



The Orange Guide

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The ORANGE 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, 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 Orange Guide*.

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

Furthermore, the Orange 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 Orange 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 phone at **212-733-3026**

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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The Orange Guide

Section 1

Laws and Regulations Governing Pfizer Field Activities and Customer Interactions

Section 1

Laws and Regulations Governing Pfizer Field Activities and Customer Interactions

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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

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 Boxed 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

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
- **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.

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 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 340B Drug Pricing Program, as well as through certain state-supported programs, including State Pharmaceutical Assistance Programs 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. Read below for more details.

Medicaid Best Price Law

Medicaid is a government program that covers the cost of prescription medicines for low-income and disabled patients. Medicaid is administered by states within broad federal rules and jointly funded by states and the federal government.

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

A failure to account for discounts or other price concessions accurately could result in inaccurate price reporting to the federal government. This could occur if, for example, Pfizer mischaracterizes discounts provided to a managed

care or retail customer, such as through a rebate disguised as an educational grant or by paying more than 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*.

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.

False Claims Act

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

The **False Claims Act (FCA)** prohibits entities and individuals from submitting or inducing another to submit a false claim for reimbursement from the federal government. The federal government has used the FCA to investigate and prosecute pharmaceutical companies for falsely reporting best price, paying kickbacks to 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

Key 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.

Promotional Labeling

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

Labeling includes all labels and other printed, written, or graphic matter:

- Upon any article or any of its containers or wrappers
- Accompanying such article

This includes sales materials in the Veeva Customer Relationship Management (Veeva CRM) system and other promotional materials.

Advertising

The FDA strictly regulates the advertising of all prescription drug products marketed in the United States. Advertising includes advertisements published in journals, magazines, newspapers, and other periodicals, as well as broadcast media such as radio, television, and telephone.



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

- Be consistent with the product's FDA-approved labeling
- Contain balanced statements about the product's benefits as well as risks
- Be truthful and not misleading
- Be supported by [substantial evidence](#)
- 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

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.

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 TV, 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.

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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, etc. 	<ul style="list-style-type: none"> Blister pack arrived empty Vial is leaking liquid Syringe is jammed Product is/may be counterfeit
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 his 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
 - My Reporting App (MYRA) on their mobile device
 - Veeva 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, gender, 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 share Protected Health Information (PHI) about their patients without a [Business Associate Agreement \(BAA\)](#) or patient authorization, in limited circumstances. HCPs are permitted to disclose PHI to persons "subject to the jurisdiction of the FDA" for activities related to the quality, safety, or effectiveness of an FDA-regulated product or activity for which the person has responsibility.

Therefore, if an HCP reports an adverse event or other safety or product information, continue to follow the process established for collecting information about and reporting these events pursuant to [Corporate Policy 903, Your Responsibility to Report Information about Safety, Quality or Performance of Pfizer Products](#).

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

Disclosure and Transparency Laws

Open Payments is a national disclosure program from the CMS that promotes a more financially transparent and accountable healthcare system. It emerged after Congress enacted the [Sunshine Act](#) and has evolved with the passing of the [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 Manufacturing 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 [Physician Payments Sunshine Act \(Sunshine Act\)](#) 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](#).

SUPPORT Act

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

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- Research support, including all payments or transfers of value related to R&D, such as clinical site payments, study drug, and equipment that is leased, loaned, or given
- 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 3 of *The Orange 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:
 - Copay cards
 - Savings cards
 - Pill dispensers
 - Brochures
 - Vouchers
 - Prescription stamps
 - Pamphlets

Recording Disclosable Payments and Items

Colleagues must properly record all payments, meals (including the number and classification of attendees), and other items that may be disclosable, regardless of value, as part of the regular expense reporting process.



Colleagues *MUST*:

- 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
 - 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)



Colleagues *MUST NOT*:

- Approve expense reports or invoices that lack full names and appropriate expense allocation

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](#).



If a U.S.-licensed HCP expresses a desire to opt out of receiving food, beverages, or other disclosable items, **the notified colleague *MUST*:**

- 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

If an HCP who has opted out subsequently chooses to opt back in, **the notified colleague or the HCP *MUST*:**

- Contact PTI@Pfizer.com




Access and Use of Open Payments and Other Transparency Data for Analytics






The Transparency team has created resources, which include CMS Open Payments competitor and Pfizer internal payment datasets, that enable certain analyses and business insights. For specific data requests or information regarding access to these datasets and dashboards for analytics, colleagues should visit the [Global HCP/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?

FAQ: The Disclosure Process	
	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?
	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?

FAQ: Understanding the Opt-Out Process

A

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 Orange 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 7 of *The Orange Guide*.

Chapter 3: 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, phone number, e-mail address, or IP address.

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

- Geolocation data
- Financial information
- National identifiers such as social security number, information about an individual's race, ethnicity, religion, sex life/sexual orientation
- 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**, 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 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.

Pfizer's Key Privacy Principles

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

- Examples of Personal Information include a person's name, physical and e-mail addresses, phone numbers, identification numbers, preferences, unique online identifiers, or IP addresses
- Examples of activities involving collection or access to Personal Information of others 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 corporate principles require that the confidentiality and security of Personal Information be maintained in accordance with state and federal law.



Pfizer Colleagues *MUST*:

- Always disclose that they are a Pfizer employee when interacting with patients
 - 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
 - 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



Pfizer Colleagues *MUST NOT*:

- 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)
 - 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 *Pfizer Privacy Pledge* or *Patient Health Information Confidentiality Agreement* template found on [MyPfieldNet](#), as appropriate
 - If this does not satisfy the party making the request, the colleague must consult with Legal

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 a phone or fax number. Pfizer may not discriminate against or exclude consumers from participating in programs based on the fact that consumers do not opt in or opt out of providing their Personal Information. The same applies to the subsequent selling of the consumer's Personal Information.

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

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.

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

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.

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 and 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 Global Privacy Office (GPO) to determine whether an authorization is necessary and whether the template available contains the appropriate legally required terms.

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

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
- 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 phone, 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 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.



Field Commercial Colleagues MAY:

- Offer *The Privacy Pledge* and *Patient Health Information Confidentiality Agreement* to the HCP as assurance of their intent to keep Personal Information and SPI, including PHI, confidential



Field Commercial Colleagues *MUST NOT*:

- Enter into a BAA individually or on Pfizer's behalf

FAQ: Business Associate Agreements

Q

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?

A

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 *Privacy Pledge* or *Patient Health Information Confidentiality Agreement* 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

Q

If an HCP insists that I sign a facility's Confidentiality Agreement, even after I sign and show the HCP Pfizer's *Privacy Pledge* and *Patient Health Information Confidentiality Agreement*, can I sign what the HCP wants me to sign?

A

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

Q

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?

A

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.

HCP Privacy

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 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

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

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](#).

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

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:

	<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
	<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

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<ul style="list-style-type: none">▪ The worldwide list of contact telephone numbers is available online at ITSupport.pfizer.com
	<p>Pfizer Colleagues MUST NOT:</p> <ul style="list-style-type: none">• 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.

Privacy Implications Outside of the United States

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

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 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](#).

The **California Consumer Privacy Act (CCPA)** went into effect on January 1, 2020 and is the closest thing to a [General Data Protection Regulation \(GDPR\)](#)-style comprehensive privacy law in the United States. Colleagues who are working with California residents should consult with Legal on how this law may apply to them.

Foreign Corrupt Practices Act

The **Foreign Corrupt Practices Act (FCPA)** is a U.S. federal law that prohibits corrupt or improper payments to non-U.S. government officials. The definition of “government official” includes any officer or employee of, or acting on behalf of, a non-U.S. government, including any department, agency, or 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 Orange 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 7 of *The Orange Guide*.

Chapter 4: Industry Codes and Guidance Related to Field Activities and Customer Interactions

Pharmaceutical Research and Manufacturers of America (PhRMA)

PhRMA represents the nation's leading biopharmaceutical research companies. The members of PhRMA believe that ethical relationships and behavior in all interactions with 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 U.S. Field Commercial Colleagues are highlighted below.

Code on Interactions with Healthcare Professionals (PhRMA Code)

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, access to patient care and services.

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

Guiding Principles for Direct-to-Consumer (DTC) Advertisements About Prescription Medicines

PhRMA also published *Guiding Principles on Direct-to-Consumer Advertisements About Prescription Medicines* to ensure that 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 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 5: Pfizer's Government Agreements Related to Field Activities and Customer Interactions

Pfizer's 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 Current Corporate Integrity Agreement

In 2018, Pfizer paid \$23.5 million to resolve civil claims by the U.S. Government and entered into a five-year CIA. The government alleged that Pfizer's donations to charitable foundations that provided copay assistance to patients did not comply with federal law.

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

- Annual compliance training for U.S. colleagues
- CEO, Chief Compliance Officer, Management, and other certifications
- Disclosure of certain violations of company policy or law
- Annual third-party reviews of certain systems, policies, processes, and transactions
- Policies and procedures regarding donations to Independent Charity Patient Assistance Programs, Pfizer's free drug program, and financial assistance in the form of cost-sharing, such as co-pay coupons or co-pay cards
- Monitoring of certain activities associated with donations to Independent Charity Patient Assistance Programs

Pfizer's State Attorneys General Agreements

Pfizer has entered into written agreements directly with several state Attorneys General, cities, and municipalities, which impose certain integrity obligations upon Pfizer. Because these agreements are entered into with individual states, cities or municipalities, the obligations can, and do, vary among agreements and may be more restrictive than applicable law.

Generally, these agreements include obligations related to promotional activities, incentive compensation, medical information, reprints, and physician payment posting. While some obligations exist only for a pre-specified time period, some of the obligations do not expire.

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

Chapter 6: Violations and Penalties

Violations and Penalties

The Office of Inspector General (OIG), the U.S. Department of Justice (DOJ), the Food and Drug Administration (FDA), state Attorneys General, and certain local governments aggressively enforce anti-kickback 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 7: 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 HCP transparency practices, refer to the [Global HCP/HCO Transparency Reporting Portal](#) or e-mail GlobalHCPTransparencyReporting@pfizer.com
- For more information on Open Payments, please see the [CMS website](#)

State Laws

- For information on relevant state law restrictions, refer to Section 7 of *The Orange Guide*
- To determine whether an HCP is licensed in Massachusetts, Minnesota, New Jersey or Vermont, Sales Representatives should consult the physician profile within Veeva CRM, and other colleagues should consult the [HCP Lookup Tool](#)
- Additional information on state law restrictions and other tools is available under the State Healthcare Law Compliance tab on [Policy Xchange](#) or in the Compliance tab in [MyPfieldNet](#)

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, 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 [U.S. Policy and Government Relations Site](#)

Pharmaceutical Research and Manufacturers of America (PhRMA)

- For more information about the 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 Orange Guide

Section 2

Pfizer Roles Governed by This Guide

Section 2

Pfizer Roles Governed by This Guide

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

Chapter 1: Introduction

The Orange Guide is designed specifically for U.S. Field Commercial Colleagues and Patient Support Roles to help guide them in the appropriate conduct of their responsibilities by providing an overview of the laws, regulations, and Pfizer policies and guidelines that govern their activities.

Field Commercial Colleagues and Patient Support Roles are Pfizer Colleagues whose primary responsibility is to interact with Pfizer customers, and they include:

- Field Commercial Colleagues
 - Sales Colleagues
 - Account Management Colleagues
 - Navigators
- Patient Support Roles (PSRs)
 - 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)

It is important to note that the differences between Field Commercial Colleagues and PSRs are driven not only by business needs, but also the need to mitigate inherent risks specific to each role in customer/patient interactions.

Therefore, while the laws and policies discussed in *The Orange Guide* apply to all Field Commercial Colleagues and PSRs, application of those laws and policies may differ depending on the colleague's specific role.

In addition, one should assume that *The Orange Guide* policy applies in the same manner to all Field Commercial Colleagues and PSRs, except where a unique policy or application of a policy to one of the roles is specifically identified.

Chapter 2: Pfizer Roles Governed by This Guide

This chapter provides an overview of the primary types of Field Commercial Colleagues and Patient Support Roles (PSRs), their responsibilities, and general guidance around their interactions. It also provides details around additional roles that are mentioned in *The Orange Guide*. Given the dynamic, ever-evolving nature of Pfizer's U.S. commercial model, it is possible there are Field Commercial roles not mentioned here, but that nevertheless are governed by the provisions of *The Orange Guide*.

Field Commercial Colleagues

Field Commercial Colleagues include Sales Colleagues, Account Management Colleagues, and Navigators.

Sales Colleagues

The term "Sales Colleagues" generally refers to those Field Commercial Colleagues, and their managers, who are charged with the promotion of Pfizer products to drive sales in assigned Accounts and with assigned targets.

Sales Colleagues engage, influence, and educate customers throughout the selling process.

Account Management Colleagues

The term "Account Management Colleagues" refers to Field Commercial Colleagues whose primary focus is calling on and developing productive relationships with key decision-makers at Organized Customers and important institutions or accounts. These will be referred to collectively as "Accounts" or "Organized Customers (OCs)" throughout *The Orange Guide*. Key decision-makers may include persons serving in an executive or administrative capacity at an Account, but would not typically include individual prescribing Healthcare Professionals (HCPs).

The responsibilities of an Account Management Colleague may vary to some extent across business units, but typically include:

- Analyzing and understanding the local environment, Account business, and aligned Pfizer priorities to create Account plans that identify mutually beneficial opportunities
- Identifying key C-suite and therapeutic service line leaders, administrative, and decision-making roles within a prioritized Account
- Developing and maintaining effective relationships with the aforementioned stakeholders
- Establishing and maintaining product access
- Coordinating with cross-functional colleagues who interact with prioritized Accounts, including sharing relevant insights to facilitate understanding of local market/customer dynamics

See the chart below for the main differences between Business Unit (BU) and Payer and Channel Access (PCA) Account Management Colleagues.

Navigators

The term "Navigator" refers to a commercial, non-sales role that serves as the therapeutic area/coordinating point of contact for assigned HCPs and their offices. This role is focused on educating customers, assessing and

understanding customer needs for information on Pfizer's products and related resources, and ensuring coordination in the provision of information and resources by Pfizer's various customer-facing roles.

Navigators may reach out to HCPs proactively to provide information, such as product or clinical data, Pfizer news, and other approved content. They may also engage in responses to queries or notifications received via [PfizerPro](#), e-mail, or during a live/virtual interaction. Furthermore, Navigators may have disease state-only conversations with HCPs, which do not require a transition to a brand indication/safety information close.

Navigator resources have a scientific look and feel, are objective in tone and language, and minimize promotional claims. Importantly, a Navigator will not "close the sale" or ask the HCP/office to change their prescribing behavior with the intention of generating additional prescriptions of Pfizer products.

Consistent with their distinct objectives, Navigators do not have sales performance goals or other incentives tied to HCP/office prescribing, which is commonly associated with Sales Colleagues. Instead, Navigator objectives are tied to customer engagement, responsiveness, understanding and meeting customer needs with respect to information and resources related to Pfizer products, and ensuring that HCP/office engagements with Pfizer and Pfizer resources are effective, efficient, and well-coordinated.

Typical Characteristics of Field Commercial Colleagues

Review the chart below for a high-level comparison of Sales Colleagues, Account Management Colleagues, and Navigators.

Typical Characteristics of Field Commercial Colleagues				
Factor	Sales Colleagues	Account Management Colleagues		Navigators
		Business Unit (BU)	Payer and Channel Access (PCA)	
Compensation	Typically, incentive-based or "IC" with a variable component, primarily based on Sales Credit and Quota, such as a product Rx sales target for assigned customers	<p>Typically, Global Performance Plan (GPP) compensation is based on the achievement of business goals and objectives</p> <ul style="list-style-type: none"> Sales Credit and Quota is not assigned, but some compensation may be tied to achievement of revenue targets achieved more broadly by the Account Manager's BU or region 	<ul style="list-style-type: none"> Typically, GPP compensation is based on the achievement of business goals and objectives 	<p>Typically, GPP compensation is based on the achievement of objectives tied to:</p> <ul style="list-style-type: none"> Customer engagement, responsiveness, understanding and meeting customer needs with respect to information and resources related to Pfizer products Ensuring that HCP/office engagements with Pfizer and Pfizer resources are effective, efficient, and well-coordinated

Typical Characteristics of Field Commercial Colleagues				
Factor	Sales Colleagues	Account Management Colleagues		Navigators
		Business Unit (BU)	Payer and Channel Access (PCA)	
Customers	Individual HCPs	Accounts include: <ul style="list-style-type: none"> • Health Systems • Integrated Delivery Networks (IDNs) • Medical Groups • Group Purchasing Organizations (GPOs) 	<ul style="list-style-type: none"> • Accounts include: • Health Systems • Integrated Delivery Networks (IDNs) • Medical Groups • Specialty and Retail Pharmacies • Health Plans, such as Health Maintenance Organizations (HMOs), Pharmacy Benefit Managers (PBMs), and other managed care entities • Employers • State Health Departments • County/City Health Departments • Purchasing groups • GPOs • Military Accounts (VA/DoD) • Medicare • Medicaid • Advocacy Groups/Coalitions 	<ul style="list-style-type: none"> • Individual HCPs and their offices
Resources (examples)	Promotional Visual Aid specific to a Pfizer biopharmaceutical product or a therapeutic area associated with a product	Resources are generally above brand and intended to: <ul style="list-style-type: none"> • Educate customers • Improve patient outcomes by promoting wellness, disease prevention, patient awareness, and high-quality health care 	<ul style="list-style-type: none"> • Branded and unbranded resources to educate customers about Pfizer products 	Branded and unbranded resources that: <ul style="list-style-type: none"> • Have a scientific look and feel • Are objective in tone and language • Minimize promotional claims
Engagements (examples)	<ul style="list-style-type: none"> • Face-to-face or virtual product discussions to educate HCPs about the benefits and risks Pfizer products may have for individual patients 	<ul style="list-style-type: none"> • Generally, C-suite level interactions to discuss matters relating to: • Health systems and medical groups • Population health • Collaborations 	<ul style="list-style-type: none"> • Account engagements, such as those with formulary decision-makers or P&T Committee members to discuss: • Rebates 	<ul style="list-style-type: none"> • Face-to-face or virtual discussions focused on: • Educating customers • Assessing and understanding customer needs for information on Pfizer's

Typical Characteristics of Field Commercial Colleagues				
Factor	Sales Colleagues	Account Management Colleagues		Navigators
		Business Unit (BU)	Payer and Channel Access (PCA)	
		<ul style="list-style-type: none"> Quality Engagements 	<ul style="list-style-type: none"> Clinical attributes and value of Pfizer medicines Contracting 	products and related resources <ul style="list-style-type: none"> Ensuring coordination in the provision of information and resources by Pfizer's various customer-facing roles
Roles (examples)	<ul style="list-style-type: none"> Sales Representatives <ul style="list-style-type: none"> Health & Science Representatives Health & Science Professionals Area Business Managers (ABMs) Regional Business Directors (RBDs) 	<ul style="list-style-type: none"> Key Account Managers (KAMs) HIT Account Directors Vaccines Account Managers (VAMs) Alternate Site Account Executives (ASAEs) Health System Account Executives (HSAEs) 	<ul style="list-style-type: none"> PCA Account Directors Vaccines Account Directors 	<ul style="list-style-type: none"> Navigators

Patient Support Roles

Pfizer is committed to supporting patient education and access to the medicines prescribed by HCPs in a manner consistent with all applicable laws and regulations. As part of this commitment, some Pfizer brands may offer brand-specific patient support and reimbursement activities that are carried out by field-based colleagues in PSRs.

Generally, PSRs are field-based, external-facing colleagues who can seek to facilitate patient access to Pfizer medicines and associated patient support programs in a limited manner after a Pfizer medicine is prescribed by a patient's HCP, and/or to educate about Pfizer products in a non-promotional fashion.

Although PSRs may fall under the commercial business and are external-facing roles, they are separate from the sales and marketing organization and are not intended to promote or generate demand for Pfizer products.



To ensure compliance with applicable laws, **Pfizer Patient Support Roles MUST:**

- Be made available in a non-discriminatory fashion to all appropriate HCPs and eligible patients
- Provide offerings 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



Pfizer Patient Support Roles *MUST NOT*:

- Provide substantial, independent value to HCPs, HCP practices, patients, or their caregivers

Descriptions for each of the different PSRs are included below and more information regarding role requirements can be found in Section 5 of *The Orange Guide*.

Access and Reimbursement Roles

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.

Field Access Specialists (FASs)

The FAS role generally functions like the FRM, but has additional approved permissions supported by considerations such as the uniqueness of the disease state, patient population, [therapeutic class](#), and current challenges to access.

The primary difference between the roles is that FASs are able to proactively outreach to hubs and HCPs related to individual case support, while FRMs typically provide reactive support.

Patient Access Coordinators (PACs)

PACs are colleagues who interface directly with patients and/or caregivers to provide limited reimbursement support.

For principles and additional guidance for Access and Reimbursement Roles, please see [General Principles and Guidance for Patient Support Role Activities](#) on PolicyPoint.

Advocacy and Patient Education Roles

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.

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. They also share contraindications, warnings, and other relevant product characteristics.

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

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.

Overview of Additional Pfizer Colleagues Discussed in This Guide

While *The Orange Guide* is designed specifically for U.S. Field Commercial Colleagues and PSRs, there are several other colleagues mentioned in this guide. Please read the description of each function or role below.

Marketing

Pfizer **Marketers** are headquarters (HQ)-based commercial colleagues with responsibility to educate or create educational resources for customers and other stakeholders, such as HCPs, patients, and/or payers in an unbranded and/or branded capacity.

Examples of content created by Marketers include materials focused on disease state, such as burden of disease, pathogenesis, and pathophysiology. Other content may be focused on a product profile, and include efficacy, safety, and mechanism of action information.

Furthermore, Marketers leverage multiple channels of deployment, such as peer-to-peer, personal promotion, non-personal promotion, and multi-channel marketing.

Medical

Field Medical Colleagues are field-based medical colleagues who are part of the BU medical team, and their general responsibilities include:

- Engaging in Pfizer-initiated non-promotional medical communications using materials approved by the relevant Medical Review Committee (MRC)
- Responding to unsolicited medical requests (UMRs) they receive or that are escalated to them by U.S. Medical Information (USMI) or the [Pfizer Triage App](#)
- Discussing service-based activities such as Pfizer-sponsored/collaborative research, and/or consultancies

There are several different types of Field Medical Colleagues, including:

Field Medical, Therapeutic Area Colleagues (FM, TA)

- Responsible for providing designated therapeutic area/product expertise
- Primary focus is on a broad range of medical customer segments and initiatives in an assigned territory, which is typically comprised of one or more U.S. states

Field Medical, Organized Customer Colleagues (FM, OC)

- Responsible for providing designated therapeutic area/product expertise
- Primary focus is on OCs, including, but not limited to, National Payers, Regional Payers, and Specialty Pharmacy Providers (SPPs) in an assigned territory, which is typically comprised of one or more U.S. states

Field Medical, Outcomes & Analytics Colleagues (FM, O&A)

- Responsible for:
 - Educating customers on the clinical and economic impact of Pfizer medicines and products
 - Helping to inform customer decision-making and improving population health through real-world data analyses, pharmacoeconomic analyses, outcomes evaluations, and medical presentations
- Primary focus is on OCs, including, but not limited to, Formulary Decision Makers, Payers, and SPPs in an assigned territory

Please note that the activities of Field Medical Colleagues are governed by [The Green Guide: Governance for Medical Activities](#).

Payer National Account Directors (NADs)

Payer NADs are responsible for optimizing formulary access for Pfizer medicines within Commercial, Medicare, Medicaid, and federal payers.

Government Affairs

Federal and State Government Relations Colleagues are Pfizer's registered lobbyists who are responsible for advancing the company's key policy priorities in Washington, D.C. and state capitals across the U.S. In this non-promotional role, they engage with U.S. government officials, state and federal elected officials, trade associations, and other key stakeholders. In the states, these colleagues are referred to as **Government Relations Directors**, or GRDs.

Chapter 3: General Guidance for Interactions Between Pfizer Customer-Facing Colleagues

The rules of engagement for Pfizer Colleagues from different customer-facing functions vary based on role and responsibility. Role-specific direction for specific engagement types and activities is discussed in the subsequent chapters. However, there are some key points that apply regardless of role or interaction type, as outlined below.

Collaborating Compliantly



Pfizer Colleagues MUST:

- Respect role-specific boundaries and responsibilities during internal and external [collaborations](#)
 - This includes when colleagues from different functions serve as members of a team or call on the same customers
- Ensure that all written communications between colleagues reflect these principles



Pfizer Colleagues *MUST NOT*:

- Act, or even give the impression they are acting, at the direction of another function
- Discuss materials not approved for their role or leverage those resources to access customers

Subject Matter Expert (SME) Introduction Calls

In an effort to foster collaboration and introduce customers to cross-functional colleagues, Sales Colleagues and Navigators are able to schedule and lead SME Introduction Calls. SME Colleagues include Account Management, Medical, and Access and Reimbursement Colleagues.



These *SME Introduction Calls ARE intended to*:

- Introduce customers to cross-functional colleagues who may have relevant expertise and provide customers with a more comprehensive understanding of their roles



These *SME Introduction Calls ARE NOT intended to*:

- Be a substantive discussion of specific disease states, products, or HCP queries, so that the separation of roles and resources can be maintained

Practical and appropriate consideration should be given to the planning of SME Introduction Calls, as not all customers will have a reason to receive SME Introduction Calls and they may not need to be introduced to all SMEs.

Customers should be mutually agreed upon based on customer assessment and should not include customers with whom SMEs have an existing relationship. The ultimate decision lies with the SME, as they must ensure that an introduction to the customer is consistent with their objectives and criteria for customer interactions.

Guidance from each function on who might be an appropriate customer to introduce to a SME has been provided in the *SME Introduction Call Overview and Introduction Talking Points for SMEs* on iLearn.

Read below for additional role-specific guidance regarding SME Introduction Calls.



Sales Colleagues and Navigators *MAY*:

- Share business cards or leave-behind pamphlets with team members' names and contact information, if approved and available for their Business Unit (BU), following the SME Introduction Call



Sales Colleagues and Navigators *MUST NOT*:

- Detail or discuss product or disease state content during an SME Introduction Call
- Schedule SME Introduction Calls more than once per year
- Schedule SME Introduction Calls to use cross-functional SMEs to drive a commercial objective

	<ul style="list-style-type: none">Proactively position themselves as a gatekeeper for triage to SMEs, as customers may reach out independently to SMEs without going through the Sales Colleague or Navigator
✓	<p>SMEs MAY:</p> <ul style="list-style-type: none">Only use standardized descriptions relevant to their role and BU to ensure consistency in how each role is presentedShare business cards or leave-behind pamphlets with team members' names and contact information, if approved and available for their BU, following the SME Introduction Call
✗	<p>SMEs MUST NOT:</p> <ul style="list-style-type: none">Discuss any of their resources or respond to substantive inquiries during an SME Introduction Call<ul style="list-style-type: none">If a customer asks a specific question or is seeking an in-depth discussion, the SME should set up a separate time to meet one-on-one with the customer or have a one-on-one conversation with the customer after the Introduction Call concludes and other Pfizer Colleagues have left the meeting

It is also important to note that aside from the SME Introduction Calls that are only allowed at a maximum of once a year, it is acceptable to have an “ad hoc” introductory meeting if a Pfizer Colleague who is either new to Pfizer, a territory, or Therapeutic Area (TA), requests to be introduced to an HCP by their cross-functional colleague.

Chapter 4: Guidance for Interactions Between Sales and Account Management Colleagues

While Sales Colleagues and Account Management Colleagues are both considered Field Commercial Colleagues, their roles and responsibilities are different. Accordingly, there is guidance that Sales and Account Management Colleagues must follow regarding internal and external interactions.

Guidance for Internal Interactions Between Sales Colleagues and Account Management Colleagues

Collaborating Compliantly

Internal collaboration, both individually and on a group level, must respect role-specific boundaries and responsibilities. Where Sales Colleagues and Account Management Colleagues serve as members of an Account Team, their activities, similarly, should be aligned to role responsibilities. Both colleagues may share [aggregated](#) customer insights, logistical information about the Account, including contact lists, geography, and region-level dynamics.

While high-level discussion of strategies and general goal progression may be appropriate, detailed tactical project plans for each function should not be shared. Importantly, neither function should act, or even give the impression they are acting, at the direction of the other. Sales Colleagues may not discuss materials only approved for Account Management or leverage those resources to access customers. Similarly, Account Management Colleagues may not use resources approved only for Sales Colleagues.

All written communications between Sales Colleagues and Account Management Colleagues should reflect these principles. Any rewards and recognition for Account Team support must only reflect contributions and performance within the team member's remit.

Account Team Meetings

Agenda-driven attendance must be followed for all or relevant portions of Account Team Meetings. Standing meetings with all cross-functional attendees invited should be avoided. Strategic sales discussions designed to focus on driving prescription volume should exclude Account Management Colleagues. Similarly, Sales Colleagues should not be in attendance where the focus is on [contracting](#), rebates, or pricing-related content. All meeting notes or minutes capturing follow-up actions should clearly note role-specific accountability.

Guidance for External Interactions Between Sales Colleagues and Account Management Colleagues

Introductory Meetings

Outside of introductory meetings, Sales and Account Management joint external interactions should be infrequent and the program or materials to be discussed must be Review Committee (RC)-approved for joint customer interaction.

