colleagues need to comply with
 - Office staff are not required to be listed by name for in-office or in-hospital meals since the threshold is \$40 per meal
- Out-of-office meals and "snacks" 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

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- Field Medical, Therapeutic Area (FM, TA) or Field Medical, Outcomes & Analytics (FM, O&A) Colleagues may not provide out-of-office meals to Massachusetts HCPs, as the interactions they have do not meet the definition of “scientific exchange” in Massachusetts

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 PT&E requirements for meals provided to Massachusetts HCPs and Covered Persons.

Colleagues must make a good faith effort to determine whether an HCP is licensed in Massachusetts 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
- 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 Continuing Medical Education (CME) support through the process and standards associated with Global Medical Grants (GMG) to conference organizers that meet Accreditation Council for Continuing Medical Education (ACCME) standards or equivalent standards. Pfizer may not, however, provide funding directly to support meals for HCPs or to 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.

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.

Therefore, 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 Massachusetts residents or to providers or pharmacies for distribution to Massachusetts residents, subject to the following:

- Distribution of these offerings is prohibited for drugs that have an AB-rated generic equivalent
- Colleagues must accurately record and track in Veeva CRM the distribution of these items to any HCPs
- Coupon offers for all Schedule II opioids are prohibited
- Marketing and other Headquarter (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



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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

Definition of Mid-Level Practitioner

In Michigan, the regulation for starters applies to the following mid-level practitioners:

- Advanced Practice Registered Nurses (APRNs)
 - Nurse Practitioner (NP)
 - Clinical Nurse Specialist (CNS)
 - Certified Registered Nurse Anesthetist (CRNA)
 - Certified Nurse Midwives (CNM)
- Physician Assistants (PAs)

Michigan State Healthcare Regulations Regarding Starters for Mid-Level Practitioners

Michigan state healthcare regulations require pharmaceutical manufacturers to link mid-level practitioners to supervising physicians when requesting starters.

How the Policy Impacts Pfizer Colleague Activities

Advanced Practice Registered Nurses (APRNs) — Nurse Practitioners (NPs), Clinical Nurse Specialists (CNSs), Certified Registered Nurse Anesthetists (CRNAs), and Certified Nurse Midwives (CNMs)

- All starter requests recorded for Michigan RNs and APRNs must include the supervising physician's name in the transaction's call notes in Veeva CRM
 - The Veeva system does not allow us to distinguish between APRNs and RNs 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 their DEA registration number must also be added to the transaction's call notes in Veeva

Physician Assistants (PAs)

- Michigan state law now permits PAs to order and receive starters directly without recording a supervising physician's name or DEA registration number

Minnesota

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 (NP), physician assistants (PA), dentists, dental therapists, optometrists, podiatrists, pharmacists, and veterinarians are all included in the definition of practitioner in Minnesota.

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Colleagues 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 their location except as noted below.

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 (FMV) unless it is specifically permitted under the statute.

The following are not considered “gifts” under the statute and may be given to Minnesota practitioners:

- Free drug samples for free distribution to patients, also known as 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 FMV in connection with a genuine research project
- Certain publications and educational materials, including most but not all RC-approved educational materials, such as Pfizer-created branded and unbranded promotional materials; reprints; literature; and other printed materials
- Salaries or other benefits paid to employees

The restrictions below apply to all colleagues, not only Sales, and extend to interactions with Minnesota practitioners that occur outside of Minnesota.

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 anatomical models, textbooks, journal subscriptions, or online subscription services such as Epocrates (including trial memberships). If a colleague is unsure about whether an RC-approved item can be provided to a Minnesota practitioner, they should check with their manager or Compliance.

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, their meal does not constitute a gift and may be provided.

Additionally, nominal snacks provided at educational/scientific conventions or 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 \$150 in value.

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Consulting Engagements With Minnesota Healthcare Professionals (HCPs)

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.

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 meetings where the audience consists of Pfizer Colleagues
- 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.

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/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 or congress exhibit booths are also allowed. These types of meals are not considered a “gift” under the state statute.

Colleagues must make a good faith effort to determine whether a practitioner is licensed in Minnesota. To help determine whether a practitioner holds a Minnesota license, colleagues 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, Minnesota HCPs.

Minnesota can impose significant penalties on Pfizer as well as criminal misdemeanor penalties for failure to comply with this law. If a colleague has any questions concerning the Minnesota Gift Law, they should contact Compliance.