No function is permitted to deliver, with other functions present, any resources or programs that have not been approved for use by, or in the presence of, the other function.

In addition, Account Management Colleagues must be diligent to avoid the perception that their roles act at the direction of Sales, or that the Company's value-added resources are being offered as an inducement or reward to a customer for prescribing or recommendation of a Pfizer product.

Subject Matter Expert (SME) Introduction Call

Sales Colleagues and Navigators are able to schedule and lead SME Introduction Calls with Account Management Colleagues.

Please refer to Chapter 3 in this section, which contains the general guidance for SME Introduction Calls, and for more specific role guidance, refer to the *SME Introduction Call Overview and Introduction Talking Points for SMEs* on iLearn.

Chapter 5: Guidance for Interactions Between Field Commercial Colleagues and Field Medical Colleagues

Field Medical Colleagues are non-promotional roles that are focused on the medical needs of HCPs, managed care, Health Systems, and other key customers. The objective of these interactions must be non-promotional in nature. In other words, they must not be conducted with a goal of obtaining prescriptions for a Pfizer product.

However, as described in other sections of this guide, there are limited instances when Field Medical Colleagues may engage in activities governed by promotional standards, such as conducting speaker training, participating in or delivering formulary presentations, giving payer value proposition presentations, or certain other Review Committee (RC)-approved presentations.

In addition, interactions between Field Commercial Colleagues and Field Medical Colleagues must be limited to preserve the independence of Field Medical Colleagues.

Field Commercial Colleagues may not, nor should they appear to, direct the activities of Field Medical Colleagues. For this reason, internal interactions between Field Commercial Colleagues and Field Medical Colleagues and external interactions between such colleagues and Pfizer customers must be carefully considered to ensure that the content and context of the medical activity is appropriate.

Furthermore, it is important to note that Sales and Account Management Colleagues will interact with Field Medical Colleagues differently because of their responsibilities. More specifically, it is expected that Field Medical, Outcomes & Analytics (FM, O&A) Colleagues, in their role working as part of a Health System Integrated Account Team (IAT), have reason to interact more frequently with Account Management Colleagues for purposes of internal Account Team coordination. There is more flexibility in the level of appropriate internal interaction that can take place between FM, O&A Colleagues and Account Management Colleagues because of the following dynamics:

- Account Management Colleagues are not eligible for incentive compensation that is based on prescribing activity
- FM, O&A Colleagues engage in more limited proactive and responsive medical communications compared with other Field Medical Colleagues

Read below for specific guidance regarding internal and external interactions between Field Commercial and Field Medical Colleagues.

Guidance for Internal Interactions Between Field Commercial Colleagues and Field Medical Colleagues

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



However, it is important to note that in general, **Field Medical Colleagues MUST NOT** participate in internal business meetings when the primary focus is:

- Sales strategy
- Traditional managed care contract negotiation

- Rebates
- Other issues relating to pricing of Pfizer products

Objectives, Plans, and Customer Insights

Field Medical Colleagues **MUST** align field medical activities with Business Unit (BU) PCA Medical objectives.



In addition, **Field Medical Colleagues MAY:**

- Seek to understand the business goals and objectives for an Organized Customer (OC) so that they can develop fully informed medical strategies
- Share customer insights with Field Commercial Colleagues, but such insights must be in aggregate to a territory, Account, specialty, medical group, academic center, or health system
- Seek limited input from Field Commercial Colleagues on medical priorities for HCPs in aggregate, but not regarding any particular HCP



Field Medical Colleagues MUST NOT:

- Tie field medical activities to commercial Account metrics, sales targets, or financial objectives
- Take directions from Field Commercial Colleagues regarding medical activities
- Share customer insights with Field Commercial Colleagues that are specific to any particular HCP's prescribing of Pfizer products or Unsolicited Medical Requests (UMRs)
- Engage with Field Commercial Colleagues for the purpose of jointly determining medical objectives
- Share insights regarding unapproved uses of Pfizer products, unapproved products, or information about responses provided to HCPs who have made UMRs for information
- Share detailed work plans or provide information to Field Commercial Colleagues about ongoing clinical trials, consultancies, or other medical service-based activities

Customer Lists



Field Medical Colleagues MAY:

- Share their assigned customer lists with Field Commercial Colleagues



Field Commercial Colleagues MAY:

- Share their assigned customer lists with Field Medical Colleagues
- Offer suggestions to Field Medical Colleagues about adding HCPs/Accounts to their contact list

- However, the Field Medical Colleagues will work with their leaders and apply pre-determined medical criteria and make an independent determination regarding whether the HCPs/Account are appropriate to add to the list

Attendance at Field Commercial Meetings



Field Medical Colleagues MAY:

- Conduct product or disease training, using RC-approved materials
- Provide general information about medical objectives or an overview of Medical Review Committee (MRC)-approved topic(s) or materials
- Share aggregated Health System insights, information about geography or regional level dynamics, or seek feedback
 - For example, information can be shared about gaps in HCP understanding about a disease or treatment, such as general categories of medical inquiries; however, specific HCP or Health System information discussed must be in aggregate and not specific to any particular HCP's prescribing/use of Pfizer products



Field Medical Colleagues MUST NOT:

- Discuss the details of MRC-approved content or share actual MRC-approved materials with Field Commercial Colleagues, unless specifically approved for use in the presence of commercial colleagues



Field Commercial Colleagues MAY:

- Invite Field Medical Colleagues to participate in internal business meetings such as district, regional, or national sales meetings, such as Plan of Action (POA) meetings, on a limited basis and when there is a legitimate business rationale
- Invite Field Medical Colleagues to organized customer planning meetings and Health System planning meetings of a cross-functional group of colleagues who interact with the same Account
 - Examples include IAT, Account Leadership Team or Account Coordination Team (ALT/ACT), and Rare Organized Customer Connection (ROC)



Field Commercial Colleagues MUST NOT:

- Ask Field Medical Colleagues to share any type of off-label information about a Pfizer product or information about unapproved Pfizer products
- Seek assistance from Field Medical Colleagues with overcoming barriers to customer prescribing/use of Pfizer products
- Request information from Field Medical Colleagues about the substance of responses provided to customers who have made UMRs for information

	<ul style="list-style-type: none"> • Share HCP-specific prescribing data with Field Medical Colleagues • Request information about ongoing clinical trials or other research-related activities from Field Medical Colleagues • Ask for MRC materials or seek to influence the way in which medical content is developed or delivered to HCPs or other customers
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Organized Customer Planning and Coordination

✓	<p>Account Management Colleagues MAY meet with FM, O&A Colleagues regarding the following:</p> <ul style="list-style-type: none"> • Account prioritization and planning <ul style="list-style-type: none"> – Health System planning and coordination discussions must focus on the exchange of information needed to achieve independent commercial and medical objectives – Account Management Colleagues MUST NOT attempt to direct or determine medical activities • Customer needs assessments • Large project or collaboration agreement development and planning • Non-product medical activities, such as disease presentations, health trend/channel presentations, and quality of care presentations • Account-level dynamics such as: <ul style="list-style-type: none"> – Utilization of products in a specific therapeutic area – Quality metric gaps or goals – Key events, such as the placement of new products on formulary, and other information relevant to respective medical and commercial Account objectives, like benefit design and adherence rates
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✗	<p>If an OC/health system does not have an assigned Field Medical Lead, Account Management Colleagues MAY:</p> <ul style="list-style-type: none"> • Work directly with Field Medical, Organized Customer (FM, OC) or Field Medical, Therapeutic Area (FM, TA) Colleagues to discuss field medical support for an OC or particular Health System <ul style="list-style-type: none"> – The FM, TA Colleague will help to ensure the OC's medical needs are met either directly, or by connection to the FM, OC or FM, O&A Colleague best positioned to support the request • Meet with FM, OC or FM, TA Colleagues regarding Account planning, customer needs assessments, and disease state presentations
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Requests From Customers to Discuss Research


✓	<p>Field Medical Colleagues MAY:</p> <ul style="list-style-type: none"> • Evaluate customer requests to discuss research together with other Medical Colleagues as appropriate
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	<p>Field Medical Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none">Engage in detailed discussion with Field Commercial Colleagues about ongoing research-related activities
	<p>Field Commercial Colleagues <i>MAY</i>:</p> <ul style="list-style-type: none">Refer HCP/Health System inquiries regarding potential involvement in Pfizer clinical/non-interventional research to a Field Medical Colleague via the Pfizer Triage app if the customer has specifically inquired about research opportunities with Pfizer<ul style="list-style-type: none">The decision to engage with the HCP is within the complete discretion of the Field Medical Colleague, and Field Commercial Colleagues must not attempt to influence this decision
	<p>Field Commercial Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none">Ask to engage in detailed discussion with Field Medical Colleagues about ongoing research-related activities

Requests for Field Medical to Provide Supplemental Speaker Training


	<p>Field Medical Colleagues <i>MAY</i>:</p> <ul style="list-style-type: none">Discuss promotional content and questions with a contracted promotional HCP speaker who asks to meet to discuss RC-approved speaker program content or has a question related to the content, after first confirming with the speaker that such a request has been made
	<p>Field Commercial Colleagues <i>MAY</i>:</p> <ul style="list-style-type: none">Contact a Field Medical Colleague if a contracted promotional HCP speaker asks to meet with a Pfizer Medical Colleague to discuss RC-approved speaker program content or has a question related to the contentContact the Field Medical or BU Medical Colleague to request follow-up with a speaker if after holding a speaker program, the colleague thinks a speaker needs assistance from a Field Medical or Headquarters (HQ) BU Medical Colleague in order to effectively or compliantly deliver approved speaker program content


Planning for Joint External Meetings With Customers

	<p>Field Medical and Field Commercial Colleagues MAY:</p> <ul style="list-style-type: none"> • Meet internally to plan for permissible external joint meetings with HCPs, Health Systems, or other customers to share logistical information and meeting agendas • Contact each other to <ul style="list-style-type: none"> – Request a one-time introduction to an HCP or Health System, as described above and in the Subject Matter Expert (SME) Introduction Call section – Discuss logistical information about offices/Accounts – Resolve scheduling issues
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Additional Role-Specific Guidance for Internal Interactions Between Field Commercial Colleagues and Field Medical Colleagues

In addition to the general guidance above regarding internal interactions with Field Sales Colleagues, please review the following role-specific guidance.

	<p>FM, O&A Colleagues working with Accounts MUST independently design and draft all medical objectives.</p> <p>In addition, FM, O&A Colleagues working with Accounts MAY:</p> <ul style="list-style-type: none"> • Provide input in the Key Account prioritization process or the overall Pfizer Account plan for a Health System • Document medical objectives in the overall Account plan, but must keep them separate from any commercial objectives and prominently mark them as medical objectives • Serve as the primary Field Medical Colleagues, along with FM, OC, who handle the medical needs of health systems, managed care, and other OCs • Work with FM, OC Colleagues, if applicable, to determine when another Field Medical Colleague's assistance is needed with a particular OC and will coordinate the plans
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	<p>FM, OC Colleagues MAY:</p> <ul style="list-style-type: none"> • Serve as the primary Field Medical Colleagues, along with FM, O&A Colleagues, who handle the medical needs of health systems, managed care, and other OCs • Work with FM, O&A Colleagues, if applicable, to determine when another Field Medical Colleague's assistance is needed with a particular OC and will coordinate the plans
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Guidance for External Interactions Between Field Commercial Colleagues and Field Medical Colleagues

In general, Field Medical and Field Commercial Colleagues must engage with HCPs separately and independently when conducting their respective activities. However, Field Medical and Field Commercial Colleagues may meet together with HCPs or other customers in appropriate circumstances as described here.

Introductory Meetings

✓	<p>Field Commercial Colleagues and Field Medical Colleagues MAY:</p> <ul style="list-style-type: none"> • Ask each other for an introduction to an HCP/Account <ul style="list-style-type: none"> – The purpose of such meetings must be for introduction only
✗	<p>Field Commercial Colleagues and Field Medical Colleagues MUST NOT:</p> <ul style="list-style-type: none"> • Use introductory meetings to hold a substantive joint meeting with the HCP/Account, unless it is otherwise permitted



Subject Matter Expert (SME) Introduction Call

Sales Colleagues and Navigators are able to schedule and lead SME Introduction Calls with Field Medical Colleagues.

Please refer to Chapter 3 in this section, which contains the general guidance for SME Introduction Calls, and for more specific role guidance, refer to the *SME Introduction Call Overview and Introduction Talking Points for SMEs* on iLearn.




Split-Adjacent Meeting Time

✓	<p>In instances where an HCP/Health System or other customer limits the meeting time dedicated to industry, Field Commercial Colleagues and Field Medical Colleagues MAY:</p> <ul style="list-style-type: none"> • Schedule one Pfizer meeting with the HCP/Account but must then conduct consecutive independent discussions with the customer, outside the presence of the other, unless otherwise permitted to hold a joint meeting
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FAQ: Split-Adjacent Meeting Time	
	<p>I am a Sales Colleague and I have a lunch and learn tomorrow in a large room at an HCP office. The FM, TA has a scientific meeting scheduled for 1 pm, but my lunch and learn may run over. Is it ok if the FM, TA meets with an HCP at one table in the break room, while I meet with another HCP at a separate table in the same room?</p>
	<p>No. Colleagues must conduct consecutive independent discussions with the customer, outside the presence of the other. Being in different parts of the same room does not constitute “outside the presence.”</p>

Organized Customer Meetings

FM, OC and FM, O&A Colleagues are the primary Field Medical Colleagues who serve the medical needs of health systems, managed care, and other organized customers.

	<p>FM, OC and FM, O&A Colleagues MAY:</p> <ul style="list-style-type: none"> Join Account Management Colleagues at needs assessment meetings with Health Systems, where the intent of the meeting is to explore potential collaborations or projects between Pfizer and the Health System Join Account Management Colleagues at periodic meetings with Health Systems to discuss the status of collaboration activities conducted pursuant to an agreement under which both medical and commercial activities are being executed
	<p>Sales and Account Management Colleagues MAY:</p> <ul style="list-style-type: none"> Forward a formulary presentation request directly to the FM, O&A or FM, OC Colleague assigned to the Health System <ul style="list-style-type: none"> If an OC/health system does not have an assigned Field Medical Lead, they may work directly with other Pfizer Field Medical Colleagues to coordinate Formulary Committee presentations Attend Pfizer-initiated Formulary Committee presentations given by Field Medical Colleagues (generally, FM, O&A) because they are governed by promotional standards
	<p>Sales and Account Management Colleagues MUST NOT:</p> <ul style="list-style-type: none"> Attend a formulary presentation if a Formulary Committee requests in advance that certain information be provided that is off-label or unapproved for promotional use

Commercial Attendance at Non-Product Presentations Given by Field Medical Colleagues

✓	<p>FM, OC and FM, O&A Colleagues MAY:</p> <ul style="list-style-type: none"> Occasionally deliver certain non-product presentations to Health Systems categorized as Skills-Based Learning (SBL) resources, such as <i>Older Adult Sensitivity Training</i> or <i>The Art of Active Listening</i>
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	<p>Field Commercial Colleagues MAY or MAY NOT:</p> <ul style="list-style-type: none"> Attend depending on the nature of the content <ul style="list-style-type: none"> The RC or MRC determines the appropriate customer audience and may set restrictions on which Pfizer Colleagues may attend the presentation For example, the RC or MRC may prohibit attendance by Sales Colleagues or may place other restrictions on the attendance of Field Commercial Colleagues
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Customer Data Evaluation (CDE) Development and Presentations

FM, O&A Colleagues MUST conduct [Customer Data Evaluations \(CDEs\)](#) independently and without the involvement of Field Commercial Colleagues.

✓	<p>In addition, FM, O&A Colleagues MAY:</p> <ul style="list-style-type: none"> Ask Account Management Colleagues to provide input in order to identify Health Systems for which a CDE project may be useful to the Health System and patients Share certain CDE Executive Summaries with Account Management Colleagues after obtaining approval
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✗	<p>FM, O&A Colleagues MUST NOT:</p> <ul style="list-style-type: none"> Share detailed CDE results with Field Commercial Colleagues Request detailed CDE results
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✓	<p>Account Management Colleagues MAY:</p> <ul style="list-style-type: none"> Inform the FM, O&A Colleague that a Health System expressed an interest in working with Pfizer to evaluate its data Attend meetings with Health Systems where a FM, O&A Colleague presents a high-level description of a proposed CDE or an Executive Summary of a completed CDE if approved in advance by the FM, O&A Colleague's Team Leader
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Account Management Colleagues MUST NOT:

- Attempt to influence the decision to conduct a CDE, as FM, O&A Colleagues must make an independent medical determination
- Attend meetings with Health Systems when the subject of the meeting includes detailed discussion of CDEs, such as the development of the data analysis plan, implementation plans, or detailed results

FAQ: Medical and Commercial Interactions
Q

I am a Key Account Manager (KAM), and one of my Health System customers has provided me with spreadsheets that contain data on a particular disease state related to that Health System, which includes an affiliated hospital. The Health System wants me to assist in analyzing the data in order to assist them in better understanding the impact this disease has on hospital admissions. Some of this data is high-level, such as total number of hospital admissions with a specific disease broken down by various common demographic categories: gender, age cohorts, etc. One spreadsheet inadvertently contains a list of specific patients, which does not include patient names but does include length of admission, diagnosis, etc. Can I, as a KAM, receive this data from the Health System and what analysis can I perform with it?

A

Generally, no. In every situation where the Health System wishes to provide patient data for analysis, the Field Commercial Colleague should refer their FM, O&A Colleague directly to the Health System to determine what sort of data analysis may be appropriate. While in some situations Field Commercial Colleagues may perform high level analysis based on publicly available information, such situations are limited and need the approval of the relevant Product Attorney. Under no circumstance may any Pfizer Colleague receive patient-specific information unless appropriate authorizations are in place, and even then, only Pfizer Medical Colleagues will be able to receive such information. In the event a Pfizer Colleague finds themselves in possession of such information in error, they must consult Legal immediately.

Q

A Health System customer wants assistance in development of an Integrated Delivery Network (IDN)-specific guideline and treatment pathway around a specific disease state. Can Pfizer Field Medical and Field Commercial Colleagues work with the Health System on this project?

A

If there are branded or unbranded RC-approved resources, such as an independent third-party developed criteria or recommendations for treatment of a disease state, consistent with product labeling, Field Medical and Field Commercial Colleagues may utilize them with the Health System. However, if the goal of the project is to support the development of treatment guidelines, consult with Legal on how best to proceed.

Dissemination of the Medical Resources Brochure

✓	<p>Field Medical Colleagues MAY:</p> <ul style="list-style-type: none"> E-mail a PDF of their individualized brochure to the relevant Field Commercial Colleague
✓	<p>Field Commercial Colleagues MAY:</p> <ul style="list-style-type: none"> Provide HCPs with a copy of the approved Medical Resources brochure, which is intended to inform them about various Pfizer Medical Resources and how to access them, and includes contact information to enable the HCP to contact U.S. Medical Information (USMI) or a Field Medical Colleague directly Provide HCPs with a copy of the approved Medical Resources brochure in response to a general inquiry about Medical Resources at Pfizer or if an HCP prefers to follow up on their own rather than submitting an inquiry through the Pfizer Triage app E-mail the Medical Resources brochure to an HCP with a brief e-mail
✗	<p>Field Commercial Colleagues MUST NOT:</p> <ul style="list-style-type: none"> Copy the Field Medical Colleague when sending an HCP the Medical Resources brochure via e-mail

Handling of Unsolicited Medical Requests (UMRs)

Medical requests triaged to Field Medical or USMI must be unsolicited and may not be prompted by Pfizer Colleagues in any way. The Pfizer Triage process has incorporated mechanisms to confirm that the HCP's request was **unsolicited**, and that the HCP has expressed interest in receiving a Medical response.

✓	<p>Field Commercial Colleagues MUST:</p> <ul style="list-style-type: none"> Handle a UMR from an HCP that is a designated topic by triaging it to an FM, TA via the Pfizer Triage app <ul style="list-style-type: none"> Triage can be either synchronous (real-time via Medical OnDemand) or asynchronous Handle a UMR from an HCP that is not a designated topic by triaging it to USMI via the Pfizer Triage app <ul style="list-style-type: none"> The same approach must also be taken if the HCP wants a follow-up response in writing Leave the virtual or physical room to allow for a medical-to-medical interaction during real-time triages <ul style="list-style-type: none"> Colleagues should complete their business before triaging so they can leave and not return to try to pull through the Medical engagement, such as asking the HCP to prescribe based on the information obtained
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	<ul style="list-style-type: none"> • Avoid discussing the substance of the interaction with the HCP, or with the FM, TA, following the scientific discussion • Only proactively mention the availability of the new Pfizer Triage app one time for general awareness of the new capability for HCPs to receive a response to their UMRs in real time <ul style="list-style-type: none"> – When introducing this capability, colleagues should not solicit questions or suggest that they can direct the activities of other colleagues
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✗	<p>Account Management Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none"> • Contact FM, O&A Colleagues to respond to UMRs, including requests from Health System Accounts
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FAQ: Communicating Clinical Trial Results	
Q	<p>If I suspect that an HCP would be interested in learning about results from a clinical trial looking at a new use for one of Pfizer's products, am I allowed to ask a Field Medical Colleague to speak to that physician about the trial results?</p>
A	<p>No. Colleagues, including Field Medical Colleagues, are not permitted to communicate the results of an unapproved or off-label study to an HCP at the request of a commercial colleague, nor may they encourage the HCP to ask about unapproved uses. Pfizer Medical Colleagues can provide off-label information to an HCP in response to a specific unsolicited question seeking such information, as set forth in The Green Guide. Field Commercial Colleagues may never solicit questions about unapproved products or uses, whether explicitly or implicitly. Any unsolicited request for off-label information received by a Field Commercial Colleague must be either handled by triaging to an FM, TA via the Pfizer Triage app when the UMR is on a designated topic, or to USMI when it is not on a designated topic and/or the HCP wants a follow-up response in writing.</p>

Chapter 6: Guidance for Interactions Between Sales Colleagues/Account Management Colleagues and Patient Support Roles

Patient Support Roles (PSRs) seek to support access to, reimbursement of, and education about Pfizer products in a non-promotional and appropriate manner.


Because they are non-promotional, Patient Support Role interactions with Sales and Account Management Colleagues can pose significant risks to Pfizer if executed inappropriately.

	<p>At a high level, Sales and Account Management Colleagues Interactions MUST:</p> <ul style="list-style-type: none">• Be limited in frequency• Be limited to logistical discussions and background discussions about HCPs on which PSRs call
	<p>Sales and Account Management Colleagues Interactions MUST NOT:</p> <ul style="list-style-type: none">• Include discussion of patient-specific cases, HCP prescribing behavior, or sales messaging and strategy

Read below to learn more about how Sales and Account Management Colleagues may interact with PSRs in order to ensure appropriate interactions.

Guidance for Internal Interactions Involving Sales and/or Account Management Colleagues and Access and Reimbursement Roles (FRMs/FASs/PACs)

Responsibilities for Customers/Stakeholders

	<p>Access and Reimbursement Roles MUST:</p> <ul style="list-style-type: none">• Be independent from sales-related, product demand generation activities and influence• Base the decision to engage on the customer's or patient's need for the information they can provide• Make activities available in a non-discriminatory fashion to all appropriate HCPs and eligible patients, unrelated to the volume or value of business generated by any HCP and any decision by a patient to use a Pfizer medicine
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Access and Reimbursement Roles *MUST NOT*:

- Engage in clinical and off-label discussions
- Seek to engage HCPs or the patients, and patients' caregivers, of HCPs practicing in specialties excluded from Sales or Account Management Colleagues' call lists, as those specialties are unlikely to prescribe the relevant product for on-label purposes

Access and Reimbursement Roles must not be provided sales or financial performance metrics, except as described below.



Access and Reimbursement Team Lead *MAY*:

- In consultation with Compliance, 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 Field Reimbursement Manager (FRM) or Field Access Manager (FAS) contact list
 - This data may be used to determine whether Pfizer products are being prescribed, whether they are being prescribed for on- or off-label uses, and the eligible patient population seen by the HCP office, with the goal of ascertaining the HCP or office's need for the approved information that the FRM or FAS is permitted to share



Access and Reimbursement Team Lead *MUST NOT*:

- Use HCP or office prescribing and diagnosis data to:
 - Reward high-prescribing HCPs with FRM or FAS engagement
 - Target high prescribers of a competitor product for conversion of patients to a Pfizer product



Sales and Account Management Colleagues *MAY*:

- Provide the relevant Access and Reimbursement Colleague's contact information to HCPs and offices who request it
- Use the Pfizer Triage app to notify Access and Reimbursement Roles if they learn about an access and reimbursement issue with an existing patient case in an unsolicited manner
 - For example, if an HCP asks a Sales Colleague about the status of an ongoing benefit investigation, the Sales Colleague may triage the inquiry to the FRM via the Pfizer Triage app
 - The referring colleague should only use the Triage app, not e-mail, text, chat, etc.
 - The referring colleague should not collect or transmit any of the patient's [protected health information](#)
- Sales Colleagues/Account Managers should not solicit queries on access and reimbursement issues from customers

Sales and Account Management Colleagues *MUST*:

- Send the following requests to their Area Business Manager (ABM) first:
 - Subject Matter Expert (SME) Introduction Call
 - Inclusion on FRM or FAS call and contact lists

	<ul style="list-style-type: none"> This allows for proper coordination with the appropriate Access and Reimbursement Regional Director and is needed to ensure capacity is available for a good customer experience
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✗	<p>Sales and Account Management Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none"> Send the following requests directly to FAS or FRM Colleagues: <ul style="list-style-type: none"> SME Introduction Call Inclusion on FRM or FAS call and contact lists Direct or influence Access and Reimbursement Roles to engage with particular customers
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Attendance at Field Commercial Meetings

✓	<p>Access and Reimbursement Roles <i>MAY</i>:</p> <ul style="list-style-type: none"> Participate in internal Sales and Account Management teleconferences or meetings, on an as-needed agenda-driven basis, with approval from the relevant Access and Reimbursement Team Lead <ul style="list-style-type: none"> Meetings include regional and district sales meetings, but only for the purpose of providing or receiving information relevant to the Access and Reimbursement Colleague Attendance must only be for the part of the internal meeting that is directly related to the purpose of their role, such as attending a regional sales meeting to discuss reimbursement and patient access issues
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✗	<p>Access and Reimbursement Roles <i>MUST NOT</i>:</p> <ul style="list-style-type: none"> Attend meetings, or meeting portions, which focus on sales or promotional strategy, prescription volume, or sales performance
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✓	<p>In addition to the guidance above, FRMs and FASs <i>MAY</i>:</p> <ul style="list-style-type: none"> Present at the meetings described above to provide Sales Colleagues and Account Management Colleagues an overview of the relevant payer landscape for a given product or region
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Planning for Joint External Meetings With Customers

✓	<p>Access and Reimbursement Roles and Sales and/or Account Management Colleagues <i>MAY</i>:</p> <ul style="list-style-type: none"> Exchange logistical information such as key office contact/staff information and visitation requirements for pharmaceutical representatives for permitted adjacent meetings
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Access and Reimbursement Roles and Sales and/or Account Management Colleagues *MUST NOT*:

- Discuss sales objectives, strategy, or performance during this pre-meeting

Guidance for External Interactions Involving Sales and/or Account Management Colleagues and Access and Reimbursement Roles (FRMs/FASs/PACs)

Educating HCPs and Patients About Access and Reimbursement Roles



Sales Colleagues or Account Management Colleagues *MUST*:

- Remember that communication about the availability of Access and Reimbursement Roles can raise significant legal concerns if such communication seeks to induce the prescription, purchase, or referral of Pfizer products
- Educate HCPs and their offices about Access and Reimbursement Roles using only Review Committee (RC)-approved materials and talking points to help ensure compliance



Sales Colleagues or Account Management Colleagues *MUST NOT*:

- Promote the availability of Access and Reimbursement Roles as a reason to prescribe Pfizer products
- Use Access and Reimbursement Roles to differentiate Pfizer products from competitor products or suggest that Access and Reimbursement Role activities provide substantial independent value to any HCP, patient, or caregiver
- Use Access and Reimbursement Roles as levers to gain access



Access and Reimbursement Roles *MUST NOT*:

- Make the availability of offerings contingent on providing access to other Pfizer Colleagues


Introductory Meetings



FRM/FAS Colleagues and Sales and/or Account Management Colleagues *MUST*:

- Only hold joint customer meetings for one-time, in-person introductions
 - Such meetings must be for introduction purposes only and must not be used to hold a substantive joint meeting with the customer

	<ul style="list-style-type: none">– If, during a joint introductory meeting, the HCP or office staff initiates a product-related discussion with the Sales Colleague or Account Manager, the FRM or FAS Colleague should excuse themselves– Similarly, the Sales Colleague or Account Manager should excuse themselves if the HCP or office staff initiates a discussion with the FRM or FAS Colleague, such as a discussion about patient access with an FRM• Always prominently disclose that Access and Reimbursement Roles are a Pfizer Colleague or contracted on behalf of Pfizer, and must never state or imply that they are independent of Pfizer
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	<p>FRM/FAS Colleagues and Sales and/or Account Management Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Use introductory meetings, as described above, to hold a substantive joint meeting with the customer
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Subject Matter Expert (SME) Introduction Call


Sales Colleagues and Navigators are able to schedule and lead SME Introduction Calls with FRM and FAS Colleagues.

Please refer to Chapter 3 in this section, which contains the general guidance for SME Introduction Calls, and for more specific role guidance, refer to the *SME Introduction Call Overview and Introduction Talking Points for SMEs* on iLearn.

Split-Adjacent Meeting Time

	<p>In instances where an HCP or institution limits access by pharmaceutical companies, FRM/FAS Colleagues and Sales and/or Account Management Colleagues MAY:</p> <ul style="list-style-type: none">• Schedule one Pfizer meeting with the customer, but should use the allocated time to conduct consecutive, separate, independent discussions with the customer outside the presence of the other Pfizer Colleagues
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Promotional Interactions and Meetings


	<p>Access and Reimbursement Roles MUST NOT:</p> <ul style="list-style-type: none">• Attend external/customer meetings or other interactions that have a promotional purpose, such as promotional speaker programs conducted by Marketing or Sales, because the nature of their role is non-promotional
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Guidance for Internal and External Interactions Involving Sales and/or Account Management Colleagues and PALs

For relevant disease states, Patient Affairs Liaisons (PALs) have the primary responsibility for interactions with patients and caregivers at patient-focused meetings and events, such as walks and local Patient Advocacy Group (PAG) chapter meetings.


Sales/Account Management Colleagues, as well as PALs, must avoid creating even the appearance that PALs are acting at the direction of commercial activities. Interactions between PALs and Sales/Account Management Colleagues may occur as needed, but not on a routine basis. Examples of permitted reasons to interact include:

- Introduction among Pfizer Colleagues where there is a new PAL, Account Manager, or Sales Colleague in territory
- PAL Lead may inform Sales/Account Management leadership of relevant market information that PALs have received in the course of their activities
- Sharing the logistics of a mixed attendee-event that both the Sales/Account Manager and PAL are attending
 - Sales and/or Account Management Colleagues and PALs may notify each other of upcoming mixed patient-HCP events, but all planning and preparation must occur independently
 - Only logistical information about events can be shared directly




In addition to the direction above, **Sales/Account Management Colleagues MAY:**

- Attend mixed HCP/patient events to engage with HCPs/customers in attendance in limited circumstances
 - The Sales/Account Management Colleague must confirm at least one HCP/customer appointment will be held in connection with the event, and gain approval from their manager
 - Before attending an event, the Sales/Account Management Colleague must inform the relevant PAL, who will in turn inform PAG leadership
 - Once the Sales/Account Management Colleague has concluded their appointment(s), they must leave the event



Sales/Account Management Colleagues MUST NOT:

- Engage with patients, caregivers, or advocacy group members at the event
- Staff or linger near the PAL's location, such as an exhibit and display, at the event
 - Sales/Account Management Colleagues must operate independently from PALs during the event



PALs MUST NOT:

- Attend external/customer meetings or other interactions that have a promotional purpose, such as promotional speaker programs conducted by Marketing or Sales, because the nature of their role is non-promotional

Chapter 7: Additional Resources for More Information

Access and Reimbursement Roles

- For principles and additional guidance for Access and Reimbursement Roles, please see [General Principles and Guidance for Patient Support Role Activities](#) on PolicyPoint

Field Medical Colleague Roles

- For more information on Field Medical Colleague responsibilities, please see [The Green Guide: Governance for Medical Activities](#)

SME Introduction Calls

- For role-specific guidance on SME Introduction Calls, please see the *SME Introduction Call Overview and Introduction Talking Points for SMEs* on iLearn



The Orange Guide

Section 3

Guidelines for HCP Interactions and Related Field Commercial Activities

Section 3

Guidelines for HCP Interactions and Related Field Commercial Activities

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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's Field Commercial Colleagues. Compliance with the law and Pfizer policies is an essential component of successfully interacting with HCPs, and Pfizer may be held legally responsible for anything that colleagues say or show to customers.

Within *The Orange 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 purposes of *The Orange 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, and therefore, Field Commercial Colleagues should always consult relevant state laws prior to engaging with HCPs. These laws may be found in Section 7 of *The Orange 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. Examples include HCPs who are:

- C-suite administrators
- Members of the Pharmacy and Therapeutics (P&T) Committee
- Involved with Health Information Technology (HIT)
- Interested in clinical research
- Federal employees

Specific guidance to ensure compliant interactions and activities with all types of HCPs is covered in this section. For information regarding compliant interactions with Organized Customers (OCs), refer to Section 4 of *The Orange Guide*. For information regarding compliant interactions with patients and consumers, refer to Section 5 of *The Orange Guide*.

Chapter 2: Core Promotional Compliance Principles Governing HCP Interactions

Pfizer has four Core Promotional Compliance Principles to protect both colleagues and the Company when interacting with HCPs:

1. Use Only Review Committee (RC)-Approved Materials and Promotional Statements
2. Stay On-Label and Discuss Only Approved Products and Indications
3. Provide an Accurate and Balanced Presentation
4. Never Engage in Actual or Perceived Quid Pro Quo


Read below to review each in detail.

Use Only RC-Approved Materials and Promotional Statements

Each colleague is responsible for appropriate discussion of our products and therapeutic areas in a manner consistent with RC-approved materials and messaging as well as the [Food and Drug Administration \(FDA\)](#)-approved labeling. Using inappropriate selling statements, whether intentional or not, can have far-reaching consequences for Pfizer, and may result in disciplinary action.

The guidance below must be followed when presenting information to customers and/or engaging in product promotion, traditionally known as “detailing.”

General Guidance for RC-Approved Materials

	<p>Field Commercial Colleagues <i>MUST</i>:</p> <ul style="list-style-type: none">• Show only materials that have been specifically approved for their role for use with customers by the relevant RC<ul style="list-style-type: none">– These materials are prepared in accordance with FDA-approved product labeling and are designed to ensure appropriate execution– In general, if a promotional item or material is not available for ordering through PROMOSprime, Pfizer's online ordering system, or not available on Veeva Customer Relationship Management (Veeva CRM), it is not approved for discussion with customers• Use Veeva CRM as the primary resource for accessing materials used when promoting to HCPs, unless the Brand Team, Legal, or Compliance provides guidance otherwise<ul style="list-style-type: none">– Using materials in Veeva CRM helps to ensure that materials are up to date, compliant, and RC-approved– Certain other RC-approved content not in Veeva CRM may be used with customers if the Brand, Legal, or Compliance teams provide specific approval on the use of these materials
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Field Commercial Colleagues *MUST NOT*:

- Alter RC-approved materials in any way, such as adding sticky notes or handwritten notes

General Guidance for Promotional or Selling Statements



Field Commercial Colleagues *MUST*:

- Only make selling statements, including openers, closers, and probing questions, that:
 - Are consistent with the responsibilities of their role
 - Are consistent with claims contained in RC-approved materials
 - Follow all guidance and direction contained in any relevant product implementation guide(s) or other RC-approved guidance
- Only make [comparative claims](#), which are claims that compare any attribute of a product to an attribute of another product of any kind, when there are RC-approved promotional materials, including Veeva CRM slides and any applicable product implementation guides, that expressly make such claims





Field Commercial Colleagues *MUST NOT*:

- Make or imply comparative claims, especially superiority claims, unless the claim is specifically made in RC-approved promotional materials
 - The FDA considers promotional materials or claims to be false and misleading if they state or imply that a drug's safety or efficacy is comparable or superior to that of another drug's, without [substantial evidence](#) to support such statements or implications
- Make comparative claims based on the data in products' respective package inserts
- Compare results from two separate trials, because of the differences in clinical trial designs, inclusion criteria, and other factors
- Detail two or more Pfizer products in a manner that falsely or misleadingly conflates the properties of the respective products
- Make or allude to inappropriate comparative claims in internal communications, because it may create the perception that these statements are being used with HCPs
- Use superlatives like "great," "best," or "safest" in discussing a Pfizer product, as such unqualified claims are rarely supported by substantial evidence
- Use any changes to RC-approved selling statements, with customers or any external parties, until they are reviewed and approved by the relevant Brand RC



RC-Approved Materials and Promotional Statements in Specific Situations

In addition to the general guidance around RC-approved materials and promotional statements, there are requirements for specific situations that Field Commercial Colleagues must also follow. These situations may occur during electronic communications with HCPs, access and reimbursement conversations, and internal Pfizer discussions.

Written and Electronic Communications Involving RC-Approved Materials and Promotional Statements


	<p>Field Commercial Colleagues <i>MUST</i>:</p> <ul style="list-style-type: none">• Only mail or e-mail an RC-approved promotional piece to an HCP if there is explicit guidance and RC permission to do so<ul style="list-style-type: none">– Examples include Rep Triggered Letters (RTLs) and Rep Triggered E-mails (RTEs)• Only use their Pfizer e-mail account to e-mail with customers, HCPs, or colleagues regarding Pfizer business• Provide only the number associated with their Pfizer-issued device, or a personal device that has been registered with Pfizer via the MaaS360 App, to HCPs or colleagues for business purposes• Only list phone numbers registered with Pfizer on business cards
	<p>Field Commercial Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Use a non-Pfizer e-mail account, a non-Pfizer device with texting capabilities, or other social networking tools, such as LinkedIn® or Facebook® to interact with HCPs or other customers regarding Pfizer business• Use any unapproved cloud-sharing or storage applications to share or store business information or data



See [Corporate Policy 403, Acceptable Use of Information Systems](#) for additional information.

FAQ: E-mailing/Texting HCPs	
	What should I do if I receive an inappropriate text or e-mail from a customer, such as one that discusses product name and usage, including off-label information, or one that contains identifiable patient information?
	It depends. Receipt of inappropriate communications may require action on your part to ensure the communication is not improperly attributed to you or Pfizer. Consult Compliance if you are unsure if a response is necessary or if you need assistance in developing an appropriate response.

Internal Pfizer Discussions of Promotional or Selling Statements

Sometimes Field Commercial Colleagues share suggested selling statements internally, often by e-mail or before or after internal meetings.





	<p><i>In these situations, Field Commercial Colleagues MUST:</i></p> <ul style="list-style-type: none">• Ensure these statements are consistent with RC-approved selling messages and implementation guides• Mark any documents, including e-mails, that share such statements with “DO NOT DETAIL”• Obtain their manager’s approval prior to disseminating to other Pfizer Colleagues any documents containing any modifications to RC-approved selling statements, such as e-mails, PowerPoint presentations, and summaries of district meetings or workshops
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FAQ: Texting Internally	
	Is it appropriate to have internal discussions about selling statements or other substantive business topics over text message?
	No. Communications with Pfizer Colleagues via text message must be limited to logistical information only. E-mail should be used when discussing any substantive topics. Any call notes must be entered in Veeva CRM before they can be shared.


RC-Approved Materials and Promotional Statements Summary

The table below provides examples of what is permitted versus prohibited when using RC-approved materials.

Permitted vs. Prohibited	
Permitted	Prohibited
<ul style="list-style-type: none"> Using promotional materials that have been approved by the relevant RC 	<ul style="list-style-type: none"> Showing a chart created by combining two RC-approved pieces Using any RC-unapproved item as a visual aid to illustrate a point or concept, such as pill bottles, money, food, candy, water bottles, or other unapproved “props” E-mailing/texting website links that are not RC-approved for that purpose
<ul style="list-style-type: none"> Marking an “Internal Training” copy of your clinical reprint to help you learn key points 	<ul style="list-style-type: none"> Showing an HCP any promotional material that has been marked or altered in any way with highlighting, sticky notes, handwritten notes, check marks, arrows, etc.
<ul style="list-style-type: none"> Leaving a handwritten thank-you note that includes the name of the product but does not make any direct or indirect product claim 	<ul style="list-style-type: none"> Leaving a thank-you note that contains more than the name of a product, including any direct or indirect product claim, such as mentioning indications or disease state information
<ul style="list-style-type: none"> Using or disseminating Pfizer training materials and other “Do Not Detail” pieces internally for educational purposes only <ul style="list-style-type: none"> These materials and the e-mail transmitting the materials must be clearly marked as “Do Not Detail” 	<ul style="list-style-type: none"> Showing Pfizer training materials, information from web-based or mobile applications, such as formulary coverage apps not RC-approved for detailing, or other “Do Not Detail” pieces to customers
<ul style="list-style-type: none"> Sending a very brief e-mail/text to a customer, using a Pfizer-approved device, and asking if you can schedule an appointment to discuss a specific product <u>or</u> an indication <ul style="list-style-type: none"> You cannot list both because combining both the product name and indication in the same communication may result in a product claim that is subject to FDA labeling requirements Permitted examples include: <ul style="list-style-type: none"> “Dr., I’d like to set up an appointment to discuss Cibinqo with you” “Dr., I’d like to set up an appointment to discuss your adult patients with moderate-to-severe atopic dermatitis” It is a best practice to start a new e-mail thread when e-mailing a customer <ul style="list-style-type: none"> Using an old e-mail thread requires additional review to ensure consistency in using either the product name or the indication 	<ul style="list-style-type: none"> Sending an e-mail/text to a customer asking if you can schedule an appointment to discuss a specific product <u>and</u> including information relating to indication or therapeutic area <ul style="list-style-type: none"> Example: “Dr., I’d like to set up an appointment to discuss Cibinqo and atopic dermatitis with you”
<ul style="list-style-type: none"> Using an RC-approved resource to inform customers about co-pay cards and patient access/reimbursement support resources 	<ul style="list-style-type: none"> Filling out any forms on behalf of an office or patient, including, but not limited to, Prior Authorization forms or enrollment forms for Pfizer RxPathways or hubs

FAQ: Communicating Formulary Status	
	Can I discuss with physicians the formulary status of Pfizer products as compared with competitor products? If so, can I create a chart showing the different formulary statuses by health plan?
	<p>In some circumstances, it might be appropriate to discuss the formulary status of Pfizer and competitor products with HCPs provided that all statements are accurate, non-misleading, and are RC-approved.</p> <p>If the information is part of your RC-approved materials, you can point out when a Pfizer product has a favorable formulary status, but you may not state or imply that the formulary status makes the Pfizer product more effective or safer than a competitor product. You are not permitted to create a formulary status chart because this would be considered an impermissible homemade promotional piece.</p>
	What materials are available to me to help discuss formulary status?
	<p>RC-approved resources regarding formulary status vary by brand and may include cost and coverage content within an iDetail, RTLs and RTEs, and sell sheets available on PROMOSprime or print-on-demand from a print portal.</p>

Stay On-Label and Discuss Only Approved Products and Indications

	<p>Field Commercial Colleagues <i>MUST</i>:</p> <ul style="list-style-type: none"> Only promote FDA-approved products and FDA-approved uses and dosing of its products <ul style="list-style-type: none"> All promotional statements made about a drug must be consistent with the product's labeling and must be based on the information contained in RC-approved promotional materials, including approved product implementation guides Follow the process outlined for Unsolicited Medical Requests (UMRs) if an HCP asks an unsolicited question about an unapproved product, an unapproved indication, or any other clinical content that is not allowed to be discussed
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Field Commercial Colleagues MUST NOT:

- Discuss any product, uses, or indications that have not been approved, that remain under investigation, or that are under FDA review no matter how appealing or robust the scientific evidence
 - Pre-approval promotion can jeopardize the approval of a new product or indication and may result in severe penalties
- Reference a new medication or a new indication in connection with any currently unapproved products or uses when trying to schedule an HCP meeting or otherwise communicating with an HCP

Avoid Promotional Interactions With Excluded Specialty HCPs



Field Commercial Colleagues MUST:

- Make a good faith effort to avoid presenting product information to, or otherwise engaging in promotion with, HCPs who are excluded for the product that is being promoted



For any HCPs who practice in a specialty that is excluded for a specific product, **Field Commercial Colleagues MUST NOT:**

- Provide product information
- Provide starters, vouchers, co-pay cards, educational materials, or meals
- Extend invites to speaker programs

The specialty exclusion lists by product are available on [Biopharma Ops on Demand](#).

In addition, Veeva CRM functionality supports compliant detailing and starter distribution activities by indicating when an HCP belongs to an included specialty for a product, and by ensuring that a call to an excluded specialty HCP cannot be closed. Careful Veeva CRM pre-call planning will help ensure that interactions will be conducted with appropriate specialists for each product.

Although Veeva CRM will not allow Field Commercial Colleagues to record a call for an HCP that is excluded for the specified product, they should also be cautious not to promote a product to any such HCP inadvertently, such as when an HCP might unexpectedly join a group conversation about a certain product. If an excluded HCP is inadvertently detailed or has starters left with them, Field Commercial Colleagues should contact their Product Attorney or the Samples Center of Excellence (CoE).

Provide an Accurate and Balanced Presentation



All promotional materials and selling statements MUST:

- Be truthful and not misleading

Section 3: Guidelines for HCP Interactions and Related Field Commercial Activities

- Be supported by substantial scientific evidence
- Balance product safety risks appropriately

Promotion is false and misleading if it does not include relevant risk and safety information or if it is not supported by appropriate scientific evidence.

The FDA requires that all product presentations include a [fair balance](#) of a product's benefits and risks. Therefore, relevant safety information must be presented to balance any statements on the product's efficacy. The more robust the efficacy statements, the more risk information needs to be provided. This means providing the relevant warnings, precautions, side effects, and other material information that is necessary for an HCP to make an informed decision. In addition, certain products, such as those containing [boxed warnings](#), may have specific risk and safety information that must be presented in all discussions about product efficacy.

Fair balance is necessary for HCPs to make informed treatment decisions. In addition to being required by law, delivering balanced presentations, including in cases of limited or brief interactions, demonstrates Pfizer's commitment to improving patient care.

FAQ: Accurate and Balanced Presentations



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



No. The word "safe" should never be used without qualification because all products have benefits and risks, and patients may experience an adverse event. You should only make safety claims that appear in RC-approved materials, such as an "established safety profile," and you must never elaborate or rephrase such statements.

Never Engage in Actual or Perceived Quid Pro Quo

[Quid pro quo](#) is Latin for "this for that." Field Commercial Colleagues must never engage in actual or perceived quid pro quo.



More specifically, **Field Commercial Colleagues MUST NOT:**

- Offer, or appear to offer, any remuneration or item of value in exchange for inducing an HCP to prescribe a product or put a product on a formulary
 - An HCP's decision to prescribe or recommend a Pfizer product must be based solely on the best interests 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, an HCP's prescribing or recommendation of a product
 - This includes 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

Section 3: Guidelines for HCP Interactions and Related Field Commercial Activities

- Incur any expenses with an entity that is owned in whole or in part by an HCP or other customer
 - An example is doing business with a catering company or restaurant owned by an HCP
- If Field Commercial Colleagues know or become aware of an entity that could receive payment from Pfizer and is owned in whole or in part by an HCP or other customer, they must escalate this to their manager

Access and Reimbursement Materials

Field Commercial Colleagues may often need to engage in discussions with HCPs about topics relating to product access or reimbursement, but, importantly, must limit their discussion and involvement consistent with approved direction to avoid any perception that colleagues are assisting HCPs with patient access as an inducement to prescribe. Accordingly, it is important to note the following requirements.



Field Commercial Colleagues *MUST*:



- Only use RC-approved resources to inform customers about co-pay cards and patient access and reimbursement support resources
- Follow any applicable RC-approved guidance when engaging in a discussion about specific prior authorization criteria or forms
 - In order for Field Commercial Colleagues to give or show a specific prior authorization form, it must be approved by the relevant RC
- Refer a customer to the relevant function or hub via the [Pfizer Triage App](#) if they have any patient-specific reimbursement questions or issues



Field Commercial Colleagues *MUST NOT*:

- Engage in any patient-specific reimbursement support activities unless they are in a field reimbursement role, such as a Field Reimbursement Manager (FRM)
- Assist HCPs or staff in filling out a prior authorization form
- Assist HCPs or staff in completing forms related to enrollment in RxPathways or hubs

For more information related to Pfizer's hubs and their role in supporting patients with prior authorizations, please refer to Section 5 of *The Orange Guide*.

FAQ: Patient Assistance Programs and Inappropriate Quid Pro Quo	
	<p>I am a Sales Representative and in the middle of my product presentation, the HCP interrupted and said that he will only prescribe the product if Pfizer makes life easier by handling the reimbursement-related paperwork. He then asked about Pfizer's hub support. Can I provide the HCP with details of Pfizer's product hub offerings so that the HCP prescribes the Pfizer product?</p>
	<p>No. This request is for a quid pro quo. Pfizer does not provide its patient support programs as a reason for HCPs to prescribe its products. In this scenario, even using RC-approved talking points to discuss Pfizer's hub offerings could be perceived as an inappropriate inducement or reward for prescribing Pfizer products. Pfizer's patient support services are not a promotional tool, and these services should never be discussed in a way that implies that the services are a reason to prescribe or provide independent value to the office.</p> <p>In this situation, the Sales Representative should respond: "Thanks doctor, Pfizer believes strongly in supporting appropriate access to our medicines, but our patient support offerings only come into play after you have made an independent clinical determination that the product is the right one for the patient. In such a case, here is a website where you or your staff can see how the patient can be assisted with access and reimbursement issues." You should then notify your manager and/or Compliance of the HCP's comment.</p>

Chapter 3: Guidance for Common Activities Involving HCPs

Pfizer follows the **Pharmaceutical Research and Manufacturers of America (PhRMA) Code** on Interactions with Healthcare Professionals, which provides direction on common activities involving HCPs. In addition to the guidance in the PhRMA Code, it is important to note that certain state laws and federal institutions create additional restrictions on certain activities and interactions.

Furthermore, Pfizer is required to report to the government payments and other transfers of value made to HCPs and teaching hospitals. Again, certain state laws and federal institutions create additional disclosure obligations regarding payments and other items provided to U.S. HCPs.

Therefore, before engaging in activities with HCPs, colleagues should refer to state laws and guidance for federal employees found in Section 7 of *The Orange Guide*.

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



- [Documentation about HCPs/HCP interactions](#)
- [Starters](#)
- [Non-Speaker Program Meals](#)
- [Speaker programs](#)
- [Educational items](#)
- [Activities in connection with third-party events](#)

- [Attendance at Continuing Medical Education \(CME\) events](#)
- [Preceptorships and other training for Field Commercial Colleagues](#)

Documentation About HCPs/HCP Interactions

Call Notes

Call notes are written records documenting specific detailing interactions with an HCP or a member of the HCP's staff.

	<p>Sales Colleagues are not required to keep call notes documenting their details with HCPs. However, when keeping them, Sales Colleagues MUST:</p> <ul style="list-style-type: none">• Write call notes in such a way that:<ul style="list-style-type: none">– The context is clear and not misleading to an outside reader– They could not be interpreted to suggest that colleagues made any inappropriate promotional statements or engaged in inappropriate activities• Directly enter call notes in Veeva Customer Relationship Management (Veeva CRM) whenever possible<ul style="list-style-type: none">– If sharing outside of Veeva CRM is required, Sales Colleagues must ensure that the substantive content of any written records to be shared is consistent with any information that is recorded in Veeva CRM
	<p>Sales Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Use any unapproved cloud-sharing/storage application, such as Google Docs™, Dropbox™, Evernote® to communicate or share call notes with colleagues

See [Corporate Policy 403, Acceptable Use of Information Systems](#) for additional information.

Starters

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.

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.

Section 3: Guidelines for HCP Interactions and Related Field Commercial Activities

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.



Starters *CANNOT*, under any circumstances:

- Be provided to an HCP to reward the HCP for past prescribing or as a financial inducement for future prescribing

Furthermore, they *CANNOT* be provided if the HCP:

- Intends to seek reimbursement from the government for the starter
 - If a Sales Colleague suspects that an HCP is charging the government or patients for starters, the colleague must immediately stop providing starters to or assisting to order starters for that HCP and discuss the situation with their manager, North America Sample Operations, or Compliance
- Is within an excluded medical specialty
- Intends to use the starter for their personal use
- Intends to provide the starters for an off-label use
- Does not have a prescriber's license number or their number has not been verified in Veeva CRM

Biopharmaceutical companies are required to maintain records tracking the movement of all starters from the time they leave the distribution facility to the time they are delivered to an HCP. For those colleagues authorized to receive and distribute physical starters, significant losses, including inventories with unacceptably large negative variances and all thefts of starters, must be reported by North America Sample Operations to the Food and Drug Administration (FDA) within 5 business days. Some states also have reporting obligations that are more stringent than federal law.

It is essential, therefore, that Sales Colleagues notify North America Sample Operations of all thefts and starter losses *immediately* upon becoming aware of them. Record falsification and diversion of starters must also be reported by Pfizer to the FDA.


Pfizer North America Sample Operations handles all PDMA-mandated FDA reporting, as well as compliance with the reporting requirements set forth in Section 6004 of the federal Affordable Care Act, with support from the Pfizer Transparency Team.



It is critical that Sales Colleagues adhere to all policies, procedures, recordkeeping, and system requirements pertaining to starter distribution to ensure compliance with all applicable tracking and reporting laws. Because of this, Pfizer routinely conducts reviews and audits of Sales Colleagues' starter activities.

The distribution of starters is also impacted by other healthcare laws such as those dealing with fraud, abuse, and off-label promotion. In addition, several states have laws that affect whether and to whom starters may be distributed. Field Commercial Colleagues should always consult state laws prior to distributing starters to HCPs. These laws may be found in Section 7 of *The Orange Guide*.

Field Commercial Colleagues who support the ordering of starters or who are authorized to receive and distribute physical starters will receive annual training on all PDMA requirements. Colleagues with responsibility for ordering or managing starters should also be familiar with all Pfizer policies for complying with the PDMA in the [Starter Compliance Manual](#).

Starters to Defray Patients' Expenses or for Research/Charitable Activities

	<p>Starters <i>MUST NOT</i> be:</p> <ul style="list-style-type: none">• Provided to HCPs for distribution to patients as a means of mitigating their medication costs.<ul style="list-style-type: none">– HCPs seeking to assist patients with these costs should be referred to Pfizer RxPathways or the relevant product hub as described in Section 5 of <i>The Orange Guide</i>• Used for clinical trials or other research activities<ul style="list-style-type: none">– A request for medication or other clinical supplies to support legitimate scientific investigations must be referred to the relevant Medical team for consideration as an Investigator-Sponsored Research (ISR) grant• Provided to non-profit organizations for missions or other charitable activities<ul style="list-style-type: none">– Requests for medication for these purposes should be directed to the Global Health and Social Impact Team
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FAQ: Appropriate Use of Starters	
	An HCP reaches out with an urgent request for starters indicating that her patient is awaiting an insurance coverage decision and the patient is at risk of discontinuing therapy. Is it appropriate for me to provide the starters?
	No. Even if the HCP is insistent, you must politely decline indicating that starters are provided solely for the purpose of assessing the patient's experience with the prescribed product and cannot be used as a bridge to coverage or to mitigate the patient's costs in any way. The HCP should be referred to Pfizer RxPathways or to the relevant product hub, or triaged to an Access and Reimbursement Colleague where authorized. If you need assistance on how to respond to the customer verbally or in writing, contact your manager or Compliance.

Starters for Hospitals

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

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

Some hospitals and healthcare institutions have policies that require starters to be left in the pharmacy and not with the individual physicians who have requested them. Sales Colleagues may do this only after completing a paper dual-signature *In House Pharmacy Starter Activity Form (SAF)*. This form is used to document the physician's request for starters and the pharmacist's receipt of the starters in the institution pharmacy. The *In House Pharmacy SAF* can be

ordered from North America Sample Operations by logging on to [PROMOSprime](#) and choosing that item under the order category “Starter Ops Forms.”

Starters for the Department of Veterans Affairs (VA) and Department of Defense (DoD)

Meanwhile, many government institutions, such as Department of Veterans Affairs (VA) clinics and hospitals, prohibit pharmaceutical companies from leaving starters. Other government institutions that do accept starters generally require them to be provided to the Chief of Pharmacy and not to individual physicians.

Even if intended for use in private practice, starters should not be left for VA or Department of Defense (DoD) physicians at the government institution in which they work. For more information on the distribution of starters in these government institutions, refer to the [Starter Compliance Manual](#).

Free Trial Vouchers

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.

The process is as follows:

1. The HCP must give the patient a prescription for the amount of product covered by the voucher
2. The patient takes the prescription and voucher to the pharmacy, where they receive the product free of charge
3. A third-party administrator that contracts with pharmacy networks then reimburses the pharmacy


Brand Teams may offer both starters and vouchers, and Sales Representatives may distribute both starters and vouchers to the same HCP office in accordance with the principles below.



Sales Colleagues MUST:

- Carefully consider the needs of a particular HCP or office prior to distributing starters/vouchers to an HCP
 - For example, it may be appropriate to either:
 - Leave vouchers at a health system that has restrictions on drug sampling, but allows vouchers
 - Leave starters with an HCP who desires to start treatment immediately without waiting for the patient to redeem a voucher
- Clearly indicate the appropriate use of starters/vouchers to HCPs, including that:
 - Vouchers are not intended to address financial hardship and insurance delays
 - HCPs should direct patients to RxPathways and/or the applicable product hub to address financial hardship and insurance delays

	<ul style="list-style-type: none">– An individual patient should receive either a voucher or starter, but not both<ul style="list-style-type: none">▪ This prevents a patient from receiving both starters and vouchers to extend beyond a reasonable trial period, which is known as “stacking”• Record voucher disbursements completely and accurately in Veeva CRM to ensure compliance with all applicable federal and state reporting requirements
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	<p><i>Sales Colleagues MUST NOT:</i></p> <ul style="list-style-type: none">• Position vouchers to HCPs for the purpose of addressing long-term issues such as patient access or financial need• Offer or provide vouchers to HCPs contingent upon the HCP's past, current, or future prescribing practices• Offer vouchers to HCPs<ul style="list-style-type: none">– For personal use– For off-label use– Who practice in a specialty that is excluded for that specific product<ul style="list-style-type: none">▪ The specialty exclusion lists by product are available on Biopharma Ops on Demand
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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.