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
- 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

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How the Law Impacts Pfizer Colleague Activities

Pharmaceutical Sales Representatives Registration

- Pharmaceutical manufacturers are required to provide Nevada Health and Human Services (HHS) with a list of Sales Colleagues 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 Area Business Managers (ABMs) and Sales Representatives only
 - Sales Representatives also include Inside Sales Representatives (ISRs) and Contracted Inside Sales Representative (CISRs), who are colleagues that detail customers remotely over the phone/web
- Sales Representatives, including virtual-only colleagues and contract 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
- 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 every year
- 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 Area Business Manager (ABM) 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 Representative per HCP.

The information provided in the Disclosure Report includes:

- The Sales Representative registry identification (ID)
- The name, credential, National Provider Identifier (NPI), and ZIP code of the Nevada covered recipient
- The date of the interaction
- The type and amount of transfer of value provided
- The product, National Drug Code (NDC), and quantity of the sample provided

New Jersey

Definition of a New Jersey Prescriber

The definition of a New Jersey Prescriber is any New Jersey Prescriber who holds an active New Jersey license and physically practices in New Jersey. New Jersey Prescribers include:

- Physicians
- Physician Assistants (PAs)
- Podiatrists
- Advanced Practice Nurses
- Dentists
- Optometrists

The Law: Limitations on and Obligations Associated with Prescriber Acceptance of Compensation from Pharmaceutical Manufacturers

The state of New Jersey has placed restrictions on Meals and Consulting Arrangements between New Jersey Prescribers and Pharmaceutical Manufacturers.

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The law impacts the way Pfizer engages New Jersey Prescribers and restricts 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 New Jersey or who have New Jersey patients.

How the Law Impacts Pfizer Colleague Activities

Colleagues must make a good faith effort to determine whether an HCP is a Prescriber in New Jersey. To help determine whether an HCP is a prescriber in New Jersey, colleagues can check the HCP Lookup Tool. Sales Colleagues can also access this information by looking up the HCP in Veeva CRM.

Meals

Providing meals to New Jersey Prescribers must meet the following conditions:

- Meals provided at promotional meetings may not exceed \$17 for breakfast/lunch or \$35 for dinner
 - The \$17 or \$35 excludes tax, tip, and any delivery charge
 - Colleagues must submit receipts in Concur/PT&E regardless of the total meal amount
- 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 who are
 - Under a Bona Fide Services contract with Pfizer
 - Involved in a job interview for prospective employment
 - At a convention/congress exhibit booth where refreshments and snacks are provided

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
- Payment or remuneration for travel, lodging, and other personal expenses associated with Bona Fide Services are not included in the \$10,000 aggregate cap

Oregon

The Law: Pharmaceutical Representative Licensure Law

The Oregon Pharmaceutical Representative Licensure Law requires individuals, regardless of location, who market or promote prescription drugs to HCPs located within Oregon to obtain a license. Individuals who promote prescription drugs in Oregon for fewer than 15 days per calendar year are exempt from the licensing requirement.

How the Law Impacts Pfizer Colleague Activities

Colleagues who promote Pfizer products to HCPs in Oregon 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 CE requirements. License applications will require the following:

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- The applicant's full name, social security number, e-mail address, residence address, and personal 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
- A \$750 licensing fee

The initial professional education course and application are available on the [National Insurance Producer Registry \(NIPR\) website](#).

Pharmaceutical Sales Representatives who market or promote pharmaceutical products to HCPs in Oregon must track their interactions with HCPs regarding the drugs promoted for potential disclosure, including:

- A list of HCPs within Oregon that have been contacted
- The number of times the licensee contacted each HCP
- The dates the HCPs were contacted
- The location and duration of contact
- The pharmaceuticals promoted
- Whether product samples were provided to the HCP, the quantity provided, and the monetary value of those samples
- Whether promotional materials, such as brochures or demo models or gifts, were provided to the HCP as well as the monetary value of those materials/gifts
- Whether and how the licensee otherwise compensated the HCP for contact with the licensee
- The value of meals provided to the HCP

The Pfizer Global HCP Transparency Reporting Team will submit any required disclosures on behalf of the Sales Representative. Sales Representatives should continue to track all HCP interactions in accordance with Pfizer policy. Oregon can impose penalties on Pfizer Colleagues for failure to comply with this law, which may include civil penalties, license revocation, or suspension. If a colleague has any questions concerning the Oregon Pharmaceutical Representative Licensure Law, they should contact Compliance.