Non-Speaker Program Meals Provided to HCPs

Pfizer policy and the 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

General Pfizer Policy Regarding Non-Speaker Program Meals

- Non-speaker program meals provided in an in-office or in-hospital setting, including virtual, cannot 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

Section 3: Guidelines for HCP Interactions and Related Field Commercial Activities

- Out-of-office non-speaker program meals by approved colleagues to U.S. HCPs cannot exceed \$135 per attendee
 - Including food, beverage, tax, tip, and delivery charges
 - 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 \$135 limit and reported for purposes of Open Payments and State Laws
- 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 and the VA/DoD also 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 7 of *The Orange Guide*
- Colleagues cannot provide any food or other support in connection with an accredited CME activity, such as the Accreditation Council for Continuing Medical Education (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.

The table below provides a high-level summary of when Pfizer Colleagues are permitted to provide meals to HCPs based on each colleague's role.

Ability to Host Non-Speaker Program Meals					
Role	Host in-office meals?	Host in-hospital meals?	Host virtual meals (in-office/in-hospital)?	Host restaurant meals?	Host meals at conventions?
Sales Representative	Yes	Yes	Yes	No	No
Area Business Manager	Yes	Yes	Yes	No	No
Regional Business Director, Regional	Yes	Yes	No	Yes	Yes

Ability to Host Non-Speaker Program Meals					
Role	Host in-office meals?	Host in-hospital meals?	Host virtual meals (in-office/in-hospital)?	Host restaurant meals?	Host meals at conventions?
President, National Sales Lead					
Sterile Injectables	Yes	Yes	Yes	Only for non- HCPs or HCPs who do not regularly treat patients or fill prescriptions	Only for non- HCPs or HCPs who do not regularly treat patients or fill prescriptions
Account Manager, including AD, KAM, VAM	Yes	Yes	Yes	Only for non- HCPs or HCPs who do not regularly treat patients or fill prescriptions	Only for non- HCPs or HCPs who do not regularly treat patients or fill prescriptions
HQ Marketing/ Medical	Yes	Yes	Yes	Yes	Yes

Non-Speaker Program Meals Provided by Sales Representatives and Their Immediate Managers




	<p><i>All non-speaker program meals provided by Sales Representatives and their immediate managers MUST follow the following requirements:</i></p> <ul style="list-style-type: none"> Meals provided to U.S. HCPs by Sales Representatives and their immediate managers in connection with informational presentations must be limited to in-office and in-hospital settings <ul style="list-style-type: none"> The restriction applies whether the Sales Representative is providing the meal incidental to an in-person or virtual presentation While it is permissible for colleagues to provide in-office/in-hospital meals to appropriate attendees as an ancillary offering to virtual informational presentations, virtual meals present additional risk considerations and, therefore, must be only conducted in accordance with the Guidance on Promotional Meals with VCC The only time a Sales Representative or their immediate manager may provide an out-of-office meal is when they are in person with HCP attendees during a Pfizer speaker program, as covered in the Speaker Program for HCPs subsection in this chapter Meals must be incidental to the provision of informational presentations and discussions <ul style="list-style-type: none"> Only individual HCPs and office staff members who have a role in patient care and engage in an educational discussion with the Pfizer Colleague can partake in the meal
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Section 3: Guidelines for HCP Interactions and Related Field Commercial Activities



	<ul style="list-style-type: none">For the reason above, and to ensure proper reporting for disclosure purposes, Pfizer Colleagues should instruct HCPs and their staff not to unwrap or consume meals provided by Pfizer prior to the arrival of a Pfizer Colleague
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✓	<p>For meals with an anticipated large number of attendees, such as more than 20 attendees, Sales Representatives MUST:</p> <ul style="list-style-type: none">Conduct additional pre-planning and discussion with their manager about logistics to ensure there is a meaningful opportunity to engage in educational discussions with all HCPs and office staff members who partake in the meal, and to ensure accurate disclosureIdentify the precise circumstances they will encounter and how to best manage the meal, since every office operates in a different wayConsider inviting another Pfizer Colleague to assist or conduct a single presentation to provide education to all attendees at the same time, while ensuring that they can see and hear a fair and balanced presentationDiscuss with their manager the appropriateness of providing a presentation over a meal in the future with an office or customer who fails to comply with Pfizer's meal requirements, which are consistent with the PhRMA Code
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✗	<p>For meals with an anticipated large number of attendees, such as more than 20 attendees, Sales Representatives MUST NOT:</p> <ul style="list-style-type: none">Conduct the meal if they cannot ensure there will be a meaningful opportunity to provide information or education to all attendees who partake in the meal
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FAQ: Providing a Meal to an HCP Office	
	Can a Pfizer Colleague provide lunch to an HCP or medical office staff member who does not attend the informational presentation or receive educational information?
	Any individual who consumes a meal must receive educational information incidental to their meal. If an HCP or office staff member unexpectedly steps away or excuses themselves without receiving an educational presentation, the hosting colleague should schedule a near-term follow-up to ensure the information is conveyed. This requirement applies whether the colleague is presenting in person or virtually.
	Can a Pfizer Colleague set up a recurring monthly appointment, in an HCP's office, that includes a meal or snack?

	<p>No. Under the PhRMA Code, meals may only be provided to HCPs on an occasional basis, so standing monthly appointments would not be acceptable. However, the provision of a meal or snack more than once in any given month may be appropriate if there is new information to share or different attendees.</p>
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FAQ: Providing In-Hospital Meals	
	<p>What qualifies as an appropriate in-hospital meal? Can a Sales Representative or their immediate manager host a meal at a hospital food court or a cafeteria within the hospital complex?</p>
	<p>An in-hospital meal takes place in offices, conference rooms, or hospital locations that are considered part of the hospital complex. Sales Representatives or their immediate managers may provide a meal at a hospital food court or cafeteria on hospital grounds, in conjunction with an informational presentation, if it is considered part of the hospital complex. No other expenses, such as room fees, may be paid to the office or hospital in connection with meals conducted in an in-hospital setting.</p>

FAQ: Providing Meals to Pharmacists	
	<p>May Sales Representatives provide a meal to a pharmacist or pharmacy technician?</p>
	<p>Yes. However, you may not provide a meal to a pharmacist or pharmacy technician in certain states, so be sure to consult state laws in Section 7 of <i>The Orange Guide</i> prior to engaging in this activity.</p>

FAQ: Providing “In-Office” Meals to Remotely-Based Customers	
	<p>How is “in-office” meal defined for customers who are based remotely? Can a Sales Representative or their immediate manager host a non-restaurant meal in temporary meeting space rented by customers who do not have a corporate office?</p>
	<p>Sales Representatives and their immediate managers are limited to providing an “in-office” meal under the PhRMA code to ensure the meal is incidental to a substantive interaction and in the setting where the HCP typically conducts professional conversations. Some HCP customers, such as retail pharmacy managers who are licensed pharmacists who manage a territory of chain pharmacies for large retailers, are field-based without a formal corporate</p>

	<p>office. These customers occasionally rent hotel or other meeting space to conduct business. In such instances, the customer-rented space, excluding all restaurants and restaurant meeting rooms, may be considered “in-office” for purposes of this Chapter, as that is where the customer conducts professional conversations. If the customer-rented space is at a restaurant or restaurant meeting room, it is not considered “in-office,” and Sales Representatives may not provide a meal at such a location.</p> <p>Sales Representatives and their immediate managers may only expense a meal at the customer-rented location incidental to a promotional presentation and in accordance with all requirements of this Chapter. No other expenses such as the meeting space rental may be incurred. As with other “in-office” promotional opportunities, Pfizer Colleagues must follow all Pfizer policies for detailing and should leave the customers’ meeting space after the promotional discussion and incidental meal are concluded, in no way involving themselves in the customers’ other business dealings. If colleagues have questions or concerns about promotional opportunities with remotely-based customers, including the provision of meals, they should consult with Compliance.</p>
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Providing Snacks or Beverages

Pfizer policy permits Sales Representatives and their immediate managers to provide snacks or beverages to U.S. HCPs on occasion in appropriate circumstances, so long as:

- The snack does not constitute a meal and instead includes items such as coffee, other non-alcoholic beverages, or pastries
- The food or beverage items are of nominal value, defined as \$10 per attendee or less

Sales Representatives and their immediate managers may provide snacks or beverages in-office. They may also make an occasional educational presentation to an HCP out of the HCP’s office or hospital, such as in a coffee shop near the HCP’s office, along with offering a snack, unless further restricted by state law or other laws or policies. Furthermore, offering a snack or beverage out of an HCP’s office or hospital should be limited to only one or two HCPs at a time.

✓	<p>Regardless of location, <i>Sales Representatives or their immediate manager MUST:</i></p> <ul style="list-style-type: none"> • Ensure that the snack or beverage is ancillary to a planned educational or promotional engagement <ul style="list-style-type: none"> – This generally should be pre-arranged as part of a scheduled appointment • Properly record the expense of the snack or beverage <ul style="list-style-type: none"> – The value of any food or beverages provided to a U.S HCP, regardless of amount, is potentially subject to the requirements of state laws and may also require public disclosure by Pfizer
✗	<p><i>Sales Representatives or their immediate manager MUST NOT:</i></p> <ul style="list-style-type: none"> • Offer a snack in conjunction with a virtual or remote interaction • Provide a snack or beverage to gain access or entice a customer to engage

FAQ: Providing Out-of-Office Snacks/Beverages	
	Is it acceptable to make an appointment with an HCP over their lunch break for an informational presentation at a modest out-of-office venue such as a coffee shop, and expense an accompanying snack?
	Yes. However, you must make clear to the HCP when making the appointment that you are not permitted under the PhRMA Code or Pfizer policy to expense an actual meal, such as a sandwich or salad. You must also set expectations with the HCP in advance since the appointment is occurring over their typical lunch break.

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
- Headquarters (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.



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.

FAQ: Account Manager Out-of-Office Meals With HCPs	
	<p>Can a Key Account Manager (KAM) host an out-of-office meal with an HCP who serves as the medical director of a hospital system?</p>
	<p>It depends. Account Managers such as KAMs can provide out-of-office meals to an HCP who is not “regularly treating patients.” For pharmacists to be eligible for an out-of-office meal with a colleague who is permitted to host, they must not be regularly filling patient prescriptions. Typically, an HCP or pharmacist who treats patients or fills prescriptions one day per week, or approximately 20% or less, is not “regularly treating patients.” As always, there must be a legitimate business reason related to the HCP’s responsibilities outside of treating patients for meeting over a meal, and the interaction must be conducted in accordance with the provisions of this Chapter, including any other state law or restriction.</p>

Planning and Execution for Out-of-Office Meals

	<p>All out-of-office meals must follow the requirements below:</p> <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> – If the hosting colleague believes there is a legitimate justification for including more than 3 HCPs, they should discuss with their manager and align on how the host will ensure there is a meaningful opportunity for them to engage with all attendees • The host must have a legitimate business objective for the interaction and consider having a list of topics and questions or other presentation to facilitate the legitimate business discussion <ul style="list-style-type: none"> – 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 Review Committee (RC)-approved content and discussed, prior to the meal, with the host’s manager, and reviewed as needed by the relevant Product Attorney and/or Brand Medical, 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 or indication, or disease states or therapeutic areas for which Pfizer has no product <ul style="list-style-type: none"> – 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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	<p>coordinate to ensure that the overall number of events and HCP attendees is appropriate to achieve the business need</p> <ul style="list-style-type: none">• 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<ul style="list-style-type: none">– Potential hosts should use these deliverables and insights to assess the need for future meals for the same geography, disease state, or product
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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 their 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, and 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
- 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.

Business Meals Provided by Sterile Injectables Colleagues

Sterile Injectables Colleagues who do not provide clinical detailing of products may host off-site business meals or snacks/beverages for:



- Non-HCP customers
- HCPs who hold administrative positions and dedicate very little time, if any, to seeing patients or filling prescriptions

In general, the guidance previously mentioned regarding both on-site and off-site meals applies to Sterile Injectables Colleagues as well, including the need to check local, state, or hospital policies or restrictions before participating in this activity. If there is doubt as to whether a particular customer's role is administrative, colleagues should consult with their manager or Compliance.

Non-Speaker Program Meals Provided by Patient Support Roles

Field Reimbursement Managers (FRMs), Clinical Educators (CEs), and Patient Access Coordinators (PACs) may not provide food, beverages, or other items of value to HCPs/offices or patients. The only exception is for FRMs in limited instances, with approval from Compliance.

Patient Affairs Liaisons (PALs), however, may provide non-speaker program meals if they follow the guidance below.

	<p>PALs MAY:</p> <ul style="list-style-type: none">• Offer a modest meal in conjunction with an unbranded, non-promotional, educational consumer presentation, such as a Community Connections Program, subject to applicable laws, federal rules, and Pfizer policy governing the provision of meals<ul style="list-style-type: none">– Any meal should be modest as judged by local standards, with the cost not to exceed \$50 per attendee– If there is a mixed HCP-consumer audience, the consumer meal limit applies to all attendees and any meals provided to HCPs are subject to Pfizer's HCP Payment Disclosure policy• Provide snacks/beverages for under \$10 to opted-in patients, caregivers, and consumers, when meeting in person to discuss issues related to the Patient Support Role<ul style="list-style-type: none">– This must be on a limited and infrequent basis
	<p>PALs MUST NOT:</p> <ul style="list-style-type: none">• Use a meal as the primary focus of the interaction

Non-Speaker Program Meals Disclosure Requirements for 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.



When meals are provided in connection with an informational presentation to a group, the disclosable value is calculated by taking into account both actual and expected attendees. Therefore, to ensure appropriate accounting for the per-person value, the following must be tracked:

- All attendees who partake in the meal
- HCPs and non-HCP office staff
- All expected attendees
- Those who do not partake in the meal but do attend

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For more information, see Pfizer's *Field Force T&E Expense Procedure*, which is available on [MyPfieldNet](#).

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.

FAQ: Identifying HCP Meal Attendees in Sales Colleague Expense Reports	
	A Sales Colleague has provided an in-office meal to a mixed group including both physicians who are on and not on her Territory Credit List (TCL), as well as office staff. Which individuals must the Sales Colleague identify by name in her meal expense report?
	<p>All individuals who are licensed to prescribe medicines in the U.S. must be identified by name in the meal expense report, regardless of whether they appear on the colleague's TCL. These include doctors of medicine or osteopathy, medical residents, dentists, podiatrists, optometrists, chiropractors, and advanced practice nurses, such as nurse practitioners and physician assistants, who are legally authorized to prescribe by the state in which they practice. Non-prescribers, including registered nurses, pharmacists, and office staff, do not need to be identified by name, unless required by your state. Examples include when a meal is with a Nevada HCP for any dollar amount, a D.C. HCP that is \$25 or more, or a Massachusetts HCP that is \$50 or more. In these circumstances, all individuals must be listed individually in the expense report.</p> <p>For further information regarding appropriate use of the travel and expense system, Sales Colleagues should consult the Pfizer Travel & Entertainment (PT&E) guidelines available on MyPfieldNet. Refer to Section 7 of <i>The Orange Guide</i> for further details on state laws, including who qualifies as an HCP in Nevada, Massachusetts, and D.C.</p>

Speaker Programs for HCPs

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:

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- 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

Additionally, when contemplating format and venue, colleagues must plan accordingly since Brand Teams have the following targets:

- At least 50% of programs should be conducted with the speaker presenting virtually
 - When in-person programs are deemed necessary, all efforts should be made to find and use a local speaker
- A preference that any remaining programs conducted with an in-person speaker be held in non-restaurant venues

When an HCP is engaged to conduct a Pfizer-sponsored speaker program, the HCP represents Pfizer and is considered a Pfizer speaker. As a result, Pfizer is held accountable for all content presented by the HCP at the program.

Policies to conduct compliant speaker programs for all relevant Pfizer Colleagues who organize, host, and/or attend a speaker program are presented below. Additional information and guidance are also available in CentrisDirect™, the system used by Pfizer to manage speaker programs. Pfizer’s policies for conducting compliant speaker programs for consumers are discussed in Section 5 of *The Orange Guide*.



Pfizer Speaker Selection and Training

Speaker Nomination

Speaker nominations must be based on the speaker’s expertise/experience with the product or disease state, credentials, ability to communicate effectively to the targeted audience, and any other appropriate criteria set by the Brand Team.

Although the speaker should have experience with the product or disease state, past, present, or future prescribing volume may not specifically be considered as a basis for nomination. Speaker nominations are vetted by a third party against an objective set of criteria that reflects evolving industry standards and accounts for reputational risks.

Speaker nominations are also assessed regarding qualifications and tier status, presence on internal and external exclusion lists, and license status. Marketing and Medical Colleagues will make final determinations regarding nominated speakers and consider the need for additional speakers for a particular brand.

	<p>Field Commercial Colleagues MAY:</p> <ul style="list-style-type: none">• Speak with their manager if they get an unsolicited request from an HCP to become a speaker so that next steps can be determined
	<p>Field Commercial Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Nominate HCPs• Proactively attempt to gauge an HCP’s interest in becoming a speaker

- Seek to have a speaker nominated in order to establish a relationship, gain or improve access to the HCP, reward past prescribing, or induce future prescribing

Conducting a Compliant Speaker Program: Planning and Preparation

Adhere to Lead Times

Lead times are established to ensure appropriate, compliant speaker program setup and promotion.

It is highly recommended that Field Commercial Colleagues enter programs with significant lead time, such as a month in advance of the program date. This helps to ensure required attendance and should provide ample time in the event that logistical issues arise.

At a minimum:

- Program types associated with speaker honoraria require a 14-day lead time
- Other program types require a minimum 5-day lead time

CentrisDirect™ prevents program entry in cases of insufficient lead time. If necessary, colleagues should contact their program planner to request additional review.

For job aids and resources, refer to the [Speaker Program \(Centris\) Resources](#) page of Biopharma Ops on Demand.

Choose the Relevant Topic and Select an Appropriate Speaker



Field Commercial Colleagues *MUST*:

- Choose a topic that is RC-approved and included in CentrisDirect™
- Select a speaker after choosing a topic
- Use only speakers available in CentrisDirect™
 - Speakers will appear “active” in CentrisDirect™ and available for selection only when they have:
 - Completed the relevant brand’s core product or topic training, as applicable
 - Completed Pfizer’s speaker compliance training
 - Signed a Pfizer Speaker Agreement
- Solely base speaker selection on the speaker’s expertise, credentials, and their ability to communicate effectively to the targeted audience



Field Commercial Colleagues *MUST NOT*:

- Engage a speaker in order to:
 - Establish a relationship
 - Gain or improve access to the speaker
 - Reward past prescribing or induce future prescribing
- Specifically consider prescribing volume when selecting a speaker
- Host more than 3 programs in a calendar year using a speaker on their TCL

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- Host programs using a speaker on the TCL of any member of their District more than 6 times in a calendar year in the aggregate
 - For example, if a speaker is on a representative's TCL, that representative may host, at most, 3 programs in a calendar year using that speaker, and the other members of their District may only host an additional 3 programs using that speaker during the same calendar year, for a total of 6 programs
 - Colleagues who do not have a TCL but still host speaker programs, such as Vaccines Territory Managers and Oncology KAMs, must not host programs using a speaker called on by any member of their District more than 6 times in a calendar year, in the aggregate

Please note that the rules above apply regardless of product or topic, but do not apply to link programs.




Violations of these policies, including holding a program not entered in CentrisDirect™ without prior Legal approval, or entering a fictitious program date, will be subject to disciplinary action.


For more information on how to have a speaker activated in CentrisDirect™, colleagues should consult their manager, IQVIA, or the Pfizer Speaker Operations team.



FAQ: Speaker Curriculum Vitae (CV)

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

FAQ: Speaker Selection

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

FAQ: Speaker Selection	
	Possibly, but you may not engage a speaker who works for the VA until you know and understand the special rules that apply to speakers who work for the VA. Please see Section 7 of <i>The Orange Guide</i> for information about these rules.

FAQ: Scheduling	
	A non-local speaker has asked a colleague to schedule a speaker program to coincide with the speaker's personal travel schedule so that Pfizer can reimburse his personal travel expenses. Is this permissible?
	No. You cannot conduct a speaker program for the benefit of the speaker. Speaker travel is discouraged and may only be used when there is a legitimate business reason to do so in consultation with your manager or Compliance as needed. Furthermore, your scheduling decisions should only be motivated by the availability of the appropriate audience.

Ensure Speaker Has Not Opted Out

If an HCP does not want to have items of value reported, they must not accept or receive meals, speaker fees, or other value from Pfizer.

Pfizer maintains a record of HCPs who have opted out of receiving disclosable items from Pfizer, which colleagues can view on the [MyPfizerNet Compliance page](#). Colleagues should review this list prior to choosing a speaker, inviting attendees, and conducting a speaker program.

If a speaker has opted out, but nevertheless consumes a meal, the value of the meal will be reported. Furthermore, speakers may not pay for their own meals at speaker programs.

Understand the Speaker Fees


Colleagues are not responsible for negotiating the amount of a speaking fee. Fees are determined based on an independent assessment of HCP specialty categorization, which utilizes industry [fair market value \(FMV\)](#) benchmarking and national wage data.


Each speaker has a limit on the total speaking fees, not including travel expenses, that they can earn from Pfizer in a calendar year. An individual speaker's annual limit will be set through Pfizer HQ, and any increases must be approved in advance working through HQ Marketing.



Confirm Speaker Program Content



Any information provided by a speaker must be:



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

	<p>Speakers <i>MUST</i>:</p> <ul style="list-style-type: none"> • Present all required slides in the RC-approved slide deck available to the speaker in CentrisConnect™
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	<p>Speakers <i>MUST NOT</i>:</p> <ul style="list-style-type: none"> • Create or insert their own slides, including introduction, speaker bio, case study, and disease state slides <ul style="list-style-type: none"> – Speaker slide decks are locked to prevent the addition of slides or changes to approved slides • Promote their own practice in connection with a Pfizer speaker program, including distribution of their business cards • Proactively discuss investigational or unapproved uses of Pfizer products <ul style="list-style-type: none"> – Off-label information may be provided only in response to a specific, unsolicited question from an attendee – Before briefly answering an attendee's question, the speaker must state that the information to be discussed is off-label and is based on the speaker's personal experience, knowledge, or opinion – The speaker may not use unapproved slides to support the answer, and the response must be concise and narrowly tailored to the question asked <ul style="list-style-type: none"> ▪ Triage to a Field Medical, Therapeutic Area (FM, TA) Colleague through the Pfizer Triage App when the Unsolicited Medical Request (UMR) is on a designated topic ▪ Refer the UMR to U.S. Medical Information (USMI) through the Pfizer Triage App when it is not on a designated topic and/or the HCP wants a follow-up response in writing ▪ Triage can be either synchronous/real-time via Medical OnDemand or asynchronous • Engage in a consultation during a speaker program and may not review charts or otherwise provide medical advice for individual patients
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FAQ: Use of Pfizer-Approved Speaker Slide Decks	
	<p>Is a speaker required to use all slides contained in a Pfizer-approved slide deck?</p>
	<p>Yes. Speakers must present all required slides in the RC-approved slide deck. In particular, a speaker must appropriately emphasize all slides that relate to safety and risk, such as warnings, contraindications, and adverse events, to ensure fair balance, even if they appear duplicative. If the presentations listed in CentrisDirect™ allow the speaker to select certain slides from the approved deck, they must be certain to include all slides identified as mandatory in the final deck and present them at the program.</p>

FAQ: Use of Unapproved On-Label Clinical Reprints	
	Can a speaker present data from an unapproved clinical reprint that is substantiated, scientifically sound, and seems to be on-label but is not RC-approved?
	No. All information that is presented proactively must be RC-approved.

FAQ: Attendee Misses Part of the Speaker Presentation	
	What if an attendee is not present for the entire program because they arrived late or have to leave the room during a portion of the program?
	You should set expectations with the attendees ahead of time to help ensure they are able to stay for the entire program duration. However, if an attendee does miss a portion of the program, you or the speaker must review any safety or risk slides that the attendees missed. This can be done by the speaker or the Pfizer Colleague as soon as reasonably possible after the conclusion of the program.

Arrange Meeting and Speaker Logistics with IQVIA

	<p>Field Commercial Colleagues <i>MUST</i>:</p> <ul style="list-style-type: none"> Contact their IQVIA planner for assistance <ul style="list-style-type: none"> IQVIA will assist colleagues in setting up programs that are effective and compliant by, among other things: <ul style="list-style-type: none"> Booking and confirming speakers Coordinating speaker travel arrangements where approved Securing a venue Creating invitations
	<p>Field Commercial Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none"> Expense any speaker program expenses using their corporate credit card for reimbursement <ul style="list-style-type: none"> All such expenses should be processed through IQVIA

Venue Hierarchy and Requirements

Since the purpose of a Speaker program is to convey information, when an out-of-office program is necessary and appropriate, Field Commercial Colleagues must be sure that the venue is conducive to the exchange of scientific information. The venue's environment should not detract from the primary purpose.



Non-restaurant meeting room venues are preferred, and all out-of-office programs must be held in a private room or in a semi-private room. The requirements below must also be taken into account when choosing a venue:

- Noise level
 - Programs should be held in a venue that permits attendees to clearly hear the speaker's presentation without noise distractions
- Visibility
 - Slides must be clearly visible to all attendees using appropriate AV equipment
 - Colleagues should arrange to have the appropriate equipment needed brought on-site
 - Colleagues can bring their own, borrow from a colleague, or indicate their AV needs, such as a screen or projector, during program setup in CentrisDirect™
 - It is generally not appropriate to use an iPhone, iPad, or laptop to present the slides without projecting the slides onto a larger display
- Privacy
 - The content of the presentation should not be visible to or be overheard by individuals who are not intended attendees of the speaker program
- Cost/perception
 - Venue must be considered modest by local standards and must not be a high-end restaurant
 - For an out-of-office program, no more than \$100 per attendee may be spent on food, beverage, tax, tip, and, if applicable, delivery charges
 - Extraneous fees, such as room fees, must be broken out from meal costs
- Alcohol/Entertainment/Recreation
 - The PhRMA Code expressly prohibits company provision or payment for alcohol and any kind of entertainment at industry-sponsored programs
 - Ensure that the venue does not offer alcohol to attendees, or provide recreation or any other entertainment component
 - Ensure restaurants/venues do not offer alcohol for free to attendees
 - Speakers will be trained to not consume alcohol at programs

The following table provides examples of permitted and prohibited types of speaker program venues.

Speaker Program Venue Examples	
Permitted	Prohibited
<ul style="list-style-type: none">• Conference room at a co-working space, hotel, or convention center• Private room at a moderately-priced local restaurant	<ul style="list-style-type: none">• Conference room at a museum or location of a celebrity event• Private box at a theatre performance or sporting event

Speaker Program Venue Examples	
Permitted	Prohibited
<ul style="list-style-type: none">Semi-private room in the back of a restaurant separate from main dining room with three walls and a heavy curtain for privacy	<ul style="list-style-type: none">Semi-private room with glass walls allowing other patrons to view projected slides and no sound barrier to protect from restaurant noise

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

Review Policies with Speakers

Before the program, the colleague is responsible for downloading a copy of the speaker's slides from CentrisDirect™ and for holding a discussion with the speaker to review Pfizer's promotional speaker policies to ensure that they understand Pfizer's requirements for the presentation.

The colleague should reserve sufficient time to review the slide deck and applicable Pfizer policies including, but not limited to, the colleague's duty to make a corrective statement. The colleague's pre-program discussion with the speaker must include the items outlined in the Speaker Program Checklist located at the end of this subsection.

Review Attendee Requirements

Pfizer Colleagues, not the speaker, are responsible for selecting the audience for a speaker program. It is the host's responsibility to first determine the Approved Attendee designation of a proposed attendee, using the [HCP Lookup Tool](#) or CentrisDirect™ functionality. Furthermore, the host must ensure the appropriateness of an Approved Attendee for the specific program.

Once the host has a legitimate expectation that minimum requirements are met, additional appropriate attendees are permitted. Any program not meeting requirements cannot move forward.

Minimum Attendee Requirements:

- Most program types, including programs with non-product topics, such as *The Art of Active Listening*, require a minimum of 3 Approved Attendees
 - The speaker does not count toward the 3-attendee minimum
 - Attendees affiliated with the speaker are prohibited from attending a program with that speaker, including attendees who:
 - Are part of the speaker's medical practice, practice group, or institution

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- Receive compensation as an employee from the same business entity, even if they work in a different location
- Attendees are aggregated across all link sites for sponsor programs where the audience is not physically with the speaker
- In-office link programs, which require a minimum of 1 Approved Attendee, are the only exception to the minimum requirement mentioned above

The following table provides examples of individuals designated as Approved Attendees.

Approved Attendee List	
Medical Doctor (MD)	Physician Assistant (PA)
Doctor of Osteopathy (DO)	Nurse Practitioner (NP)
Doctor of Podiatric Medicine (DPM)	Licensed Practical Nurse (LPN)
Naturopathic Physician (ND)	Advanced Practice Registered Nurse (APRN)
Doctor of Pharmacy (PHARM.D)	Registered Nurse (RN)
Pharmacist (PHARM/PHR)	Clinical or Certified Nurse Specialist (CNS)
Registered Pharmacist (RPHD)	Advanced Nurse (AN)
Pharmacy Technician (PHT)	Social Worker/Master of Social Work (SW)
Pharmacy or Pharmacist Intern (PHI)	Lab or Quality Director (Only for relevant products)

For program type resources, refer to the [Speaker Program \(Centris\) Resources](#) page of Biopharma Ops on Demand and for more details on consumer programs, refer to Section 5 of *The Orange Guide*.

Determine the Appropriate Audience



While CentrisDirect™ has controls to help ensure only appropriate attendees are invited to programs, colleagues are ultimately responsible for ensuring their attendees are appropriate. Therefore, colleagues must make a good faith effort to ensure all attendees:

- Are appropriate based on minimum attendee requirements
 - Refer to the Review Attendee Requirements section for more details
- Are appropriate if they are students studying for degrees from the Approved Attendee list
- Have a legitimate interest in the subject matter
- Have a legitimate role in and responsibility for patient care
- Are not chosen for the purpose of encouraging referrals for the speaker
- Practice in a specialty not excluded for the promoted product
- Do not hold active licenses from states imposing restrictions on providing meals if colleagues plan to provide one at the program
 - Some states may prohibit or limit providing food or beverages to HCPs licensed in those states, including during speaker programs, regardless of where the HCP practices or where the speaker program occurs



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- Field Commercial Colleagues should always consult state laws prior to engaging with HCPs, which can be found in Section 7 of *The Orange Guide*
- Are in good standing as it pertains to topic and product cap rules
 - Attendees are prohibited from attending more than 2 speaker programs per year on the same topic or 3 speaker programs per year on the same product
 - For example, if an attendee has already attended 2 programs on the same topic, they may only attend one additional program on that same product in a calendar year, and it must be on a different topic
- Are not active Pfizer speakers on the topic being presented
 - Speakers are prohibited from attending in a non-speaking capacity if they have received topic training
 - It may be appropriate for active speakers to attend on other products or topics for which they have not received speaker training
- Are not on the opted-out list
 - Colleagues should review the list on the [MyPfieldNet Compliance page](#) of HCPs who have opted out of receiving disclosable items from Pfizer prior to inviting attendees to a speaker program

FAQ: Appropriate Attendees

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

FAQ: Speakers to One Medical Office or Practice



	May a Pfizer Colleague invite a speaker to speak in-office to attendees at a single medical office or practice?
	Yes, provided the legitimate expectations outlined in the Review Attendee Requirements and Determine the Appropriate Audience sections are met.

FAQ: Providing In-Office Meals to Office Staff	
	<p>When conducting an in-office speaker program at a medical office, is it okay to provide a meal to office staff in addition to individuals on the Approved Attendees List and other appropriate attendees at the program?</p>
	<p>It depends. You should only provide a meal if legitimate expectations outlined in the Review Attendee Requirements and Determine the Appropriate Audience sections are met. If this is not met or they are unable to attend the program to receive the information presented, they should not consume the meal or be included in the attendee roster.</p>

Manage Invitations, RSVPs, and Cancellation of Programs

Managing the Preparation and Distribution of Invitations


Invitations for events can be found in CentrisDirect™. They contain important disclaimers and information for attendees that help colleagues and Pfizer ensure compliance. These reminders reinforce that alcohol and spouse attendance are prohibited, attendees must be present for the entire program, and that certain state law restrictions may be in place.



	<p>Field Commercial Colleagues <i>MUST</i>:</p> <ul style="list-style-type: none"> • Use only approved invitations • Usually distribute in person or by regular mail <ul style="list-style-type: none"> – Colleagues may also deliver approved speaker program invitations via e-mail, but only using the approved template found in CentrisDirect™ • Set expectations with potential attendees ahead of time to ensure that they can stay for the entire program duration: <ul style="list-style-type: none"> – Out-of-office programs: A minimum of 45 minutes, inclusive of Q&A – In-office or virtual programs: A minimum of 30 minutes, inclusive of Q&A – Webconference programs: The minimum required length of the link program(s) is determined by the location of the sponsor program
	<p>Field Commercial Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none"> • Alter the approved invitations in any way • Include any accompanying communications



Section 3: Guidelines for HCP Interactions and Related Field Commercial Activities

Managing RSVPs


As the host of a speaker program, the Field Commercial Colleague has primary responsibility for managing attendance.

	<p>Field Commercial Colleagues <i>MUST</i>:</p> <ul style="list-style-type: none">• Collect and record RSVPs<ul style="list-style-type: none">– When a Pfizer Colleague is entering RSVPs on behalf of any attendees, they should <i>only</i> enter such RSVPs when the HCP has clearly indicated their intention to attend the program– Colleagues <i>MUST NOT</i> enter RSVPs:<ul style="list-style-type: none">▪ When it is unclear whether an HCP will attend▪ When the HCP has only expressed interest but not confirmed attendance▪ When the colleague only believes that the HCP <i>might</i> attend• Process and confirm RSVPs• Manage the headcount<ul style="list-style-type: none">– In general, colleagues should manage their invitations to help ensure that, even with potential cancellations, they will meet the minimum attendee requirements for their speaker program• Ensure the appropriateness of all attendees<ul style="list-style-type: none">– Remember, guests of attendees, including their spouses or domestic partners, are not permitted to attend Pfizer promotional speaker programs unless they independently qualify as appropriate attendees– Guests of the Pfizer speaker, including their spouse or domestic partner, are also prohibited
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FAQ: Speaker Suggesting or Inviting Attendees	
	May a program speaker or invitee personally invite other prospective attendees? May a speaker suggest attendees?
	<p>A speaker or invitee may suggest other attendees to you in advance of the program, but it is your responsibility to first determine that each of the prospective attendees is appropriate, and then to extend the official invitation. RSVPs for the program should not be collected by the speaker or other attendees.</p> <p>You cannot conduct a speaker program for the benefit of the speaker, and therefore, it would be improper to invite attendees at the request of a speaker without an appropriate business rationale for including them. Your sole purpose in holding the speaker program must be to educate attendees about Pfizer products, or other topics in an approved presentation.</p>

FAQ: How to Handle RSVPs From Uninvited Guests	
	What should I do if a receptionist at an office I call on indicates that they will be attending a speaker program to which they were not invited?
	Because a receptionist's responsibilities are generally administrative, they would not be an appropriate attendee. It is your responsibility to inform them that they should not attend the program. You must ensure that all speaker program attendees are appropriate, given their role in and responsibilities for patient care and their legitimate interest in the program content.

Managing Cancellations

	<p>Field Commercial Colleagues MUST:</p> <ul style="list-style-type: none">• Cancel program types associated with speaker honoraria a minimum of 5 days prior to the program date to avoid potential honoraria payment<ul style="list-style-type: none">– If a program is cancelled more than 5 business days in advance or if the speaker requests the cancellation, Pfizer is not required to pay the speaker's fee• Attempt to reschedule if Pfizer cancels a speaker program within 5 business days of the scheduled engagement and the speaker requests payment<ul style="list-style-type: none">– Pfizer is contractually obligated to pay the speaker their speaking fee, with very limited exceptions– Field Commercial Colleagues must make every reasonable effort to reschedule a cancelled program within 90 days of such cancellation and the speaker will be obligated to conduct the program for no additional speaking fee<ul style="list-style-type: none">▪ Please note that the program may occur more than 90 days after the date of cancellation as long as the program is rescheduled on the same topic within 90 days• Cancel other program types as soon as possible to avoid necessary charges, such as room rental, food and beverage, and vendor management fees
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For job aids and resources regarding managing Invitations, RSVPs, and cancellation of programs, refer to the [Speaker Program \(Centris\) Resources](#) page of Biopharma Ops on Demand.

FAQ: Attendee Cancellations	
	<p>For an upcoming out-of-office program, I have three RSVPs from appropriate Approved Attendees and have a legitimate expectation that they will all attend. Two other appropriate attendees have also RSVP'd that they will attend. On the day of the program, one of the individuals who is an Approved Attendee informs me that she will be unable to make it. Do I have to cancel the program?</p>
	<p>Yes.</p>


Conducting a Compliant Speaker Program: During the Program



Capture Electronic Sign-Ins at Speaker Programs

CentrisDirect™ will allow Pfizer Field Commercial Colleagues who are added to a program as hosts or collaborators to capture attendee sign-ins on their tablet devices or laptops. The use of electronic sign-ins is required, barring a technical issue. If colleagues are unable to utilize the electronic sign-in feature, they are required to maintain a written sign-in sheet and to upload that sign-in sheet into CentrisDirect™ at closeout.

Screen Walk-In Attendees


Appropriate attendees may attend programs, even if they are not directly invited, if there is room for them at the program.

	<p>Field Commercial Colleagues <i>MUST</i>:</p> <ul style="list-style-type: none"> • Attempt to match all walk-in attendees to existing customer profiles in CentrisDirect™ in order to ascertain whether each is an appropriate attendee based on Pfizer's policies, including brand-specific specialty exclusions, state license restrictions, etc. • Ask appropriate screening questions to help verify that the attendee is not a member of an excluded specialty or licensed in a state with restrictions if there is no match in CentrisDirect™ • Respectfully ask a walk-in who is an inappropriate attendee to leave <ul style="list-style-type: none"> – Colleagues must be courteous and explain the reason that they cannot attend the program – If an inappropriate attendee refuses to leave the program, the individual's attendance must still be documented in CentrisDirect™
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FAQ: How to Handle Uninvited Guests	
	What should I do if an attendee brings a spouse/domestic partner who is not otherwise an appropriate attendee to a speaker program? Is it OK for the guest to stay if the attendee agrees to pay for their meal?
	No. You must remind the attendee that Pfizer guidelines and the PhRMA Code prohibit guests, spouses, or domestic partners from attending Pfizer speaker programs. This is clearly stated on the approved speaker program invitation. If the guest does not independently qualify as an appropriate attendee, you must respectfully ask that they leave the program.


Monitor for Consistency With Product Labeling

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



	<p>During the program, Field Commercial Colleagues MUST:</p> <ul style="list-style-type: none"> • Project the RC-approved slide deck from their Pfizer device on a projector if in person • Control the webconference for all webconference sponsor site programs <ul style="list-style-type: none"> ▪ This allows the Field Commercial Colleague to control the flow of the slides, ensure the speaker appropriately covers all slides, and it maintains the ability to make corrective statements if necessary ▪ A speaker must NOT control the webconference • Monitor the presentation to ensure that the speaker's discussion is consistent with the slides and the product's labeling <ul style="list-style-type: none"> – Monitoring is the primary responsibility of Field Commercial Colleagues in attendance at speaker programs and takes precedence over other activities, such as dealing with food service issues – Allows colleagues to ensure that the speaker: <ul style="list-style-type: none"> ▪ Reviews the mandatory compliance slide(s), which includes statements that Pfizer is sponsoring the presentation and that the speaker is presenting on Pfizer's behalf at the beginning of the program ▪ Presents the safety information in the presentation, consistent with product labeling ▪ Includes any warnings, contraindications, adverse events, and other safety information in order to provide a fair and balanced presentation ▪ Makes every effort to review this information with any attendee who arrives after that information has been presented or leaves prior to it being presented <ul style="list-style-type: none"> • This should be done as soon as reasonably possible at the conclusion of the program and can be handled by the Field Commercial Colleague or speaker • Follow these steps if a speaker presents off-label information during their presentation that was not in response to a specific unsolicited question
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Section 3: Guidelines for HCP Interactions and Related Field Commercial Activities

	<ul style="list-style-type: none">– Promptly and courteously clarify to the audience that the off-label information provided is not within product labeling and is not a part of the approved Pfizer presentation<ul style="list-style-type: none">▪ This should be done as soon as possible after the speaker has presented the off-label information, even if the speaker proactively informs the audience that the information is off-label– Remind the speaker after the presentation that Pfizer’s guidelines require that off-label information be provided only in response to a specific, unsolicited question– Indicate, as prompted in the system, that a violation was committed by the speaker when closing out the program in CentrisDirect™<ul style="list-style-type: none">▪ Once submitted, Field Commercial Colleagues will be contacted for additional information▪ Speakers who proactively speak off-label may be subject to further action, up to and including deactivation– Keep in mind that the mandatory compliance slide(s) at the beginning of each speaker program notifies attendees that a Pfizer Colleague must make a corrective statement if the speaker presents information that is inconsistent with an FDA-approved label or Pfizer policy<ul style="list-style-type: none">▪ Please note that if the speaker answers an unsolicited off-label question briefly and as permitted by policy as stated earlier in this Chapter, no “corrective” statement is required, and no policy violation should be indicated when you close out the program
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	<p>Field Commercial Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Ask questions of the speaker during speaker programs, unless necessary to help ensure approved content is presented appropriately<ul style="list-style-type: none">– Colleagues must ensure that any such question is not likely to lead to discussion of any unapproved content
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Please note that different rules may apply to speaker programs with consumer audiences. For information regarding presentations to consumers, refer to Section 5 of *The Orange Guide*.

FAQ: Alcoholic Beverages	
	What do I do if an HCP attendee insists on being provided an alcoholic beverage?
	Under Pfizer policy, you should ensure the program venue does not offer alcohol to any attendee or speaker. If an attendee insists on being served alcohol, they must be informed that the PhRMA Code and Pfizer policy prohibit the provision of alcohol and the attendee will be required to pay for their alcohol bill individually. Discuss with your manager the appropriateness of inviting the attendee to subsequent programs.

Make Approved Handouts Available

✓	<p>Field Commercial Colleagues MUST:</p> <ul style="list-style-type: none">• Make hard copies of the approved United States Package Insert (USPI) for each Pfizer product being discussed available at each in-person presentation<ul style="list-style-type: none">– For virtual programs, the USPI is readily accessible by attendees in the chat function of the virtual platform• Ensure that any other RC-approved educational materials to be distributed to program attendees are specifically approved for such purpose• Only disseminate paper copies of CentrisDirect™ presentation slides at a program if permitted by the product RC• Be the individual responsible for copying and disseminating any approved materials to attendees<ul style="list-style-type: none">– The speaker must not take on this responsibility
✗	<p>Field Commercial Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Hand out copies of slides created by the speaker, even if they have been RC-approved through the Speaker Slide Exceptions Process• Provide any other handouts, such as token gifts for speaker program attendees

Conducting a Compliant Speaker Program: Closing Out the Program

✓	<p>After a program, Field Commercial Colleagues MUST:</p> <ul style="list-style-type: none">• Enter program information in CentrisDirect™ to close out the program• Flag any policy violations that may have occurred<ul style="list-style-type: none">– If there is not an appropriate check box for a violation, colleagues should select “Other Reportable Incident” and they will be contacted for further details• If an attendee has opted out, but still consumes a meal, their meal consumption must still be recorded<ul style="list-style-type: none">– Attendees may not pay for their own meals at speaker programs
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Summary: Speaker Program Checklist for the Host of the Program

The following table provides a checklist of policies to follow when hosting speaker programs.

Speaker Program Checklist for the Host of the Program	
Lead Time	<ul style="list-style-type: none">• Speaker programs must be submitted in CentrisDirect™ with the following minimum required lead times:<ul style="list-style-type: none">– Program types associated with speaker honoraria require a 14-day lead time

Speaker Program Checklist for the Host of the Program	
	<ul style="list-style-type: none"> – Other program types require a minimum 5-day lead time
Limits on Speaker Utilization per Calendar Year	<ul style="list-style-type: none"> • On Territory Credit List (TCL): 3 programs for a speaker on a colleague's TCL for all products on which they speak • Within District: A speaker may be utilized a maximum of 6 times total by all members of a District if that speaker appears on the TCL of any District member • Colleagues who do not have a TCL: Must not use a speaker called on by any member of their district more than 6 times in a calendar year, in the aggregate <ul style="list-style-type: none"> – This applies regardless of product or topic but does not apply to link programs • Examples of these colleagues include Vaccines Representatives, Oncology KAMs
Food and Beverage Limits	<ul style="list-style-type: none"> • Unless further restricted by state or other laws, food and beverages (no alcohol) must be modest by local standards and: <ul style="list-style-type: none"> – Out-of-office: must not exceed \$100 per attendee, including tax, tip, and if applicable delivery charges <ul style="list-style-type: none"> ▪ Extraneous fees, such as room fees, must be broken out from meal costs – In-office: must not exceed \$40 per attendee, including tax, tip, and delivery charges
Determining Appropriateness of Attendees	<ul style="list-style-type: none"> • While CentrisDirect™ will assist in the determination of attendees' appropriateness, colleagues must still make a good faith effort to ensure that all attendees: <ul style="list-style-type: none"> – Practice in an appropriate specialty that is not excluded for the promoted product – Do not hold active licenses from states that impose restrictions on meals if colleagues plan to provide one at the program – Are appropriate based on Pfizer's attendee rules
Pre-Program Discussion	<ul style="list-style-type: none"> • Review with the speaker prior to each program: <ul style="list-style-type: none"> – Pfizer policies, including colleagues' duty to make a corrective statement – Approved slide deck downloaded from CentrisDirect™
Projecting Slides	<ul style="list-style-type: none"> • Colleagues are responsible for projecting the slides using their Pfizer device with a projector as needed to ensure the presentation is the current, unaltered, RC-approved version
Compliance Slide(s)	<ul style="list-style-type: none"> • All speaker programs must start with a review of the mandatory compliance slide(s), which includes statements that Pfizer is sponsoring the presentation and that the speaker is presenting on Pfizer's behalf <ul style="list-style-type: none"> – Either the speaker or the representative may present the mandatory compliance slide(s)
Slide Decks	<ul style="list-style-type: none"> • Speakers may only present RC-approved slide decks • Speakers must present all required slides in the RC-approved slide deck and must not add any non-RC-approved slides or other content
Corrective Statement	<ul style="list-style-type: none"> • The information provided verbally by the speaker must also: <ul style="list-style-type: none"> – Be consistent with the RC-approved slides and product labeling – Balance benefits and risks • Pfizer Colleagues in attendance: <ul style="list-style-type: none"> – Should be familiar enough with the deck and package insert to identify inappropriate statements or other issues with the speaker's presentation – Must make a corrective statement, as required

Speaker Program Checklist for the Host of the Program	
Handouts	<ul style="list-style-type: none"> Only RC-approved educational information that has been approved for such distribution can be handed out to attendees
Time Requirements	<ul style="list-style-type: none"> Set expectations ahead of time to ensure attendees can stay for the entire program duration: <ul style="list-style-type: none"> Out-of-office programs: A minimum of 45 minutes, inclusive of Q&A In-office or virtual programs: A minimum of 30 minutes, inclusive of Q&A Webconference programs: The minimum required length of the link program(s) is determined by the location of the sponsor program If an attendee misses part of the program, the speaker or a Pfizer Colleague should make every effort to review any safety/risk slides that were missed as soon as reasonably possible
Venue	<ul style="list-style-type: none"> Must be appropriate and conducive to a scientific or educational presentation. No “high-end” restaurants and no alcohol
Insufficient RSVPs	<ul style="list-style-type: none"> A program with insufficient appropriate RSVPs cannot go forward: <ul style="list-style-type: none"> Cancel program types associated with speaker honoraria a minimum of 5 days prior to the program date to avoid potential honoraria payment Attempt to reschedule if Pfizer cancels a speaker program within 5 business days of the scheduled engagement and the speaker requests payment Any cancellation must be communicated as soon as possible to the speaker
Entering RSVPs	<ul style="list-style-type: none"> When a Pfizer Colleague is entering an RSVP on behalf of an attendee, they should do so only when the HCP has clearly indicated their intention to attend the program
Minimum Attendance Requirements	<ul style="list-style-type: none"> At least 3 appropriate individuals from the Approved Attendees List who are not affiliated with the speaker are required to attend The program may not proceed if there are fewer than 3 attendees
Restrictions on Attending Same Topic or Product	<ul style="list-style-type: none"> Individuals are prohibited from attending a program on/for: <ul style="list-style-type: none"> Same topic: More than 2 times during a calendar year Same product: More than 3 times during a calendar year Non-product programs: Individuals may attend more than 3 non-product programs per year but no more than 2 non-product programs on the same topic
Active Speaker Attending in Non-Speaking Capacity	<ul style="list-style-type: none"> An active speaker for Pfizer may not attend a speaker program in a non-speaking capacity if the speaker has received training on the topic that will be discussed
Tracking Attendees for Transparency and Disclosure	<ul style="list-style-type: none"> All attendees should be tracked, regardless of whether they have opted out of receiving meals or other disclosable value In particular, remember to capture all attendee sign-ins electronically for Sunshine and SUPPORT Act purposes and to appropriately screen all attendees, including walk-ins, to meet our state law obligations
Reporting Speaker Program Violations	<ul style="list-style-type: none"> If a speaker commits a violation of Pfizer policy, colleagues must: <ul style="list-style-type: none"> Correct the violation during the program Coach the speaker after the program Report the violation in the closeout process in CentrisDirect™

Other Types of Speaker Program Formats

Speaker Programs at Third-Party Meetings


Third-party meetings held by groups such as local medical associations, residents at institutions, or local disease advocacy organizations may provide colleagues with an opportunity to promote Pfizer products to individuals who are gathering for another independent purpose.



Holding a promotional program in this circumstance must be based on a legitimate Pfizer business purpose and cannot be based on a desire to support or otherwise fund an independent meeting.





Field Commercial Colleagues *MUST*:

- Submit programs in CentrisDirect™ prior to the program date with the minimum required lead time described above
- Have a legitimate promotional speaker program in connection with the meeting
- Adhere to all Pfizer policies and processes regarding speaker programs, such as:
 - Programs at third-party meetings must meet the duration and content requirements of other speaker programs
 - If the customer permits spouses or guests to attend its meeting or there will be excluded specialties in attendance, holding a Pfizer speaker program in connection with the meeting would not be appropriate
- Make it clear to the customer or organization that Pfizer is not a sponsor of its business meeting, including in e-mails and/or invitations from the customer
 - Explain that Pfizer is engaging in a separate promotional activity with attendees of the meeting
 - Identify a clear start and end to the Pfizer promotional program to the audience to avoid the misperception that Pfizer is supporting any part of the meeting itself
 - Please note that this does not apply to large events such as congresses, where Pfizer may be an appropriate sponsor
- Only offer a meal as part of the Pfizer program
 - If colleagues decide to provide a meal:
 - It must be incidental to, and not otherwise the focus of the program
 - It cannot be offered more than 30 minutes in advance of, nor any time after the completion of, the Pfizer program portion of the meeting
 - If a third party provides the meal, colleagues may engage in promotion as long as it is made clear that Pfizer is not responsible for providing the meal
 - Meals provided by third parties will not be reported as part of Pfizer's payment disclosure policy
- Capture all attendee information in CentrisDirect™
 - Before confirming the program, colleagues should coordinate with the third party to ensure that they will receive all necessary information about the attendees
 - This will help determine that all planned attendees are appropriate under Pfizer policy

	<p>Field Commercial Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none"> Stay for, or participate in, other parts of the meeting agenda <ul style="list-style-type: none"> If a colleague were to participate in any way in the content of the non-Pfizer portions of the meeting, the entire meeting might be considered a promotional event and could then be governed by the same promotional rules that apply to all Pfizer speaker programs and other promotional activities <ul style="list-style-type: none"> Please note that this does not apply to large events such as congresses, where Pfizer may be an appropriate sponsor Split the cost of a meal with the host of a third-party meeting
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FAQ: Third-Party Meeting Publicity	
	I am an Account Manager and I plan to host a speaker program at a third-party meeting. Since the topic of the program does not address products or disease states, may I work with the host of the third-party meeting to publicize the program?
	Yes. Specifically, you may ask the host to include the Pfizer program on the agenda for the third-party meeting. You may also provide the host with an approved invitation for the third party to distribute to attendees.

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

Speaker Programs at Third-Party Continuing Education Events



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





- The Pfizer program must be conducted in a room physically separated from the space where CE activity is conducted
- Colleagues must clearly communicate to attendees at the start of the program that it is a separate Pfizer promotional presentation not accredited for CME credit
- Pfizer cannot provide meals or beverages in connection with the Pfizer program

Section 3: Guidelines for HCP Interactions and Related Field Commercial Activities

- Any meals provided by a CME provider must be made available to all CE event attendees, including those not attending the Pfizer presentation
- This policy applies to all programs at CE events, including programs hosted by Account Managers with topics that do not address products or disease states
- No advice or input may be provided regarding the content of the medical education activity
- No financial or other support, including payment for event expenses or meals, assistance with setting up logistics, or handling non-Pfizer speaker arrangements, may be provided in connection with the Pfizer program:
 - Financial support for a CE event may only be funded by an independent medical education grant requested through Pfizer's [GMG website](#)

For more information, see Section 6 of *The Orange Guide*.

FAQ: Meals Provided by Medical Education Organizers During a Pfizer Speaker Program	
	The organizers of a medical education event intend to offer a meal to attendees during my promotional speaker program. Can I still conduct the program?
	Yes. As long as Pfizer is not paying for the meal and it will be made available to all event attendees, including those not attending the Pfizer presentation, it is acceptable for the meal to be provided during the Pfizer program. Be sure to make clear that Pfizer is not providing the meal or sponsoring the medical education event.

FAQ: Physical Separation of Speaker Programs at Medical Education Events	
	The organizers of a medical education event require that Pfizer pay a fee to cover expenses that are directly associated with a promotional speaker program, such as the cost to rent a separate presentation room. Must this fee be paid through a medical education grant from the office of Global Medical Grants (GMG)?
	No. Standard fees required to cover the FMV of logistical expenses associated only with the Pfizer speaker program may be paid by the appropriate Pfizer Colleagues.
	I've been offered an opportunity to provide a promotional speaker program during a medical education event, but the organizers have told me that no separate room will be available. Can I still hold the program?
	Generally, no. However, if it is possible to physically separate your presentation space within the event room, you may consult with Compliance about an exception to determine if and how the program may be conducted appropriately under the circumstances.

Educational Items to HCPs

✓	<p>In accordance with the PhRMA Code and Pfizer policy, 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>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.



FAQ: Out-of-Pocket Gifts for HCPs	
Q	Can I pay for a gift for an HCP out of my own pocket if I do not expense it?
A	No. It is not appropriate to purchase personal gifts, or any other items of value for HCPs in the course of doing business, even if you pay out-of-pocket and do not seek reimbursement from Pfizer. The gesture could appear to be an attempt to illegally influence prescribing in violation of anti-kickback laws. This principle applies to any item of value expensed personally, including meals. If you have any questions, please refer to the Field Force Travel & Entertainment Policy on PfieldNet and remember that The Summary of Pfizer Policies on Business Conduct (The Blue Book) and Corporate Policy 203, Conflicts of Interest require you to avoid even the appearance of a conflict of interest.



Other Activities in Connection With Third-Party Events

Exhibits and Displays at Third-Party Events

Pfizer promotes Pfizer products and RC-approved information and materials to customers by paying for an exhibit or display table at an organization's event. An exhibit or display opportunity may occur at a variety of venues and programs.

Pfizer pays solely for the space to promote our products and must not pay more than FMV for the display opportunity. Funding that Pfizer allocates to an exhibit or display at independent educational programs should not be used to fund other aspects of the program, such as speaker honoraria, rental fees, or food. The location of the display should also be separate and apart from any independent educational activity.

	<p>Field Commercial Colleagues <i>MUST</i>:</p> <ul style="list-style-type: none"> • Ensure all Sales-funded exhibit and display requests are reviewed and approved by their manager <ul style="list-style-type: none"> – An event brochure should accompany the exhibit or display request because it helps to validate the FMV of the exhibit opportunity by listing the levels of exhibit/display opportunities and describe the space/services that are being purchased at each level • Submit all Sales-funded exhibit and display requests to their designated Program Activity Coordinator (PAC) for processing and approval through Ariba <ul style="list-style-type: none"> – This should be done at least four weeks prior to the date of the event
	<p>Field Commercial Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none"> • Participate in an exhibit or display without having received prior approval

FAQ: Paying for Display Space at a Private Practice Event	
	<p>I received an invitation from one of my specialty practice groups to pay a display fee to set up an exhibit at the practice's business meeting. Can we pay for the display?</p>
	<p>Generally, no. Payments to private practice groups are subject to increased scrutiny and are generally impermissible, particularly at events exclusively for members of the practice or events which are aimed at benefiting the practice's business. However, there may be exceptions to this rule that you should discuss with your manager or Compliance. For example, payment might be permissible in a situation where other pharmaceutical companies will be providing an exhibit and if the event involves the participation of a larger community of physicians, not just employees of the practice, such as an event that provides CE credit.</p>

Promotional Opportunities in Connection With Third-Party Meetings

Third-party meetings, including those held by local medical associations or Residents at institutions, such as a journal club or Residents' meeting, may provide colleagues with an opportunity to promote Pfizer products to HCPs who are gathering for another independent purpose.

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

Colleagues should follow the key principles below to help ensure that any promotional activities conducted in conjunction with third-party meetings are appropriate.