Vermont

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 (HCPs)
- Partnerships and corporations comprised of HCPs
- Officers, agents, and employees of HCPs, such as nurses and office staff
- Hospitals, nursing homes, pharmacists, and any other person authorized to dispense prescribe products or purchase them for distribution

Examples of HCPs in Vermont include:

- Physicians
- Nursing homes
- Nurse Practitioners (NPs)
- Dentists
- Nurses and HCP office staff
- Physician Assistants (PAs)



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- Hospitals
- Pharmacists
- Licensed Clinical Social Workers and Psychologists
- Health plan benefit administrators
- Members of the Green Mountain Care Board, whether or not they are licensed HCPs

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 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 a colleague becomes aware of any such occurrence, they must report it immediately to StateHealthcareLawCompliance@pfizer.com.

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. The meal and gift restrictions apply even when a Vermont HCP is located in another state.

In addition, certain expenditures have to be reported, so all colleagues must ensure that their records of these expenditures are accurate and complete.

Colleagues must make a good faith effort to determine whether an HCP is licensed in Vermont. To help determine whether an HCP holds a Vermont license, colleagues 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, Vermont 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.

In addition, colleagues must not invite Vermont HCPs to Pfizer speaker programs at which food is provided even if the program is conducted outside of Vermont.

However, 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 provided in connection with a job interview. In addition, refreshments such as coffee and snacks provided by Pfizer at a booth during 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



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- Articles, journals, and other educational items
- Certain conference [sponsorships](#)
- Rebates and discounts
- Authorized expenditures related to clinical trials
- Compensation at FMV for Bona Fide 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.

Disclosure of Expenditures to Vermont Healthcare Professionals (HCPs)

Most allowable expenditures to Vermont HCPs—or other institutions covered by the law such as Vermont academic institutions, Vermont nonprofit hospital foundations, and professional, educational, and patient organizations representing or serving HCPs 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 a "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. This includes 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
- Prescribed products distributed free of charge or at a discounted price pursuant to a Pfizer Patient Assistance Program

The Law: Vermont Price Disclosure

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
- **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 [Statutory Price Disclosure for Vermont Prescribers](#).

The following table identifies which forms are required in connection with typical promotional activities.

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Promotional Activities and Required Forms	
Promotional Activity	Action Required
Face-to-face meeting with HCPs, such as 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	<ul style="list-style-type: none">• Inform Vermont HCP that the 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 a 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 a colleague has any questions, they should contact Compliance.

Chapter 3: Key State Employee Gift Laws

Summary of Key State Employee Gift Laws

Almost all states have restrictions on interactions with state employees, including Healthcare Professionals (HCPs) employed by state institutions. A summary of the most significant state restrictions is provided below. Review the information following the table for more in-depth details for each State.

If a colleague has any questions about state employee gift restrictions, they should:

- Consult with the appropriate Government Relations Director (GRD)
- Consult Compliance

State	Important Provisions of the State Law	Requirements
Colorado	<ul style="list-style-type: none"> • State employees may not receive anything of value worth more than \$75 from a company (as a whole, not by employee) per year 	<ul style="list-style-type: none"> • 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 \$75 annual limit
Louisiana	<ul style="list-style-type: none"> • State employees are prohibited from performing certain compensated services for pharmaceutical companies • State employees have a \$70 cap on food, drinks, and refreshments provided during a single event 	<ul style="list-style-type: none"> • 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 \$70 during the event
New York	<ul style="list-style-type: none"> • State and local employees are prohibited from receiving gifts 	<ul style="list-style-type: none"> • 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

Details of Key State Employee Gift Laws

Here is a more in-depth review of the key State employee gift laws that are summarized in the table above.

Colorado

Definition of Healthcare Professional (HCP) State Employee

A Colorado state employee includes any HCP employed—either full-time or part-time—by the State of Colorado, any community HCPs employed by a Colorado county or municipal government, and any physicians employed at the University of Colorado Health Sciences Center.

If a colleague is not sure whether an HCP is employed by the State of Colorado or just affiliated with a state institution, they must confirm their relationship with the state prior to providing any meals or items of more than

Section 9: State Healthcare Laws and Interactions with State Employees

nominal value to the HCP. If the HCP receives regular compensation directly from a state institution, they are likely considered a state employee and are therefore subject to the restrictions discussed in this section.

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, such as money, service loan, travel, entertainment, hospitality, or promise worth more than \$75 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 their official duties.

How the Law Impacts Pfizer Colleague Activities

Collectively, Pfizer Colleagues are prohibited from providing gifts, including meals, which have a total value over \$75 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 \$75 in items and meals from Pfizer as a company during any calendar year. The \$75 annual limit is not per Pfizer Colleague.