Field Commercial Colleagues *MUST*:



- Adhere to all Pfizer policies and processes regarding detailing
 - For example, colleagues should use Veeva CRM to record all attendees at a product detail, regardless of whether a meal is provided
- Make a good faith effort to avoid presenting product information to HCPs who are excluded for the product they are promoting, or HCPs whom they believe are unlikely to prescribe the product for on-label use
- Make it clear to the customer or organization that Pfizer is not a sponsor of its business meeting
 - Explain that Pfizer is engaging in a separate promotional activity with attendees of the meeting
 - Identify to the audience a clear start and end to the Pfizer promotional activities to avoid the misperception that Pfizer is supporting any part of the meeting itself
 - In the context of journal club meetings or similar presentations, Field Commercial Colleagues must make every effort to identify the agenda topics
 - Colleagues may detail before or after such a presentation only if the agenda topics for the program do not appear to contain off-label information respective to a product supported by the Field Commercial Colleague
 - If a colleague participates in any way in the content of the non-Pfizer meeting, the entire meeting may be considered a promotional event and is then governed by the same rules that apply to all Pfizer promotional activities
- Only provide a meal if the third-party meeting is at an in-office or in-hospital setting
 - If colleagues provide the meal, it must be offered as part of the detail and incidental to the program
 - If a third party provides the meal, colleagues may engage in promotion as long as it is made clear that Pfizer is not responsible for providing the meal
 - Meals provided by third parties will not be reported as part of Pfizer's payment disclosure policy



Field Commercial Colleagues *MUST NOT*:

- Provide frequent, regular, or recurring meals

	<ul style="list-style-type: none"> • Distribute invitations, or any other written material created by the host organization, unless the material has been RC-approved • Be present during any discussion of a Pfizer product that they anticipate will be inconsistent with that product's labeling • Split the cost of a meal with the host of a third-party meeting • Provide any food or other financial support in connection with an accredited CME activity (ACCME, ACPE, or ANCC) <ul style="list-style-type: none"> – Even if a colleague is offered time to promote while providing a meal to attendees at an accredited medical education conference, they must decline that opportunity since any type of financial support for accredited CE, including payment for event expenses or meals, can only be funded through an independent professional education grant <ul style="list-style-type: none"> ▪ Requests for these grants should be sent by the requestor through Pfizer's GMG website
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FAQ: Detailing at Journal Club Meetings	
	<p>I've been invited to make a promotional presentation at a journal club meeting held at a local hospital. Is it permissible for me to make a promotional presentation? And if so, can I provide a modest meal?</p>
	<p>Field Commercial Colleagues may provide a promotional presentation in this scenario. However, you should not attend or provide content or logistical support for any portions of a third-party meeting that are accredited for CME.</p> <p>You may provide a meal as part of the presentation only if no part of the meeting involves CME and you comply with all applicable Pfizer policies, including ensuring that:</p> <ul style="list-style-type: none"> • The audience is appropriate and does not contain HCPs who practice in excluded specialties • You have a legitimate opportunity to present information about Pfizer products • Any meals that are offered during the presentation are incidental to the program • All attendees are appropriately recorded in Veeva CRM and all expenditures in PT&E • You segregate the Pfizer promotional presentation from the rest of the meeting • All relevant state restrictions on the provision of meals and other items are followed <p>If you are unsure whether the promotional opportunity is appropriate, contact your manager or Compliance.</p>

Attendance at Continuing Medical Education (CME) Events

Grand Rounds/Tumor Boards

Grand Rounds and Tumor Boards are specific types of third-party educational meetings that typically occur in the institutional setting. They are an important teaching tool for doctors, residents, and medical students.

Section 3: Guidelines for HCP Interactions and Related Field Commercial Activities

The format usually includes a presentation of medical information and a discussion led by a speaker. The objective of these meetings is to educate HCPs on evolving areas of clinical practice.

Many institutions, such as teaching hospitals, provide routine weekly or monthly Grand Rounds/Tumor Boards, which tend to be open to the entire medical professional community. A large percentage of Grand Rounds/Tumor Boards involve CME credits for the attending HCPs.

With prior manager approval and adherence to the following requirements, Field Commercial Colleagues are permitted to attend CME-related Grand Rounds/Tumor Boards to further their education in a relevant therapeutic area. Grand Rounds/Tumor Boards attendance must not be used as a means to access customers or to gain access to information about off-label uses of a product the Field Commercial Colleague supports.

- Please note that if a Grand Rounds/Tumor Board event is non-CME, then Field Commercial Colleagues are expected to adhere to *The Orange Guide* [policy on third-party meetings](#) set forth in this chapter and the additional restrictions in this section do not apply
- Additionally, for widely attended CME-related events that are not classified as Grand Rounds/Tumor Board, please adhere to the guidance provided in the [Medical Congresses/Conventions](#) subsection in this chapter

The requirements below apply to Field Commercial Colleague attendance at Grand Rounds/Tumor Boards.



Field Commercial Colleagues *MUST*:

- Make every effort to identify the agenda topics for the program they wish to attend, prior to the program
 - Attendance at the program is permissible only if the majority of the agenda topics for the program do not appear to contain off-label information respective to a product supported by the Field Commercial Colleague
 - If the agenda topics are not off-label, but lack relevance to the Field Commercial Colleague's respective therapeutic area, then the manager should assess whether there is a sufficient business need for the Field Commercial Colleague to attend the event
 - Prior written approval from the attendee's manager, via the Grand Rounds/Tumor Board SharePoint site, is required, with e-mail requests and approvals generated by the applicable SharePoint system
 - [Oncology](#)
 - [Vaccines](#)
 - [All other Business Units \(BUs\)](#)
- Comply with rules of the sponsoring institution
- Ensure that any promotional efforts following attendance will be consistent with all RC-approved messaging regarding their Pfizer products
- Provide written certification of attendance to their manager within 7 days following the event via the Grand Rounds/Tumor Board SharePoint site
- Inform their manager if there were any areas of noncompliance with these requirements within 3 calendar days after attending a program
 - In such case, the manager must promptly notify the RBD and Compliance to set up a discussion as to whether any additional action is warranted

Section 3: Guidelines for HCP Interactions and Related Field Commercial Activities

- Report any reportable safety information learned during the Grand Rounds/Tumor Board programs as discussed in this Chapter and in [Corporate Policy 903, Your Responsibility to Report Information about the Safety, Quality, and Performance of Pfizer Products](#)



Field Commercial Colleagues *MUST NOT*:

- Attend more than 24 Grand Rounds/Tumor Boards per year
 - No more than 12 of them may occur with an individual institution within a calendar year
- Engage in sales or promotional activities while in the location of the Grand Rounds/Tumor Board program or in conjunction with such program
- Provide any meals at the host facility or in connection with the Grand Rounds/Tumor Board program at any point during the day of the event
- Wear Pfizer ID badges, unless required by the institution
- Attend any program that they know is likely to involve substantial discussion of investigational Pfizer compounds or topics that are inconsistent with labeling for an approved Pfizer product
- Discuss or use any off-label information learned during their attendance at the Grand Rounds/Tumor Board program
- Attend any program where they know that [Protected Health Information \(PHI\)](#), such as a patient's name, date of birth, or social security number, will be made accessible during their attendance
 - If a Field Commercial Colleague comes into contact with PHI at any event, they should follow the requirement outlined in Section 1 of *The Orange Guide*
 - Unless approved by the RBD, the manager should not approve further attendance by any Field Commercial Colleague at an event in which PHI has been made available to attendees

Medical Congresses/Conventions/Widely Attended CME Events

CME lectures often take place during medical conventions, symposia, and congresses. Field Commercial Colleagues' attendance at such CME-accredited programs can present legal, perception, and other risks.

Therefore, in the case of widely attended medical congresses or conventions, where such events are open to external invitees from other institutions, Field Commercial Colleagues may attend CME-accredited lectures subject to the requirements below.



Field Commercial Colleagues *MUST*:

- Obtain manager approval
- Ensure attendance is occasional
- Ensure that any promotional efforts following attendance at the CME event will be consistent with all RC-approved messaging



Field Commercial Colleagues *MUST NOT*:

- Attend CME-related congresses, symposia, or large convention events that are likely to involve substantial discussion of investigational Pfizer compounds or topics that are inconsistent with labeling for an approved Pfizer product
 - For example, if there are 3 topics listed on a program agenda, and only 1 of them involves off-label information about the Field Commercial Colleague's product, the Field Commercial Colleague may attend the program because the majority of the topics do not involve relevant off-label information
- Engage in promotional activity at the CME event or leverage the event to access customers
- Initiate conversations with prescribers or discuss Pfizer products if approached by an HCP while at the CME event
- Discuss or use any off-label information learned during attendance of the event

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

Preceptorships and Other Training for Field Commercial Colleagues

Preceptorships

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

Preceptorships may only be organized by colleagues who are Area Business Manager-level and above. Such managers must consult with and obtain the approval of Compliance before engaging in these activities.

When setting up a mentorship or preceptorship, Pfizer Colleagues must remind HCPs serving as mentors or preceptors that they have a legal obligation to obtain their patients' written authorization before Pfizer Colleagues may be allowed to observe any consultation, examination, or treatment of any patient, or have access to information about their health or medical condition

Other Training for Field Commercial Colleagues

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



Field Commercial Colleagues *MUST NOT* pay an HCP to train colleagues for the purpose of:

- Giving the HCP the opportunity to practice making presentations
- Ensuring that the HCP reads certain information

- Building a relationship with the HCP
- Gaining or improving access to the HCP
- Rewarding past prescribing
- Inducing future prescribing

Chapter 4: Guidance for HCPs in Different Settings and/or With Non-Clinical Responsibilities

Field Commercial Colleagues must be aware if an HCP they are calling on is employed by the government or has additional responsibilities that may impact the general guidance discussed throughout this section of *The Orange Guide*.

These include HCPs who are:

- C-suite administrators
- Members of the Pharmacy and Therapeutics (P&T) Committee
- Involved with Health Information Technology (HIT)
- Interested in clinical research
- Federal employees

Review the information below to learn more about each different HCP type, including additional requirements when interacting with them. For information regarding Specialty Pharmacy HCPs, see Section 4 of *The Orange Guide*.

HCPs Who Are C-Suite Administrators

Pfizer has an interest in calling on C-suite administrators at practice groups and other Organized Customers (OCs) because they increasingly have a role in influencing access to medicine. Working with these customers has both business and legal risks if not conducted in an appropriate manner.


C-suite administrators at practice groups and OCs often will also be HCPs, sometimes even reserving part of their time for treating patients. Therefore, the manner in which colleagues engage C-suite administrators must align with their role as a Pfizer Colleague and the resources and messaging they are allowed to provide.





Sales Colleagues MUST:

- Engage these individuals in their capacity as HCPs rather than Administrators
- Limit their engagements to product and disease state discussions as well as other topics approved for them, such as extending invitations to speaker programs where appropriate
- Only use resources approved for their roles and available on [PROMOSprime](#) and in Veeva Customer Relationship Management (Veeva CRM)
- Only participate in joint meetings with the Account Manager and customer on an infrequent basis when there is a legitimate business need to do so, and the programs or materials to be discussed are Review Committee (RC)-approved for joint sales and account management customer interactions
 - The Sales Colleague may play an active role in identifying C-suite administrators or other contacts at medical groups or OCs who might be appropriate contacts for Account Managers

	<ul style="list-style-type: none">– If the circumstances warrant the Sales Colleagues making an introduction in person, the Sales Colleague is generally permitted to sit in on an introductory meeting between the customer and the Account Manager
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	<p>Sales Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Use resources approved for Account Managers only• Participate in other meetings between the Account Manager and the customer
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	<p>Account Managers <i>MAY</i>:</p> <ul style="list-style-type: none">• Engage C-suite administrators at an institutional level, focusing on topics such as population health management and quality initiatives• Only use resources approved for Account Manager roles and available on PROMOSprime
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	<p>Account Managers <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Engage in product promotion to individual HCPs unless expressly approved to do so• In some instances, Account Managers may have limited product responsibilities that usually relate to formulary placement at OCs• Use resources approved for Sales Colleagues only
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HCPs on the Pharmacy and Therapeutics (P&T) Committee

The P&T Committee of an Account decides which pharmaceutical products are included on the formulary. P&T Committees typically make formulary decisions based upon assessments of safety, efficacy, tolerability and, increasingly, cost-effectiveness.

In some cases, organizations with P&T Committees may be acting on behalf of Medicaid, [Medicare Part D](#), or other government healthcare programs. P&T Committee members are charged with an important responsibility, and therefore, are expected to avoid both actual and perceived conflicts of interest when making formulary decisions.

It is Pfizer policy to not engage in any activity that could be construed as improperly influencing the independent judgment of a P&T Committee member.

Day-to-Day Interactions

Field Commercial Colleagues and Field Medical Colleagues interact with P&T Committee Members in a variety of ways:

- Field Commercial and Field Medical Colleagues may attend or present at P&T Committee meetings where formulary decisions are considered
- Field Commercial Colleagues may interact with a P&T Committee member in the member's capacity as a practicing HCP

Section 3: Guidelines for HCP Interactions and Related Field Commercial Activities

Field Commercial Colleagues may also interact with P&T Committee members as part of their normal Pfizer day-to-day activities. The four Core Promotional Compliance Principles and the same policies that govern interactions with other HCPs should be used as the guide to compliant interactions with the HCPs that are P&T Committee members.



When interacting with HCPs who may also be P&T Committee members, ***Field Commercial Colleagues MUST NOT:***

- Show them "special treatment" because of their status on a P&T Committee
 - The mere increase of detailing or interactions during a pending formulary decision in and of itself generally is not considered "special treatment," so long as the purpose is to provide relevant, on-label information
 - However, increasing the number of meals provided in connection with the increase in detailing or calls is not permitted
 - Colleagues must notify their manager promptly if a committee member requests special treatment
- Discuss an HCP's P&T Committee membership status with other colleagues in a manner that implies preferential treatment based on their committee membership
- Treat P&T Committee members differently during a pending formulary decision than at other times

While the requirements above cover day-to-day interactions, for information on how to approach adding a product to formulary, refer to Section 4 of *The Orange Guide*.

FAQ: Questions From a P&T Committee Member About Their Status



If an HCP asks if I know whether or not they are a P&T Committee member, what should I say?



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

FAQ: Offering a Meeting Over Lunch to a P&T Committee Member





If I run into a member of a P&T Committee in the hall at a hospital, may I offer to buy them lunch and discuss the benefits of a Pfizer product while we eat?



Yes, as long as it is consistent with Pfizer policy on meals for HCPs and the hospital's P&T Committee does not restrict this type of interaction. Your interactions with P&T Committee members are governed by the same Pfizer policies that govern your interactions with HCPs. If the hospital doesn't prohibit it, Pfizer policy permits you to engage in a product promotional


	discussion over an occasional modest meal. Pursuant to the PhRMA Code and Pfizer policy, Sales Colleagues may only provide a meal to HCPs at in-office or in-hospital settings and in conjunction with informational presentations/discussions.
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FAQ: Calling on a P&T Committee Member Not in Call Cycle





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

HCPs Who Are Involved With Health Information Technology (HIT)

As our customers' breadth and depth of Electronic Health Record (EHR) use increases, Pfizer seeks to educate customers about its products that may improve patient care through appropriate and compliant engagement on HIT topics and functionality.

	<p>Traditional Sales Colleagues, most notably Sales Representatives and Area Business Managers, MAY only engage customers on HIT topics in two ways:</p> <ul style="list-style-type: none"> • Deploy RC-approved HIT Tools approved specifically for use by Sales Colleagues <ul style="list-style-type: none"> – Examples may include pieces that explain how to place Pfizer products in their bookmarks or favorites list – Only HIT Tools available on PROMOSprime are approved for Sales Colleague use • Engage a customer on HIT issues to identify leads and introduce them to Account Team colleagues <ul style="list-style-type: none"> – Sales Colleagues may play a role in connecting Account Team colleagues with the key individuals who may have responsibilities directly or indirectly related to HIT – This could require limited discussion of HIT to gauge interest and determine the appropriate contact for introduction to the Account Team colleagues, and it should only involve the use of HIT Tools approved for Sales Colleagues – Sales colleagues may arrange or attend an introduction meeting, but once the introduction is made, they should not attend any future meetings between the customer and Account Team colleagues related to HIT
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FAQ: Listing of Pfizer Products in an EHR System	
	I understand that for launch products, one of the challenges is to get the product listed in the customer's EHR system so that the HCP can find it easily on their screen. I know that a Pfizer product is expected to be approved by the Food and Drug Administration (FDA) in the near future. Am I permitted to speak with the customer about how to list the product in their EHR system so that it will be listed as soon as possible after it has been approved?
	Generally, it is not appropriate for commercial colleagues to discuss a product with a customer prior to FDA approval. If no RC-approved materials or messaging exist, such discussions are not permitted.

FAQ: Sales Colleagues' Role in Introductions	
	I am a Sales Representative, and I recently learned that an HCP I have called on for years has taken on a key HIT role in her medical group. May I ask her if she would be interested in discussing HIT and quality initiatives with a Pfizer Key Account Manager (KAM)? Could I sit in on the meeting?
	This would be a good example of where it is appropriate for you to assess the HCP's interest in meeting with the Account Team for introductions. Remember that you may only use HIT Tools approved for Sales Colleagues to support your discussion. Furthermore, to the extent it would help facilitate the meeting, you may show up in person at the first meeting to introduce the KAM, but you may not attend any future meetings between the customer and Account Team colleagues related to HIT.
	I am a Sales Representative, and I was speaking with a KAM in the lobby of a hospital when an HCP I know with HIT responsibilities came walking by. I introduced the HCP to the KAM, and the two of them agreed to meet next week to discuss HIT topics. May I join them for that first meeting?
	No. At this point, the KAM and the HCP have already met each other, and your presence at the scheduled meeting would not do anything further to facilitate the introduction. There is no other proper justification for you to sit in on the meeting, so you should not attend.

For more information regarding HIT, refer to Section 4 of *The Orange Guide*.

HCPs Interested in Clinical Research

Some HCPs may also be involved or interested in becoming involved in clinical research.

	<p>If an HCP has specifically inquired about research opportunities with Pfizer, Field Commercial Colleagues MAY:</p> <ul style="list-style-type: none">• Triage questions about Pfizer-sponsored or investigator-initiated research to a Field Medical Colleague either synchronously or asynchronously through the Triage app
	<p>Field Commercial Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Attempt to influence the decision to engage with the HCP, as that is within the complete discretion of the Field Medical Colleague

HCPs Who Are Federal Employees

As Pfizer's sales to the federal government continue to increase, interactions with government officials, such as the Director of Medicaid, and government employees, such as a physician at a federal institution or at 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 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 \(DHA\)](#)
- [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 the:

- 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:

- [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

Section 3: Guidelines for HCP Interactions and Related Field Commercial Activities

Pfizer Sales Colleagues may interact with HCPs and other employees who work for these government agencies and institutions on a full- or part-time basis or otherwise qualify as federal government employees. Account managers may also interact with federal government employees who make decisions on formularies and purchasing.

When compared to the general HCP guidance, there are often additional requirements on promotional activities that are conducted with HCPs who are federal government employees. To learn more about the requirements for interacting with federal employees, refer to Section 7 of *The Orange Guide*.

Chapter 5: 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](#)

Privacy

- For more information on Pfizer's policies for protecting patient privacy, see Section 1 of *The Orange Guide*

State Laws

- For information on relevant state law restrictions, see Section 7 of *The Orange Guide*
- To determine whether an HCP is licensed in Massachusetts, Minnesota, New Jersey or Vermont, Sales Representatives should consult the physician profile within Veeva CRM or the [HCP License List](#), and other colleagues should consult the [HCP Lookup Tool](#)
- Additional information on state law restrictions is also available on [Policy Xchange](#) under the State Healthcare Law Compliance tab and on [MyPfieldNet](#) under the Compliance tab

Disclosure/Transparency

- For more information on Pfizer's HCP Disclosure Policy, see Section 1 of *The Orange Guide*
- For more information on Pfizer's HCP transparency practices, refer to the [Global HCP/HCO Transparency Reporting Portal](#) or e-mail GlobalHCPTransparencyReporting@pfizer.com
- For more information on Open Payments, please see <https://www.cms.gov/OpenPayments/About/Law-and-Policy.html>

PhRMA

- For Q&A on the PhRMA Code, see the [Global Policy Xchange](#) on Biopharma Ops on Demand
- For more information about the PhRMA Code, refer to the PhRMA website at <https://phrma.org/resource-center/Topics/STEM/Code-on-Interactions-with-Health-Care-Professionals>

Pfizer's Field Force Travel & Entertainment (T&E) Expense Procedure

- More information on Pfizer's Field Force T&E Expense Procedure is available on [MyPfieldNet](#)

Written and Electronic Communications

- For more information on the acceptable use of information systems, see [Corporate Policy 403, Acceptable Use of Information Systems](#)

Starters

- Questions may be referred to North America Sample Operations, the relevant Sales Manager, Legal, or Compliance
- For Pfizer's policies for complying with the PDMA, see the [Starter Compliance Manual](#)
- Sales Colleagues who need to order "In House Pharmacy" Starter Activity Forms (SAF) can obtain them by calling Standard Register at **800-313-8263**

Section 3: Guidelines for HCP Interactions and Related Field Commercial Activities

- For more information on distributing starters in government institutions, see Section 2 of *The Orange Guide*

Non-Speaker Program Meals Provided to HCPs

- For more information on Pfizer's meal and educational item guidelines based on the PhRMA Code, including an FAQ on the PhRMA Code, refer to the [PhRMA Guidelines tab on Policy Xchange](#) or e-mail StateHealthcareLawCompliance@pfizer.com
- For more information on the execution of Virtual Customer Communications (VCCs) or other approved virtual platform presentations with meals see [Guidance on Promotional Meals with VCC](#)
- For more information regarding processes for capturing and recording promotional meals in PT&E, refer to the guidance available at http://opsource.pfizer.com/PfieldnetDocuments/PTE_Entering_in_a_Promotional_Meal_Expense.pdf

Speaker Programs for HCPs

- For more information about Pfizer's procedures for conducting speaker programs, please refer to the [Speaker Program \(Centris\) Resources](#) page on Biopharma Ops on Demand
- For more information about retaining HCPs for activities other than speaker programs, including advisory boards and colleague training, refer to the ["HCP Engagements" tab](#) on the Global Policy Xchange on Biopharma Ops on Demand
- Refer any additional questions to the Speaker Operations team, your manager, or Legal or Compliance

Preceptorships

- For more information on documentation to be completed for preceptorships, see the [HCP Engagements Tab](#) on the Global Policy Xchange on Biopharma Ops on Demand. Refer any questions to your manager, Legal, or Compliance

Interactions with Members of the Pharmacy and Therapeutics (P&T) Committee

- Questions related to P&T interactions may be referred to your manager or Legal or Compliance
- For medical inquiries, contact Pfizer Medical Information at **800-438-1985**

Interactions with Consumers

- For more information on interacting with consumers, including policies for conducting compliant speaker programs for consumers, see Section 5 of *The Orange Guide*

Interactions with Pfizer Field Medical Colleagues

- For more information on interacting with Field Medical, Outcomes & Analytics (FM, O&A) and/or Field Medical, Therapeutic Area (FM, TA) Colleagues, see Section 2 of *The Orange Guide* and/or [The Green Guide: Governance for Medical Activities](#)



The Orange Guide

Section 4

Guidelines for Organized Customer Interactions and Related Field Commercial Activities

Section 4

Guidelines for Organized Customer Interactions and Related Field Commercial Activities

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

Chapter 1: Introduction

There are many customer organizations that Pfizer Field Commercial 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 Orange Guide*.

OCs include:

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

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

Furthermore, the guidance regarding different types of contractual arrangements between Pfizer and OCs is also reviewed. These types of contractual arrangements include Non-Discount Arrangements and Discount Arrangements.

Finally, since OCs are increasing their use of Health Information Technology (HIT), this section provides guidance for interactions involving HIT.

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: Activities and Interactions With Organized Customers

Pfizer interacts with Organized Customers (OCs) in a wide variety of settings to enable patients to access our products and help improve the delivery of health care. The same Core Promotional Compliance Principles that apply for Field Commercial Colleague interactions with HCPs also apply to engagements with OCs.

This chapter provides guidance to help ensure compliant interactions with OCs. For more information regarding compliant interactions with HCPs, refer to Section 3 of *The Orange Guide*. For more information regarding compliant interactions with patients and consumers, refer to Section 5 of *The Orange Guide*.

Anti-Kickback Considerations

The [Anti-Kickback Statute](#) prohibits payments intended to induce someone to purchase, prescribe, endorse, or recommend a product that is reimbursed under federal or state healthcare programs. The Anti-Kickback Statute may be implicated by certain transfers of remuneration to a customer. Given these risks, it is essential to properly evaluate any potential transfer of remuneration to an OC.

The [Office of Inspector General \(OIG\)](#) Compliance Program Guidance for Pharmaceutical Manufacturers has identified key factors that courts have considered when evaluating an arrangement that implicates the Federal Anti-Kickback Statute. These factors alone do not determine whether an arrangement is illegal, but careful consideration is required in any arrangement that could be interpreted negatively under these factors:

- Does the arrangement or practice have a potential to interfere with, or skew, clinical decision-making?
- Does the arrangement or practice have a potential to undermine the clinical integrity of a formulary process?
- If the arrangement or practice involves providing information to decisionmakers, prescribers, or patients, is the information complete, accurate, and not misleading?
- Does the arrangement or practice have a potential to increase costs to federal healthcare programs, beneficiaries, or enrollees?
- Does the arrangement or practice have the potential to be a disguised discount to circumvent the Medicaid Rebate Program Best Price calculation?
- Does the arrangement or practice have a potential to increase the risk of overutilization or inappropriate utilization of items—in other words, Pfizer products—or services?
- Does the arrangement or practice raise patient safety or quality of care concerns?

Avoid Combining Types of Transactions

As more and more OCs have emerged, the lines between customer types, such as payers, prescribers, and purchasers, have begun to blur. As a result, it is important to ensure separation among Field Commercial Colleague roles to avoid the actual or perceived commingling of transactions, which could raise anti-kickback and pricing concerns.






Field Commercial Colleagues *MUST*:

- Always consult Legal before undertaking any activities that are functionally aligned to other roles within the organization, even if the risks are not apparent

Section 4: Guidelines for Organized Customer Interactions and Related Field Commercial Activities

	<ul style="list-style-type: none">– What is appropriate for an Account Management Colleague may not be appropriate for certain sales roles• Ensure that when engaging with a Health System, particular initiatives are pursued by themselves and must not be predicated on other programs or additional performance of any kind
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	<p>Field Commercial Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Combine certain types of transactions to avoid implicating pricing or anti-kickback concerns<ul style="list-style-type: none">– When different transactions are commingled inappropriately, there can be a risk that the value to the Health System of that separate, non-rebate related arrangement would need to be considered and included as a discount to the Health System for purposes of price reporting under rules of the Medicaid Drug Rebate Statute• Leverage any additional arrangements, such as a non-formulary arrangement, in order to secure preferential formulary status• Discuss grants, Service Agreements, Organized Customer and Payer Tools and Resources (OCP Resources), or other items of value in connection with formulary discussions<ul style="list-style-type: none">– An example would be if OCP Resources were offered to secure formulary placement instead of for the resources' own approved purposes
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FAQ: Discussing Payer Rebates	
	<p>One of my customers is a Health System that manages its own formulary and is owned by or affiliated with a payer. Pfizer's product does not have favorable access at the Health System. I would like to engage in discussions with this Health System about the clinical benefits of a product and the potential benefits to their patients. Can I discuss rebates received by the affiliated payer customer under contract with Pfizer? Can I provide tools or engage in adherence arrangements in conjunction with or in exchange for formulary access?</p>
	<p>No. Pfizer Colleagues must not discuss rebates received by a Health System affiliated with a payer or any other customer with another Health System, as that would violate contractual confidentiality obligations Pfizer has with those customers. Even if a Health System is affiliated with the payer customer, Pfizer's contract is with the payer, and discussions related to the terms of those contracts must remain confidential.</p> <p>Additionally, Pfizer Colleagues must not provide tools or engage in adherence arrangements in conjunction with or in exchange for formulary access. Commingling other arrangements with formulary discussions elevates risk under the federal Anti-Kickback Statute and raises the risk that separate, non-rebate arrangements might need to be considered for purposes of price reporting.</p>

Offering Organized Customer and Payer Tools and Resources

Occasionally Pfizer offers certain educational, quality-based programs and resources to OCs. These Review Committee (RC)-approved resources are referred to as 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
	<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 HCP• Gain or improve access for Sales Colleagues• Help a customer satisfy any accreditation or credentialing requirements

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 Orange 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 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.



Section 4: Guidelines for Organized Customer Interactions and Related Field Commercial Activities

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 <i>MUST</i> 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<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<ul style="list-style-type: none">▪ 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
	<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

Section 4: Guidelines for Organized Customer Interactions and Related Field Commercial Activities

For more information about currently available tools and resources, please review the resources and the associated utilization guidance at [PROMOSprime](#).

FAQ: Use of Quality Programs	
	A Health System is trying to attain National Committee for Quality Assurance (NCQA) Patient-Centered Medical Home (PCMH) accreditation. Can I offer a menu of six or seven Payer and Channel Access (PCA) Quality Programs to aid them in meeting the accreditation standards?
	No. Pfizer's policy does not permit providing Quality Programs to Accounts primarily for the Health System to meet its NCQA accreditation. The decision to provide each Quality Program must be based on Pfizer's goals of improving health outcomes, patient awareness, wellness, disease prevention, and high-quality health care. If you have any questions, consult with the relevant Product Attorney.
	Can Quality Programs be used to get access or to assist in building relationships with an Account? What about PROMOSprime and other OCP Resources?
	No. The use of Quality Programs or other tools to gain access or for relationship-building purposes can raise red flags under anti-kickback laws. These tools and resources must be offered to Accounts with the same intent for which they are created, which is to promote wellness, disease prevention, patient awareness, and high-quality health care.