Pfizer Review Committee (RC)-approved educational items of more than nominal value, such as anatomical models, may not be provided to Colorado state employees who are HCPs 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 \$75 limit for Colorado state employees:

- Unsolicited Pharmaceutical Research and Manufacturers of America (PhRMA) Code compliant food and beverage snack items of nominal value which are not part of a meal
 - Examples include doughnuts and non-alcoholic beverages such as soft drinks and coffee
- Unsolicited RC-approved educational items of nominal intrinsic value
- Fair market value (FMV) payments for an employee's provision of services, such as speaking or consulting services

Louisiana

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 Pharmacy and Therapeutics (P&T) Committee members
- State prisons
- State rural health clinics

A **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



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- Under the supervision or authority of an elected official or another employee of the governmental entity

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 \$70 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 nonpublic servants, at the event.

How the Law Impacts Pfizer Colleague Activities

Louisiana public servants cannot be engaged as promotional speakers for Pfizer.

If a colleague is not sure whether a potential speaker is a Louisiana public servant, they must confirm their status prior to engaging the person as a speaker. If the person receives regular compensation directly from one of the institutions mentioned above, they are probably a public servant and would be prohibited from receiving compensation from Pfizer for speaking.

The Louisiana Board of Ethics has stated, however, that a public employee can serve as a consultant—for example, at a marketing advisory board—as long as the consultant services are related to their 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, they 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.

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 \$70/person, per occasion.

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 a colleague has any questions concerning the Louisiana laws discussed here, they should contact Compliance.

New York

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.

The Law: Restrictions on Gifts to State and Local Officers and Employees

New York prohibits all its elected officials, state officers and employees, state legislators, state legislative employees, municipal officers, and municipal employees from receiving any gift directly or indirectly.

“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 their official duties.

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 which are not part of a meal. New York interprets “nominal” as a value of \$15 or less. Examples include doughnuts, cookies, and non-alcoholic beverages such as soft drinks and coffee.

If a colleague is 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, they 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, they are likely a state official and would be governed by the restrictions discussed in this section.

If a colleague has any questions, they should contact Compliance.

Chapter 4: State Laws for Savings and Free Trial Programs

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, such as cards or vouchers and any related advertising.

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.

State Law Requirements	
California	<ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> – Branded drugs until the first “Therapeutically Equivalent” generic product approved by the Food and Drug Administration (FDA) has been nationally available for at least 3 months <ul style="list-style-type: none"> ▪ This does not apply to biologics/biosimilars – An individual who has completed any applicable step therapy or prior authorization requirements for the branded prescription drug as mandated by the individual’s health plan – A discount, repayment, product voucher, or other reduction in an individual’s out-of-pocket expenses is not associated with their 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	<ul style="list-style-type: none"> • 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

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State Law Requirements	
	voucher, or copay program voucher, such as when a patients can use a copay card at a limited number of pharmacies in the state
Colorado	<ul style="list-style-type: none">• Copay offerings are not permitted to be offered directly to pharmacists
Louisiana	<ul style="list-style-type: none">• Copay offerings are not permitted to be offered directly to pharmacists
Tennessee	<ul style="list-style-type: none">• Colleagues must contact Biopharma Operations for information regarding requirements to register programs with the Tennessee Division of Commerce & Insurance

Furthermore, a number of states have adopted broad restrictions on various manufacturer practices relating to controlled substances, including coupons and other forms of copay relief.

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 Global Product Counsel (GPC), with consultation with Pricing & Access Legal as appropriate.

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.

Chapter 5: Additional Resources for More Information

Federal Employee Interactions and Lobbying

- Lobbying questions may be referred to the relevant Government Relations Director (GRD), the Pfizer Washington, District of Columbia (D.C.) office, or Compliance
- Federal Employee Interaction questions may be referred to your lead National Account Manager or Compliance
- Take the online training module on how to complete the federal Lobbying Disclosure form

Educational Grants

- For more information on Pfizer's educational grant process refer to the [Independent Medical Grants Standard Operating Procedure \(SOP\) \(SOP GNT01\)](#)

State Laws

- For more information on state law restrictions, contact compliance or send questions to StateHealthcareLawCompliance@pfizer.com
- To determine whether a Healthcare Professional (HCP) is licensed in Massachusetts, Minnesota, New Jersey, or Vermont, Sales Representatives should consult the physician profile within Veeva Customer Relationship Management (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](#)

Disclosure/Transparency

- For more information on Pfizer's HCP transparency practices, refer to the [Global HCP/Healthcare Organization \(HCO\) Transparency Reporting Portal](#) or e-mail GlobalHCPTransparencyReporting@pfizer.com
- For more information on Open Payments, please see the [Centers for Medicare & Medicaid Services \(CMS\) website](#)