FAQ: Discussing Pfizer Products or Branded Resources While Meeting With Customers	
	If I am meeting with an OC to discuss Unbranded Customer OCP Resources, am I permitted to discuss Pfizer products or branded OCP Resources during that meeting?
	<p>It depends on RC guidance. If approved by RC with respect to the specific Unbranded Customer OCP Resource, you are permitted to discuss Pfizer products during the meeting only if your discussions about Pfizer products are clearly separate from your discussions about the Unbranded Customer OCP Resource.</p> <p>In doing so, you must ensure that the OC understands that the resource is not related to the promotion of Pfizer products, and that Pfizer does not expect or intend that the OC use our products as a condition of providing the resource. The resource must be provided with no strings attached.</p>

FAQ: The Value of OCP Resources in Meeting Objectives	
	I am a Key Account Manager (KAM). Can I conduct a financial Return on Investment (ROI) analysis on implementation of an OCP Resource?
	<p>It depends on the OCP Resource and what you are measuring. You must not conduct a product-specific ROI analysis on an unbranded resource as you are not permitted to calculate and cannot use OCP Resources to achieve a gain in market share. Similarly, you are never permitted to conduct an ROI analysis on the deployment of SBL resources at a specific customer.</p> <p>For other OCP Resources that are focused on a specific therapeutic area, depending on the therapeutic area, it may be appropriate to measure market growth after implementation. Consult the Global Product Counsel responsible for the therapeutic area to ensure an ROI analysis is appropriate.</p>

Chapter 3: Guidance for Agreements With Organized Customers

Pfizer enters into a variety of contractual arrangements with its Organized Customers (OCs). Common types of commercial contractual arrangements include:

- Non-Discount Arrangements
- Discount Arrangements

Read below for more information on these different types of arrangements.

Non-Discount Arrangements

Pfizer enters into Non-Discount Arrangements with 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

These different types of Non-Discount Arrangements are discussed in more detail below.

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.



To ensure compliance when entering into Non-Discount Arrangements with OCs, **Field Commercial Colleagues MUST:**

- Work with a member of the Pricing and Access Legal team to assist with contract development as well as to mitigate compliance risks
- Ensure the Non-Discount Arrangement serves a legitimate business purpose for Pfizer
 - Only purchase those goods or services for which Pfizer has a bona fide need
 - Paying for unneeded goods, services, or data can increase the risk that the arrangement is viewed as an illegal kickback
- Pay FMV for the goods, services, or data
 - Paying above or below FMV increases the risk that the arrangement may be viewed as a kickback
- Memorialize Non-Discount Arrangements between Pfizer and its OCs in a written contract
 - Remember, because contracts can be oral or written, colleagues can unintentionally bind Pfizer if they do not capture these agreements in a written contract



Field Commercial Colleagues MUST NOT:

- 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

- 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
- Make oral promises to customers

Purchase Agreements and Service Agreements

Purchase Agreements

The term **Purchase Agreement** refers to a Non-Discount Arrangement between Pfizer and an OC where Pfizer is procuring an item of tangible value to Pfizer. Frequently, Pfizer seeks to purchase data to which an OC has access by virtue of the OC providing services to its patients, members, or affiliated physicians.

Service Agreements

The term **Service Agreement** refers to a Non-Discount Arrangement between Pfizer and an OC where the OC is hired to perform services for Pfizer.

OCs are in the unique position of having access to patients taking Pfizer products, to members for whom they provide health benefits, and to providers who are affiliated with them. For this reason, Pfizer may, from time to time, retain the OC to engage with such individuals or to disseminate certain information on Pfizer's behalf.

Common types of Service Agreements include those for dissemination of:

- Patient Educational materials
- Medication Compliance programs
- Quality Care programs

An example of a Service Agreement could include engaging an Integrated Delivery Network (IDN) to provide clinical and technical input into the development and testing of prototype Pfizer resources, such as a Health Information Technology (HIT) tool or a population health quality resource intended for use with OCs, including HCPs.

Quality Care programs are initiatives intended to support optimal patient care and typically involve contractual deliverables such as slide presentations, summary descriptions, infographics, or similar, but do not include systematic data-driven activities involving data analysis. Quality Care Programs can be led by Commercial, Medical, or jointly.

Privacy laws may limit the scope of permissible activities OCs may engage in when interacting with patients on Pfizer's behalf. Colleagues should consult a member of the Pricing and Access Legal team about any questions on the permitted scope of OCs' interactions or communications involving patients or clinicians.

Guidance Around Purchase and Service Agreements



Field Commercial Colleagues *MUST*:

- Only enter into Purchase Agreements and Service Agreements that support a bona fide Pfizer business need
- Memorialize Purchase Agreements and Service Agreements between Pfizer and its OCs in a written contract

Section 4: Guidelines for Organized Customer Interactions and Related Field Commercial Activities

- Gain approval for all Purchase Agreements, Service Agreements, and other arrangements from the Pricing and Access Legal team
- Gain approval from Pricing and Access Legal when deviating from the Pfizer-approved template for either a Purchase or Services Arrangement in those instances where a Pfizer-approved template has been developed
- Consult the Pricing and Access Legal team, who will consult with the Pfizer Global Privacy Office as needed, to ensure each arrangement complies with federal and state privacy laws



Field Commercial Colleagues *MUST NOT*:

- Discuss Purchase Agreements, Service Agreements, or other arrangements in connection with rebate negotiations
- Reference, verbally or in writing, existing Discount Arrangements
- Enter into Purchase Agreements or Service Agreements for the purpose of inducing the placement or maintenance of Pfizer products on a formulary

Other Non-Discount Arrangements

Patient Education Programs and Medication Compliance Programs

Patient Education Programs allow Pfizer to provide Review Committee (RC)-approved health information to an OC's patients or members, subject to certain payment and authorization requirements under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

With very limited exceptions, unless HIPAA authorizations are obtained from patients or members, Pfizer may only provide unbranded health information to the OC's patients or members.

Medication compliance programs, commonly referred to as refill reminder or adherence programs, are outreach programs that provide patients with information about the product they are taking, remind them of the importance of staying on therapy as prescribed, and remind patients to refill their prescriptions.

These programs may be implemented without seeking patient authorizations if Pfizer and the OC comply with the requirements of the HIPAA refill reminder exception.

All materials provided as part of a patient education program or medication compliance program must be reviewed and approved by the appropriate Pfizer RC or member of the Pricing and Access Legal team.

Collaborations

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. It is different from a traditional service arrangement, where Pfizer might pay an OC an FMV fee to perform a service on behalf of Pfizer, in that it includes in-kind contributions by more than one party. Collaborations may present additional risks in that they generally would not qualify for protection under a safe harbor to the Anti-Kickback Statute.

Unlike a Service Agreement, which is more of a vendor-type relationship, a [Collaboration Agreement](#) documents a transaction of a more significant nature that involves contributions provided by each party.

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This section focuses on collaborations with OCs. Please note that collaborations with not-for-profit entities, such as policy or patient advocacy organizations, are addressed in Pfizer's [Funding Requests for Not-for-Profit Organizations Standard Operating Procedure \(SOP\)](#).

In a collaboration, it is important that both Pfizer and an Account make relatively equal contributions towards the identified, shared public health objective. Pfizer may provide funds, resources, or expertise to the collaboration.

Often, Pfizer is involved to some extent in the creation of the materials or other activities, such as providing suggestions or feedback, and may receive the right to use the materials or other output created pursuant to the collaboration.

The ultimate control of the goals, activities, and messaging around a collaboration may be retained by the participating OC(s), Pfizer, or both. Regardless of the arrangement, Pfizer will always obtain the right to review—via RC or the Product Attorney, where applicable—any materials for accuracy and compliance with relevant laws and regulations as well as Pfizer policies and procedures.

Evaluating Potential Collaborations

The following steps must be followed when evaluating a potential collaboration with an OC.

4. Identify when a project is considered a collaboration and requires a Collaboration Agreement
5. Follow the Intake Committee process
6. Determine appropriate value

1. Identify When a Project Is Considered a Collaboration and Requires a Collaboration Agreement





Collaborations with Accounts must advance public health goals and provide specific, appropriate, and commensurate business value to both the Account and Pfizer.

Additional, specific factors to consider in evaluating whether a potential project is a collaboration include:

- Complexity and customization
 - Projects with Accounts vary in size and complexity
 - Some projects consist of the deployment of an approved Pfizer tool without any customization, while others involve the use of multiple tools, and may involve participation from cross-functional Pfizer Colleagues
 - In general, the more a project involves customized solutions rather than off-the-shelf tools, the more likely the project will rise to the level of a collaboration
- Provision of Pfizer tools
 - Provision of individual off-the-shelf tools to an Account in accordance with company policies does not rise to the level of a collaboration
 - Use of multiple Pfizer tools or the need to customize existing Pfizer tools may necessitate a Collaboration Agreement
 - Colleagues should take care to ensure that the use of multiple or customized tools is warranted for the project, as excessive or inappropriate use of these tools could create potential kickback risk for Pfizer
- Length of the project
 - The longer a project is expected to take, the more likely it will rise to the level of a collaboration requiring a Collaboration Agreement
 - Longer projects may be more complex and are more likely to involve the sharing of data and/or the creation of a publication
- Other deliverables from the Account
 - Pfizer may sometimes negotiate to have an Account develop certain materials or undertake certain activities, such as mailings to the Account's HCP employees, as part of a project

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- In order to secure these or other Account obligations, a Collaboration Agreement may be necessary. However, depending on the details, a Service Agreement may be more appropriate

FAQ: Is This a Collaboration?	
	As part of my work with an Account, I will facilitate two off-the-shelf, RC-approved workshops and share related patient education materials. Is a Collaboration Agreement required?
	No. The work you describe is a project not requiring a Collaboration Agreement. The resources have not been tailored for the Account, the timeline is defined and short, and the nature of the interaction is transactional rather than complex. However, to the extent there are implementation guidelines and guidance on the use of those materials, you must follow that guidance.
	I am discussing a project with an Account that may involve HIT Initiatives, educational staff training, development of an adherence platform, and creation of a joint Steering Committee with Pfizer participation. The Account is willing to create and share with Pfizer a related dashboard report around specific data points with Pfizer. Is a Collaboration Agreement required?
	<p>Yes, you have described a collaboration, which would require a Collaboration Agreement. Pfizer would have extended involvement in the execution of the project, by participating on the Steering Committee and working with the Account on HIT Initiatives.</p> <p>The Account has also committed to provide certain deliverables to Pfizer, which should be memorialized in an agreement to ensure accountability and protect Pfizer's interests. In addition, this proposed project concept would likely require review and approval by the HIT Center of Excellence (HIT CoE).</p>

Colleagues should always consult the relevant Pricing and Access attorney regarding specific scenarios, as there are multiple factors to weigh before the final determination of whether an Account engagement is a project or collaboration, and whether an agreement, such as a Collaboration Agreement, Service Agreement, or Data Use Agreement, is required. To the extent the agreement does not qualify as a Collaboration Agreement, colleagues should consult with a Pricing and Access attorney on the process for engaging in other agreements such as Service Agreements and Data Use Agreements with OCs, and whether they may require review by the Intake Committee.

2. Follow the Intake Committee Process


To help ensure compliance with all relevant policies and mitigate potential risks, an Intake Committee process has been designed to review potential advanced projects with OCs that require contractual agreements between the parties.

The Intake Committee:

- Is responsible for reviewing and providing recommendations regarding Collaboration Agreements as well as Service Agreements with certain types of OCs

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- Determines steps required to comply with Pfizer policies, seeking input from Brand Legal, Medical, Marketing, Patient and Health Impact including Health Economics and Outcomes Research (HEOR) or Real-World Evidence Center of Excellence, and other functions as needed
- Assists in determining whether the value of certain provided activities, or activities with like components that Pfizer may contribute to a collaboration, is appropriate



	<p>Account-Facing Colleagues MUST:</p> <ul style="list-style-type: none">• Engage in concept discussions prior to the Intake Committee submission<ul style="list-style-type: none">– The discussions should be with the relevant brand team, including the relevant Product Attorney and Brand Medical, to ensure the appropriateness of the proposal, including whether the proposal aligns with brand team strategies, and determine whether the concept will require review by the HIT CoE and Intake Committee before proceeding with the project• Bring their proposals before the Intake Committee for a concept review, especially when the content of the proposed project involves novel or unusual terms
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For more details about the Intake Committee, please review the *Intake Committee Standards and Norms*.

3. Determine Appropriate Value

When working with an Account on a collaboration or other transaction and assessing Pfizer's contributions in a collaboration versus the Account's contribution, there is specific guidance for Account-Facing Colleagues.

	<p>Account-Facing Colleagues MUST:</p> <ul style="list-style-type: none">• Work with the relevant Product Attorney to help ensure the appropriateness of their offers and requests as part of the negotiation that determines the value to Pfizer<ul style="list-style-type: none">– Working with the relevant Product Attorney helps ensure that Pfizer will receive appropriate value from the transaction– The value Pfizer receives must be obvious, tangible, measurable, and must be commensurate with the value provided by Pfizer under the collaboration– If an equal exchange of value between Pfizer and the customer does not exist, Pfizer could be viewed as providing a payment or value to influence a customer improperly• Coordinate with Legal to take into account the intangibles provided by Pfizer to the Account that may be considered valuable<ul style="list-style-type: none">– For example, advice or counseling provided by a Pfizer Colleague to an Account related to Quality Process improvements, depending upon the details of that assistance, could be perceived as value in the form of consulting services for which the Account normally would pay a third-party vendor– If not appropriately accounted for in the collaboration, such services may elevate anti-kickback and other risks• Partner with Legal to fully document all collaborations via a Collaboration Agreement
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FAQ: Accountable Care Organization (ACO) Requirements	
	<p>Accountable Care Organizations (ACOs) are looked upon as a way to facilitate more coordinated, efficient, and higher quality care for patients. Can I help my Account meet the requirements of an ACO?</p>
	<p>If the primary objective of the proposed collaboration is to help the Account become an ACO, then it is unlikely that Pfizer can engage in this collaboration. Part of the FMV assessment of Pfizer's contributions is that it must not only be fairly equal to an Account's contributions, but Pfizer must also get an appropriate value from the collaboration. A collaboration that is aimed at helping an Account become an ACO on its face does not appear to have any tangible, appropriate value to Pfizer and only benefits the Account, even though the project appears to support a public health interest objective.</p>



Clinical Research Considerations and Medical Affairs Involvement

Pfizer will only fund and support legitimate medical research. This means the research must seek to answer a genuine scientific or clinical question through validated scientific clinical and research methodologies. These determinations must be made free of commercial influence. Commercial colleagues must refer any requests from an OC to engage in clinical research on behalf of Pfizer to a Medical Affairs colleague for appropriate follow up.

As with other financial transactions between Pfizer and HCPs or OCs, attempting to influence prescribing behavior or improve Pfizer's relationship with the recipient by providing money for research may violate federal or state anti-kickback laws.

The impact on an HCP's prescribing behavior or an OC's purchase or recommendation of a Pfizer product must not be taken into consideration when deciding whether to engage an HCP as an investigator, or fund or support independent medical research by an HCP or OC.

Review the requirements below before discussing a potential Non-Discount Arrangement with an OC regarding clinical research and/or Medical Affairs Involvement.

	<p>Account-Facing Colleagues <i>MUST</i>:</p> <ul style="list-style-type: none"> Recognize that some concepts may be defined by Pfizer policies as research studies, which require independent medical oversight by Pfizer Medical colleagues <ul style="list-style-type: none"> Drawing this distinction may be necessary if an Account seeks to measure the impact of a patient intervention, including certain non-drug interventions, such as a digital health innovation, patient counseling, or adherence materials Because the conduct and publication of a study can expose Pfizer to risk, studies must be done in compliance with applicable research and publication policies
	<p>Account-Facing Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none"> Support an OC's or HCP's scientific or medical research to: <ul style="list-style-type: none"> Establish, maintain, or improve Pfizer's relationship with the individual HCP or the related OC

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| | <ul style="list-style-type: none">– Gain or improve access to the HCP or the related OC– Reward past prescribing or induce future prescribing– Influence formulary decision-making |
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Pfizer policies and procedures help ensure that Pfizer-sponsored clinical research complies with applicable healthcare laws, regulatory requirements, ethical standards, and industry guidelines.

Discount Arrangements

Only Field Commercial Colleagues who have responsibility for and received the appropriate training should offer Discount Arrangements to OCs. Furthermore, only Discount Arrangements that have the necessary approvals should be offered.

Pfizer offers [Discount Arrangements](#), or price concessions, in order to meet competition and to make its products available to customers and patients. Discount arrangements can be offered prospectively as invoice discounts as well as retrospectively through rebates.

Pfizer may offer Discount Arrangements to various OCs such as: Distributors, Specialty Pharmacy Providers (SPPs), IDNs, Long-Term Care Pharmacy Providers, Group Purchasing Organizations (GPOs), [Pharmacy Benefit Managers \(PBMs\)](#), Managed Care Organizations (MCOs), and state and federal government programs.

Read below for guidance about the following:

- Discount Arrangements: Pfizer's price concessions to OCs
- [Contracting](#): The process of negotiating and entering into Discount Arrangements with OCs

Discount Arrangement and Price Reporting Guidance

There are certain safe harbors that permit legitimate activities that might otherwise be seen as violating the Anti-Kickback Statute. These include:

- [Discount Safe Harbor](#), which allows Pfizer to discount the price of a product, provided that the discount is properly reported to the government and complies with other safe harbor requirements
- [Managed Care Safe Harbor](#), which permits Pfizer to provide a wide array of discounted items or services to certain eligible MCOs under specified circumstances

Discount Arrangements may:

- Be set forth in writing, preferably as a contract between Pfizer and the OC
 - Occasionally these can be done in the form of a less comprehensive writing, such as an invoice or reconciliation statement, to ensure that the arrangement meets the applicable safe harbors to the Anti-Kickback Statute
- Affect the price that state and federal healthcare programs pay for Pfizer products
 - Pfizer must be sure to include all eligible price concessions made to OCs in the prices it reports to the government
 - Failure to do this may cause Pfizer to submit a false report to the federal government and create liability under the False Claims Act
 - For example, to participate in the Medicaid Drug Rebate Program, Pfizer must provide the federal government a rebate equal to the greater of 23.1% of Average Manufacturer Price (AMP) or the difference



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- between a manufacturer's Best Price and the AMP for each unit of product paid for by State Medicaid agencies
- Pfizer calculates and reports the Best Price for each Medicaid covered product to the federal government
- When reporting Best Price, Pfizer must take into consideration all cash discounts, free goods contingent upon a purchase requirement, volume discounts, and rebates, other than rebates under the Medicaid Drug Rebate Program itself
- In addition, free or reduced-price services, grants, other price concessions, or other benefits offered to induce a sale may also be considered pricing terms
- Affect a number of other government programs in which Pfizer participates, including Medicare, 340B Drug Pricing Program, and its Federal Supply Schedule agreement with the [Department of Veterans Affairs](#)

Contracting Guidance

Only Field Commercial Colleagues who have been authorized and received the appropriate training are permitted to negotiate and participate in the contracting process. Unauthorized colleagues who receive customer questions pertaining to contracts should inform their management.

To help ensure the accuracy of Pfizer's price reporting and compliance with the Discount Safe Harbor and other applicable laws, colleagues with contracting authority must follow the guidance below.

	<p>Field Commercial Colleagues <i>MUST</i>:</p> <ul style="list-style-type: none">• Only offer Discount Arrangements to OCs if they have contracting responsibility and have received the appropriate training• Only offer Discount Arrangements that have the necessary approvals<ul style="list-style-type: none">– There should not be any discussion of side deals or other offers that are not part of approved offer• Ensure all Discount Arrangement terms are clearly set out in a writing, preferably a contract• Keep discussions with OCs about Discount Arrangements separate from discussions about other potential business discussions or opportunities, including any pull through activities
	<p>Field Commercial Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Discuss grants, sponsorships, additional service contracts, collaborations, tools and resources, or other items of value in connection with Discount Arrangements<ul style="list-style-type: none">– These items may have to be included in Pfizer's government pricing calculations• Provide grants, additional service contracts, or other items of value in return for the purchase, prescription, or recommendation of Pfizer products<ul style="list-style-type: none">– This may be considered an improper inducement under the Anti-Kickback Statute and is prohibited by Pfizer policy

When it is not possible or practical to have separate meetings on Discount Arrangements, the following guiding principles will help mitigate risk:

Prior to the Discount Arrangement Meeting

- Distribute an agenda

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

During the Discount Arrangement Meeting

- Stick to the agenda
- Firewall discussions into appropriate segments
 - One recommendation is to separate all discussions when Pfizer is purchasing goods or services from the OC from those when Pfizer is providing discounts, goods, or services to the OC
- Coordinate the attendance of individuals who are not part of the contracting process by having individuals either step out of or arrive later during a joint meeting so that individuals who should not be privy to contracting discussion are not in attendance
- Manage any attempts by the OC to link discussions of multiple projects by deferring the issue for future conversation or delegating the issue to colleagues not in attendance
- Approach discussions of non-contracting business opportunities carefully during the negotiation period prior to, and around the time of, rebate contract expiration

After the Discount Arrangement Meeting

- Evaluate the contracting offer and other business proposals independently and on their own merits
 - Separate business teams within Pfizer should do the respective evaluations
- Be mindful of how financial and other notes regarding the contracting offer and other business opportunities may appear in hindsight
 - For example, the valuations for each business opportunity on the same worksheet may imply that the opportunities are connected and interdependent even if the intent was otherwise
 - Pfizer's internal documentation should keep Discount Arrangements and other OC business separate
 - Internal analyses of Discount Arrangements should be separate and independent from the analysis of other business activities with the relevant OC
- Be aware that in some instances, Legal may advise the business unit to have a cooling-off period between contract negotiations and other arrangements, or other discounting discussions

Swapping Discounts between Commercial and Part D Plans


Many PBMs currently manage both commercial and [Medicare Part D](#) books of business. These organizations will negotiate discounts from pharmaceutical companies on behalf of the government under Medicare Part D, as well as on behalf of their own commercial business.

The government has expressed concern that entities will use Medicare Part D leverage to obtain preferential discounts for their commercial books of business.



"Swapping" describes a situation whereby a PBM and pharmaceutical company agree to swap access to the organization's Medicare Part D book of business in exchange for greater rebates for the organization's commercial books of business.

A PBM might be willing to accept higher costs under Medicare Part D in exchange for lower commercial plan costs because the government subsidizes a portion of its Part D plan costs, while it often remains entirely at risk for its commercial plan costs.

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	<p>Account-Facing Colleagues <i>MUST</i>:</p> <ul style="list-style-type: none">• Avoid situations that could create a perception of swapping• Conduct Commercial and Medicare Part D negotiations separately, and preferably at separate meetings, to avoid the appearance of swapping<ul style="list-style-type: none">– If separate meetings are not possible, follow the meeting guidelines in this chapter regarding Discount Arrangement Meetings• Ensure that internal and customer-facing documentation regarding Commercial and Medicare Part D negotiations clearly distinguish between the two<ul style="list-style-type: none">– This is best achieved by creating separate presentations and offer sheets for OCs and analyzing Commercial and Part D offers in separate internal documents
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	<p>Account-Facing Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Engage in swapping
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FAQ: Meetings on Commercial and Part D Contracts	
	May I discuss a commercial contract and a Part D contract in the same meeting with an OC?
	Yes. You may do this if the two are not linked or discussed at the same time. For example, it is acceptable to discuss the commercial contract during the first half of your meeting, and then indicate to the OC that you are moving on to the Part D contract discussion for the remainder of your meeting. You should also ensure that only the relevant attendees are present for each portion of the discussion, and any documentation demonstrates that the arrangements are independent of each other.

Antitrust and Competition Laws


Antitrust and competition laws protect free enterprise by prohibiting agreements between Pfizer and our competitors to set prices, terms, or conditions of sale. Please note that the term “prices” includes discounts.

To ensure full compliance with U.S. antitrust laws, review the requirements below.


	<p>Account-Facing Colleagues <i>MUST</i>:</p> <ul style="list-style-type: none">• Only offer Discount Arrangements that have received the necessary approval<ul style="list-style-type: none">– Pfizer carefully assesses Discount Arrangements prior to offering them• Offer similarly situated OCs the same prices and discounts unless there is an exception or defense<ul style="list-style-type: none">– Antitrust laws prohibit discriminatory pricing and promotional practices
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	<ul style="list-style-type: none">– More specifically, U.S. antitrust laws prohibit selling goods of like grade and quality to competing purchasers who are resellers of those goods at different prices where competition will be damaged
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	<p>Account-Facing Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Discuss the following Pfizer topics with any competitor or with multiple OCs at any time:<ul style="list-style-type: none">– Pricing policies– Current or future prices, discounts, rebates, or other terms and conditions of sale generally or as they relate to other OCs– Current or projected profits or profit margins– Current or projected costs– Business, marketing, and promotional plans– Bidding policy or its intent to bid or not to bid for particular business– Plan to do business or not do business with particular OCs– Intention to engage or not engage in particular research activities• Discuss an OC's current or projected profit or profit margins
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Discount Arrangements and Confidentiality

	<p>Account-Facing Colleagues <i>MUST</i>:</p> <ul style="list-style-type: none">• Use caution in discussing Discount Arrangements with anyone other than the eligible OC<ul style="list-style-type: none">– The contracts under which Pfizer extends Discount Arrangements often contain confidentiality provisions that limit both parties' ability to share them with third parties and may even limit Pfizer's ability to share their terms internally within Pfizer
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	<p>Account-Facing Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Share the terms of an OC's Discount Arrangement without review of the governing contract by Legal<ul style="list-style-type: none">– This includes instances where colleagues seek to share information with a customer of a Pfizer Customer, such as a plan under a PBM
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Chapter 4: Guidance for Interactions With Specific Organized Customers

In addition to the guidance throughout this section, there is also specific guidance for interactions with certain Organized Customers (OCs), including:

- Specialty Pharmacy Providers (SPPs)
- Employers
- Pharmacy and Therapeutics (P&T) Committees

Read below for more information on these different types of OCs.

Specialty Pharmacy Providers (SPPs)

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 SPPs, which are distinct from traditional retail pharmacies in their more comprehensive coordination of many aspects of patient care, disease management, and patient access to therapy. SPPs 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.

SPPs employ HCPs, including both pharmacists and nurses, 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 non-discount and discount contractual arrangements with certain customers when it procures services. Pfizer enters into Non-Discount Arrangements with SPPs to participate in Defined SPP Networks and/or to provide Supplemental Services to patients that have been prescribed a Pfizer product dispensed by such SPPs. All of these arrangements raise specific legal risks if not handled by Pfizer Colleagues in an appropriate manner.

Types of Contractual Relationships Between Pfizer and SPPs

Defined Distribution Networks

Through distribution agreements, Pfizer contracts with certain SPPs that meet pre-defined objective inclusion criteria to dispense a particular Pfizer product as part of a Defined SPP Network.

Defined SPP Networks are designed to:

- Ensure consistent and high-quality patient care
- 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 Pricing and Access Legal. All pharmacies seeking access to a Defined Distribution Network must be reviewed by the SAS CoE against such pre-defined objective inclusion criteria.

Supplemental Services Contracts

Through Service Agreements, Pfizer contracts with SPPs to provide specific services to help support patients prescribed a Pfizer product. These Supplemental Services are in addition to a SPP's Core Services, which are services that the SPP provides to its patients as part of its normal business practice.



Supplemental Services may include, but are not limited to:

- SPP's dissemination of Pfizer patient educational materials
- Product adherence counseling
- Provision of data or information to Pfizer about product usage

All Supplemental Service arrangements with SPPs are developed by the SAS CoE and must be approved by Pricing and Access Legal.

Interactions with SPPs

Because of the nature of the relationship and the influence healthcare professionals employed by SPPs often develop with patients, it is important to ensure that Pfizer's interactions with SPPs are managed appropriately and Pfizer Colleagues do not interfere with the independent clinical judgment of the SPP HCPs.

	<p>Pfizer Colleagues <i>MUST</i>:</p> <ul style="list-style-type: none">• Ensure interactions with SPPs remain appropriate and compliant with Pfizer's policies
	<p>Pfizer Colleagues <i>MUST NOT</i> directly or indirectly:</p> <ul style="list-style-type: none">• Interfere with the carefully defined contractual arrangements between Pfizer and the SPP, including by providing any items of value to SPP personnel other than as expressly stated in Pfizer's contract with the SPP• Interfere with the independent clinical judgment of HCPs, including both prescribers and SPP clinicians• Interfere with the relationship between the patient and their HCPs, including both prescribers and SPP clinicians

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- Encourage SPP 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 SPP to the exclusion of other SPPs
- Use SPP personnel, including SPP clinicians or sales representatives, as an extension of the Pfizer sales force, or as a mechanism for delivering Pfizer promotional messaging to either HCPs or patients

FAQ: Request for SPP Recommendations



How should a Pfizer Sales Representative respond if an HCP asks if there is a SPP that the sales representative or Pfizer recommends to the HCP?



The Pfizer Sales Representative may not show a preference for any particular SPP over another, regardless of whether the product is in a defined network. If the product is part of a defined network, all pharmacies who are part of the defined network must be presented to the HCP without directing an HCP to any particular pharmacy in that network. Therefore, you must only share lists of pharmacies and messaging that have been reviewed and approved by the relevant Review Committee (RC).

Specialty Access Solutions National Account Director (SAS NAD) Interactions with SPPs

SPPs are sometimes owned by or affiliated with other healthcare organizations.

Organized SPP Customers are SPPs that are aligned to payers, Pharmacy Benefit Managers (PBMs), and similar organizations. The Specialty Access Solutions National Account Directors (SAS NADs) serve as the primary Pfizer contact for Organized SPP Customers. They also manage relationships through aggregators that contract with the non-Organized SPP Customers for Supplemental Services.

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

Other Field Commercial Colleague Interactions with SPPs

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

Field Commercial Colleagues other than SAS NADs, such as Sales, KAMs, and other Account Management roles, must receive prior approval from their management, Payer and Channel Access (PCA), the Global Product Counsel, and Pricing and Access Legal before engaging with SPP personnel. The process for obtaining such approval is described in Chapter 20 of *The White Guide*.

In addition to receiving approval, colleagues are also required to follow any Business Unit (BU)-specific guidance on appropriate engagement with SPP personnel applicable to their role.

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Sales Interactions with SPP HCPs and SPP Office Staff

Subject to the approval identified above, Pfizer Sales Representatives may engage with HCPs and office staff at SPPs, including SPPs at IDNs/CoEs, consistent with the requirements discussed in Section 3 of *The Orange Guide*.

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

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



Sales Representatives *MUST*:

- Ensure that interactions are for educational purposes only
- Only use materials and messaging specifically approved for use with SPPs during these interactions



Sales Representatives *MUST NOT*:

- Attempt to influence the SPP personnel's decision-making
- Make any express or implied requests for the SPP personnel to recommend Pfizer products either to patients or HCPs
- Discuss product discounts, rebates, reimbursement details to SPPs, participation in Pfizer's SPP Defined Networks, or Purchase or Service Agreements with any personnel at an SPP
 - In the event that a Pfizer Sales Representative learns that the SPP wishes to discuss such a contractual arrangement, the matter must be referred to the SAS NAD covering the SPP
- Share complaints about SPP performance issues that are relayed to them by customers, such as slow dispense times or inadequate inventory, to any SPP personnel directly or indirectly
 - The Pfizer Sales Representative must elevate potential SPP performance issues that they learn about to their sales manager, who can share the information with the appropriate SAS NAD

Sales Interactions with SPP Sales Representatives

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



Subject to the approval process referenced above, **Pfizer Sales Representatives *MAY*:**

- Have limited interactions with SPP sales representatives on a periodic, infrequent basis, and only when there is a legitimate business purpose to share appropriate information





Pfizer Sales Representatives *MUST NOT*:

- Leverage SPP sales representatives to:
 - Build relationships with the SPP
 - Gather general payer information regarding Pfizer products

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	<ul style="list-style-type: none">– Seek information about market shares of competitive products within the SPP, top prescribers, product volumes, and 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 SPP sales representatives• Meet jointly with the SPP representative and a prescriber or HCP office• Provide Pfizer materials to the SPP sales representative– In the event that a SPP sales representative reaches out to a Pfizer Sales Representative with a product question or request for product information, the Pfizer Sales Representative should refer the SPP sales representative to the SPP's own clinical personnel to answer the product-related question• Share or discuss patient-specific information, even if de-identified, including information regarding the status of fulfillment of prescriptions at the SPP or with a payer, when interacting with SPP sales representatives• Share information about an HCP's prescribing patterns, or coordinating targeting of or visits to HCPs with the SPP business representative, as such actions may be perceived as inappropriately steering business to a particular SPP
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In addition, SPP sales representatives generally should not attend educational presentations provided by Pfizer Sales Representatives or by Pfizer Medical Colleagues for SPP HCPs.

FAQ: SPP Sales Representative Request for Patient Brochures or Welcome Kits	
	How should a Pfizer Sales Representative respond if an SPP sales representative requests patient brochures or welcome kits for Pfizer products?
	The Pfizer Sales Representative should advise the SPP sales representative that Pfizer will follow-up with the SPP's clinical personnel regarding the request. If the SPP is in a Defined SPP Network for the product, or the SPP is providing Supplemental Services for the product, the Pfizer Sales Representative should refer the request to the assigned SAS NAD for follow-up rather than following up directly.

Employers

Pfizer also calls on employers that make decisions regarding the access their employees have to medicines.


To best leverage existing relationships and avoid providing inconsistent messages, colleagues should consult a PCA representative and the Director of National Employer Accounts in their region to ensure proper coordination of activities with employers.

Pharmacy and Therapeutics (P&T) Committees


The P&T Committee of an Account decides which pharmaceutical products are included on the formulary. P&T Committees typically make formulary decisions based upon assessments of safety, efficacy, tolerability and, increasingly, cost-effectiveness.

Beyond the general day-to-day interactions with P&T Committee members that were covered in Section 3 of *The Orange Guide*, there are additional requirements when Field Commercial Colleagues attempt to have a product added to a formulary.

Generating Support for Formulary Placement

	<p>Field Commercial Colleagues MAY:</p> <ul style="list-style-type: none">• Work together to identify HCPs who may be willing to advocate for access to Pfizer products• Ask Pharmacy & Therapeutics (P&T) Committee members and other influential HCPs for their support<ul style="list-style-type: none">– Remember that any discussions with potential advocates must be focused on the strength and weight of the scientific, medical, and clinical evidence for the relevant product(s) and are at all times governed by Pfizer's policies on product promotion, including the four Core Promotional Compliance Principles• Engage in certain activities in an effort to generate support for formulary placement of Pfizer products as long as nothing of value is promised or given to an HCP or P&T Committee member in return for their testimony or support<ul style="list-style-type: none">– Examples of permitted activities include:<ul style="list-style-type: none">▪ Providing RC-approved educational materials to influential HCPs that would like to advocate for Pfizer products▪ Requesting influential HCPs testify before a P&T Committee▪ Assisting with certain minor logistical matters such as requesting time slots on behalf of HCPs who have agreed to testify▪ Asking influential HCPs to write letters or otherwise communicate with members of the P&T Committee to show their support for a Pfizer product
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It should never appear that Pfizer is engaging in a concerted effort to improperly influence an upcoming formulary decision. Examples of activities that could be construed as improperly influencing a P&T Committee decision are shown below.

	<p>Field Commercial Colleagues MUST NOT:</p> <ul style="list-style-type: none">• Invite a P&T Committee member to become a speaker, consultant, or member of an advisory board if the invitation is even partially motivated by a desire to influence an upcoming formulary decision<ul style="list-style-type: none">– Consistent with the Pharmaceutical Research and Manufacturers of America (PhRMA) Code, Pfizer requires any HCP who is a member of a P&T Committee and also speaks or consults for Pfizer to disclose to their P&T Committee the existence and nature of their relationship with Pfizer
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- Write letters or create talking points for use by an HCP or P&T Committee member who would like to advocate for a Pfizer product
- Provide a P&T Committee member a meal, particularly one that is extravagant or otherwise not in compliance with the PhRMA Code, in order to influence or reward their advocacy
- Provide any payment, such as an exhibit/display fee or speaker fee, to a P&T Committee member or their institution if the payment is even partially motivated by a desire to influence an upcoming formulary decision
- Provide any unapproved item to a P&T Committee member
- Link financial support from Pfizer, either directly or indirectly, with influence over that P&T Committee member's exercise of judgment in serving on their P&T Committee
 - To avoid violating anti-kickback laws, Pfizer strictly prohibits linking financial transactions, other than disclosed rebate or Discount Arrangements, or anything else of value to P&T Committee decisions
 - Outside of certain limited exceptions, anti-kickback laws prohibit manufacturers from providing anything of value in order to influence formulary decisions
 - Any separate financial arrangements could also affect Pfizer's government pricing obligations under federal and state law
- Include offers of any sort to provide quality or product support programs, educational or research grants, [charitable contributions](#), exhibit or display payments, or other arrangements, including speaking engagements in exchange for formulary positioning

FAQ: Generating Support for Formulary Decisions

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

FAQ: Responding to Requests for Funding by P&T Committee Members

	While I am giving a presentation on a Pfizer product under formulary review, what if a P&T Committee member asks for a grant or charitable contribution? Should I schedule a separate meeting to explain Pfizer's process for considering these requests?
	You must never affirmatively raise the topic of providing a grant or charitable contribution to a P&T Committee member or their organization. However, if the member makes a specific

	<p>unsolicited inquiry about grants or charitable contributions you should address it briefly, as long as you state the following:</p> <ul style="list-style-type: none">• A decision to provide the requested funds will in no way be influenced by the P&T Committee's formulary decision• At the conclusion of your product discussion, you can provide information about the procedures for submitting a request to Pfizer• The decision on whether to provide requested funds will be made by an independent multi-disciplinary group and will not be impacted by the pending formulary decision
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Formal Product Presentations to P&T Committees

The next step in having a product added to formulary is often the formal product presentation to the P&T committee.

Who May Present?

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

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

What Information May Colleagues Present?

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

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

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

Each Pfizer product team is responsible for creating and maintaining a slide deck that is appropriate for use during formulary presentations. Only these and other RC-approved materials may be used when Pfizer has requested the opportunity to present information. If a colleague would like to add slides to the slide deck, the slides must be approved by the appropriate RC before use.

If a P&T Committee makes a specific unsolicited request for off-label information during the presentation, only Medical Colleagues or an HQ-approved physician consultant may respond to the request in accordance with the guidelines set for them, which include:

- Acknowledging that the information is off-label
- Providing a brief answer that is truthful, not misleading, based on substantial scientific evidence, and non-promotional in tone

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- Continuing with the original presentation


Field Commercial Colleagues may remain in the meeting during this time, but if a more extensive answer or discussion is needed to respond to the customer's request, the Medical Colleague should submit an unsolicited medical request or speak to the customer after the meeting out of the presence of Field Commercial Colleagues.

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

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


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

	Field Medical Outcomes and Analytics Colleagues MAY respond to requests for: <ul style="list-style-type: none">• Unapproved but on-label information, such as when no RC-approved materials exist to use in a response• Pharmacoeconomic or outcomes information if they have materials approved for such responses, because of their background and training
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	Payer Account Medical Lead Colleagues MAY respond to requests for: <ul style="list-style-type: none">• Unapproved but on-label information, such as when no RC-approved materials exist to use in a response
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	<ul style="list-style-type: none">• Pharmacoeconomic or outcomes information if they have materials approved for such responses, because of their background and training• Both unapproved and off-label information as authorized by Brand Medical<ul style="list-style-type: none">– Responses to payer customers must be brief• Real-world data and/or real-world evidence and engage Payer customers proactively with output from approved data sources, such as Pfizer-licensed data marts
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	<p>Field Medical Director Colleagues MAY respond to requests for:</p> <ul style="list-style-type: none">• Both unapproved and off-label information
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In the absence of a specific request for such information about our products, no colleague may present unapproved or off-label information about Pfizer products to a P&T Committee or one of its members.

FAQ: Joint Sales and Medical P&T Presentations	
	May Field Commercial Colleagues and Medical Colleagues present together to a P&T Committee?
	Maybe. If the presentation consists of on-label information that the Field Commercial Colleague could otherwise present by themselves, then the Field Commercial Colleague and Medical Colleagues may present together. The Field Commercial Colleague must not participate in any unsolicited scientific exchange of information, which might occur during or after the presentation. On the other hand, if the Medical Colleague intends to present scientific information that is in response to a medical inquiry made by the P&T Committee, the Field Commercial Colleague cannot present together with the Medical Colleague but can remain in the room.

FAQ: Hospital Protocols and Treatment Pathways	
	May I detail an HCP who is involved in the development of a hospital clinical protocol or pathway who is in a position to influence which products are included in the protocol or pathway?
	Yes. You may detail any such HCP if your detailing is otherwise done in accordance with all applicable principles found in <i>The Orange Guide</i> including the four Core Promotional Compliance Principles.

	May I detail an HCP in order to ask the HCP to consider inclusion of a Pfizer product in a hospital's clinical protocol or pathway?
	Yes. Pfizer Colleagues may encourage an HCP to consider including a Pfizer product in a hospital protocol or pathway provided that such use would be consistent with labeling and promotion, is strictly limited to approved, on-label messaging of the Pfizer product, and all principles found in <i>The Orange Guide</i> are followed.
	May I participate in the development of a hospital clinical protocol?
	No. Pfizer Sales Colleagues are not permitted to assist hospitals with drafting or otherwise developing hospital clinical protocols, pathways, or order sets. In certain circumstances, if available, Pfizer Colleagues may utilize RC-approved materials to engage with HCPs about the importance of developing a protocol or to advocate for the inclusion of a Pfizer product in a protocol or pathway within an approved indication or disease area.
	May I use a hospital protocol or pathway in detailing sessions?
	Only if the RC has approved the use of such hospital protocol or pathway. You may not distribute a protocol and it may not be used or discussed outside of the originating institution.

Chapter 5: Guidance for Interactions Involving Health Information Technology (HIT) Initiatives

The use of digital health care, including the use of Health Information Technology (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 and Pfizer HIT educational resources with the intent to help 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 Orange Guide*.

HIT Initiatives can pose legal risks to Pfizer if not designed and implemented in an appropriate manner. In order to manage legal risks appropriately, it is important for all Field Commercial Colleagues to understand:

- What educational HIT resources Field Commercial Colleagues may provide to customers based on their role
- Appropriate messaging about the HIT resources

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Given the potential risks associated with HIT Initiatives, Field Commercial Colleagues must always ensure that any customer engagement regarding HIT resources is consistent with Pfizer policy, the Core Promotional Compliance Principles, and any implementation guidance. Read below for more specific requirements.



Field Commercial Colleagues *MUST*:

- Use only those HIT educational resources approved by the relevant Review Committee (RC) for use by their specific role
 - RC-approval of HIT resources are tailored to both the customer type and the role of the Pfizer Colleague delivering the HIT resource
- Follow all implementation guidance associated with the HIT resource, including the appropriate user and audience
 - Approval for one purpose does not mean approval for all purposes, and therefore, resources approved for a particular customer type may only be used with that customer
 - Depending on the content, some HIT resources may require implementation by, or in conjunction with, appropriate Field Medical Colleagues
 - Colleagues should consult their Product Attorney if they require guidance on when to involve Field Medical Colleagues
- Only provide customers with HIT resources for reasons consistent with the purpose for which the resource was approved
 - In limited circumstances, their Product Attorney may allow for the use of certain customized resources that have not been RC-approved
 - This will occur most frequently in the context of workflow assessments, collaborations, and discussions leading to a collaboration
 - See below for additional information on workflow assessments and collaborations with an HIT component
- Adhere to the RC-approved messages when using HIT resources, whether the HIT Tool contains branded content or is unbranded and addresses a therapeutic area in which Pfizer has a public health goal
 - While HIT resources are generally unbranded, any branded or unbranded resources must be consistent with any relevant Pfizer product's Food and Drug Administration (FDA)-approved labeling
 - Branded HIT resources may be offered to educate customers about the appropriate use of our products
 - Above brand HIT resources may educate customers about improving patient outcomes and promoting quality health care without referring to particular Pfizer products
- Offer or provide approved HIT educational resources without any expectation of financial return to Pfizer



Field Commercial Colleagues *MUST NOT*:

- Offer nor appear to offer any remuneration, service, or item of value to induce or influence an HCP to prescribe a product or position it on formulary
 - The decision to prescribe or recommend a product must be based on the best interests of patients and not on anything of value offered by or on behalf of Pfizer

- Present or characterize HIT resources as assisting customers in obtaining financial incentives, reimbursements, or increased revenue
- Condition the offer or provision of a program on increased prescribing or improved formulary status
 - If a colleague gives, or could be perceived as giving, a customer an HIT resource or expertise as an inducement for prescribing or recommending a Pfizer product, then that could implicate state or federal anti-kickback laws
- Combine different types of transactions to avoid the potential implication of pricing and/or kickback risks
 - If an offering of value inadvertently affects or could appear to affect the prices of Pfizer products that a customer is purchasing, that could cause Pfizer to inaccurately report the price of its products in its submissions to the federal government under the Medicaid Drug Rebate Program and other healthcare programs
- Discuss HIT educational resources in connection with formulary discussions or attempt to leverage any additional arrangements, such as a non-formulary arrangement, in order to secure preferential formulary status
- Promote or discuss a specific Pfizer product in connection with an unbranded HIT resource
- Encourage or implicitly suggest off-label use of a Pfizer product in any HIT discussion, branded or unbranded
 - Remember that it is possible to promote a Pfizer product inappropriately without mentioning the product and when speaking above brand
- Conduct 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
- Conduct a Return on Investment (ROI) analysis on HIT Initiatives/resources or create other metrics/analyses linking the HIT Initiatives to the success of a Pfizer product, such as metrics tied to prescription rates, conversion rates, or similar performance measures

Health Information Technology Center of Excellence (HIT CoE)

Pfizer is striving to leverage technology to enhance health outcomes and improve patient care.

As we increasingly engage with our customers and external partners to provide HIT Initiatives, it is more critical than ever before that we act with the utmost integrity and manage these Initiatives in a compliant way to help improve patient care and health outcomes and protect Pfizer.


Accordingly, Pfizer has established an HIT Center of Excellence (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 will review all biopharma and digital initiatives or resources that involve health information that may impact a clinical decision. Following endorsement by the HIT CoE, HIT Initiatives and/or resources will go to the relevant RC or Medical Review Committee (MRC) for final review and approval before use with customers. See the [HIT CoE website](#) for detailed information about the HIT CoE process and a toolkit to guide development of HIT Initiatives/resources.

HIT Engagement Policies 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.

The requirements by role are reviewed below. If colleagues are unsure whether a certain activity might be in scope for their role, they should contact their Product Attorney.

Sales Colleagues

	<p>Sales Colleagues <i>MAY</i> only engage customers on HIT topics by:</p> <ul style="list-style-type: none">• Deploying RC-approved HIT educational resources approved specifically for their role and available to them through PROMOSprime or Veeva Customer Relationship Management (CRM)• Identifying leads and introducing them to Account Managers/Account Directors or HIT Account Director colleagues
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Account Managers/Account Directors

	<p>Account Managers/Account Directors <i>MUST</i>:</p> <ul style="list-style-type: none">• Deliver only branded and unbranded HIT educational resources and associated messaging<ul style="list-style-type: none">– Approved for use by Account Managers/Account Directors– Consistent with the training they have received<ul style="list-style-type: none">▪ An example of a branded HIT resource is a piece that educates HCPs on how to bookmark a Pfizer product in an EHR system▪ An example of an unbranded HIT resource is a slide deck that provides a high-level description of how above brand disease screeners or patient education materials could be incorporated into an EHR• Ensure that the piece they would like to use is RC-approved for use by Account Managers/Account Directors and is not expired<ul style="list-style-type: none">– This means that the resource in question should be available on PROMOSprime• Always confer with their HIT Account Director before proposing the use of any HIT resource with a customer<ul style="list-style-type: none">– Some of the HIT resources approved for use by Account Management Colleagues are designed to spur discussion about how Pfizer can work with the customer to improve patient care; these may set the stage for more advanced discussions that may require leadership by an HIT Account Director or a Field Medical Colleague with expertise in clinical informatics
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	<p>Account Managers/Account Directors <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Alter RC-approved materials except where specifically authorized by the RC
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- For example, an RC-approved template may permit a colleague to customize an HIT resource by inserting the customer's name

FAQ: Using Approved HIT Resources



While discussing a quality initiative relating to a therapeutic area where Pfizer has a public health goal, one of my fellow Key Account Managers (KAMs) recently told me that she had a positive experience sharing a particular RC-approved resource with the customer. She sent it to me by e-mail and told me that it is approved to show a customer on the iPad, but it is not approved to leave behind. May I show this to my customer at my next meeting?



Maybe, but you should not use an e-mailed copy. Before using the resource, you should first check to see that the piece is approved for use by your specific role and is currently available on PROMOSprime. It may be that the piece has expired or otherwise been replaced with a more current version. Always be sure to get your content directly from PROMOSprime. Additionally, certain HIT resources may require presentation with an HIT Account Director and/or a Field Medical Colleague with expertise in clinical informatics. You should refer to the implementation guidance for the resource for direction on implementation.

HIT Account Directors

The HIT Account Director role is focused on technical and operational considerations of EHR use. They work closely with Field Medical Colleagues with clinical informatics expertise that focuses on the clinical considerations of EHR use. They are a type of Account Manager and member of the Account Team with advanced HIT expertise as well as account management training in relevant therapeutic areas.

Accordingly, there are certain HIT resources, including some unbranded, disease state-specific resources that only an HIT Account Director, in some cases jointly with a Field Medical Colleague with clinical informatics expertise, may share with a customer.

These resources may include but are not limited to:


- Disease State and Prevention Toolkits, which are educational tools on EHR considerations surrounding a disease state and/or its prevention
- EHR Reference Guides, which describe technical and/or functional options in a therapeutic area, including considerations for health systems and providers to address care gaps in specific disease areas
- EHR Insights resources that include case examples, workflow and implementation considerations, or highlighted areas of industry practice related to HIT


All HIT resources must be RC-approved for the intended use and implemented consistently with the relevant implementation guidance. Resources that involve a clinically detailed discussion may require presentation with a Field Medical Colleague with clinical informatics expertise.



HIT Account Directors work with Account Teams to build on discussions initiated with a customer by the Account Team. Accordingly, Account Team Colleagues must consult with their HIT Account Director to anticipate those situations where the HIT Account Directors' expertise may be necessary to engage the customer on topics involving HIT. This team approach ensures that the Account Team and the HIT Account Director are providing an appropriate,

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consistent, and compliant HIT message, and it also confirms that the HIT Account Director will be available to work with the customer in a timeframe that works for all parties.

	<p>HIT Account Directors MUST:</p> <ul style="list-style-type: none">• Focus on technical and operational considerations of EHR use and work closely with Field Medical Colleagues with clinical informatics expertise that focuses on the clinical considerations of EHR use• Focus on education and awareness of EHR functionality that supports patient care in the relevant therapeutic area• Limit engagements to HIT resources and messaging approved for their specific role<ul style="list-style-type: none">– In many cases, this means the deployment of RC-approved HIT resources found on PROMOSprime– May sometimes participate in the development of customized solutions for the customer under an approved Collaboration Agreement• Discuss with the customer options for potentially leveraging Pfizer HIT resources, without conducting any programming, coding, or actual operation of the customer's HIT system
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	<p>HIT Account Directors MUST NOT:</p> <ul style="list-style-type: none">• Act as general HIT consultants for customers• Perform the actual computer programming, configurations, or coding necessary to implement the HIT resources
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FAQ: Appropriate Interaction with HIT Account Directors and Sales	
	<p>I am an HIT Account Director, and I was recently asked by an Area Business Manager to come to one of her meetings and lead a session about HIT. The purpose of the session would be to train her Representatives on HIT so that they could properly deploy approved HIT resources and identify leads for the Account Team. Am I able to provide training to this Sales team on EHRs and other HIT topics?</p>
	<p>No, that would not be an appropriate request of an HIT Account Director. If a Field Commercial Colleague seeks additional HIT training, please advise them to reach out to the training team. The training team can help them find the appropriate training resources and identify additional learning needs.</p>

Role of Medical in Account Team Activities Involving HIT

Often HIT engagements include discussion of clinical topics related to EHR use with the customer. In those instances, Field Medical Colleagues with clinical informatics expertise in a colleague's therapeutic area should be involved early in the process to ensure that they can have appropriate involvement and provide customer support.

For example, if an HIT Account Director is providing an RC-approved resource to educate the customer about options for patient screening within the EHR, and the resource requires the customer to make certain clinical decisions about



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what kinds of information should be factored into the screening process, then it would not be appropriate for the HIT Account Director to discuss those clinical decisions.

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. Refer to the implementation guidance associated with the resource for direction on the appropriate user and audience for the resource.

The HIT Account Director and the Account Manager must work with their Field Medical Colleagues to anticipate those situations where the Field Medical Colleague's clinical informatics expertise may be required to assist the customer with proper implementation of the Pfizer resource. 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 activities, unless otherwise outlined in MRC-approved implementation guidance.

For further information, review the [HIT CoE website](#).

FAQ: Working with Field Medical	
	How do I know if the implementation of an HIT resource might require clinical decisions on the part of the customer?
	The implementation guidance for the resource should provide clear guidance on which roles can use the resource with customers and whether medical involvement is required. In the absence of specific guidance on implementation of the resource, always consult your Field Medical Colleague before working with the customer to implement an HIT resource that is intended to impact a clinical decision. There may be instances where decisions have to be made about clinical content and clinical context along with diagnostic codes that provide appropriate sources of data, and a Field Medical Colleague with clinical informatics expertise would need to be present or lead the discussion with the customer.

HIT Initiative Process

The length, structure, and complexity of an HIT Initiative can vary with the objectives of Pfizer and the customer and may dictate which Pfizer Colleagues can be involved.

A simple HIT Initiative may consist of one face-to-face meeting using a single approved HIT educational resource. A more complex engagement may involve multiple HIT educational resources and require the expertise of an HIT Account Director and involvement of a Field Medical Colleague with clinical informatics expertise.

The example below outlines an HIT Initiative where the involvement of an HIT Account Director and Field Medical Colleague with clinical informatics expertise is necessary to determine whether opportunities exist to engage in an HIT Initiative. For additional examples, please refer to the HIT CoE toolkit.

Account Engagement

The first step in the HIT Initiative Process is Account Engagement.

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During this step, an Account Manager will:

- Work with the customer to understand customer needs, and whether those needs overlap with Pfizer objectives in a particular therapeutic area
- Further determine whether an opportunity exists to educate the customer on EHR functionality and Pfizer HIT resources to help improve disease state awareness and patient care
 - This occurs only if the customer and Pfizer can agree upon mutually aligned objectives intended to improve patient care in a therapeutic area of interest
- Coordinate with the HIT Account Director and appropriate Field Medical Colleague with clinical informatics expertise to determine what steps, if any, may be taken towards engaging in an HIT Initiative

Workflow Assessments

Once there is customer agreement and proper coordination between the customer, Account Manager, HIT Account Director, and appropriate Field Medical Colleague, the next step is for the HIT Account Director and Field Medical Colleague to jointly conduct a workflow assessment.


Other Account Management Colleagues, such as KAMs and Advanced Customer Engagement (ACE) Directors, may be present during workflow assessment discussions with customers, but such activities must be led by the HIT Account Director and appropriate Field Medical Colleague. Sales Colleagues are not permitted to be involved in customer workflow assessments.

A [workflow assessment](#) is:

- An evaluation of how patients flow through an institution's clinical care process for a given disease state or therapeutic area
- An exercise to understand the potential ways in which a customer's EHR capabilities can help enhance disease awareness and patient care in the disease state or therapeutic area

The HIT Account Director must conduct the workflow assessment jointly with an appropriate Field Medical Colleague with clinical informatics expertise. The workflow assessment must not be remunerative and must not constitute a transfer of discernible value to the customer.

Read below for more requirements.

	<p>During a workflow assessment, the HIT Account Director and Field Medical Colleague MUST:</p> <ul style="list-style-type: none">• Remember that the focus is to educate and raise awareness of opportunities to use existing EHR functionality and Pfizer-approved resources to improve patient care in a disease state in which Pfizer has an aligned interest and expertise• Meet with the customer in person or virtually and review the system's customer-stated workflow in the therapeutic area in question, using RC-approved resources as described in the Workflow Assessment Implementation Guide• Conduct the workflow assessment consistent with guidance in the Workflow Assessment Implementation Guide
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During a workflow assessment, **the HIT Account Director and Field Medical Colleague MUST NOT:**

- Provide expertise on the overall use of the customer's HIT system or otherwise provide general HIT consulting services
- Observe the treatment of actual patients or view the [Protected Health Information \(PHI\)](#) of any patient
 - It is the responsibility of each Pfizer Colleague to ensure that they are not exposed to PHI
- Agree to enter into a [Business Associate Agreement \(BAA\)](#) individually or on Pfizer's behalf since Pfizer generally does not act as a [business associate](#) for purposes of HIPAA
 - If a colleague is asked to sign a confidentiality agreement or BAA, they should contact their Product Attorney
 - Remember, a confidentiality agreement will not address patient privacy concerns and does not permit Pfizer employees to receive PHI
 - For more information about HIPAA, refer to Section 1 of *The Orange Guide*.



After completion of a workflow assessment, **the HIT Account Director and Field Medical Colleague MAY:**

- Jointly develop a readback report, which is a report of the findings to be presented to the health system, using RC-approved templates/resources





Workflow assessment readback reports MUST BE:



- Drafted using the RC-approved insights materials
 - Refer to the Workflow Assessment Implementation Guide for further details
- High-level, educating on insights and opportunities to improve patient care for the health system to consider implementing
- Used to further educate and build awareness on the implementation of approved resources in a relevant therapeutic area
- Aligned with input from the broader Account Team to ensure that the report:
 - Is consistent with Pfizer strategies in the relevant therapeutic area
 - Contains accurate and appropriate feedback with respect to any clinical or medical content
 - Includes appropriate clinical content and conveys appropriate clinical intent when appropriate
- Approved by the appropriate business unit approver and Product Attorney before it can be used with a customer
 - Please note they do not require RC-approval





Workflow assessment readback reports MUST NOT:

- Contain any guidance regarding the achievement of Merit-Based Incentive Payment System (MIPS)/Medicare Access and CHIP Reauthorization Act (MACRA) guidelines, earning or obtaining financial incentives, or otherwise improving reimbursement
- Contain detailed recommendations or solutions and should be limited in scope to the relevant therapeutic area

FAQ: Purpose of a Workflow Assessment	
	<p>I'm an HIT Account Director, and I worked with a KAM to schedule an assessment of an Account's workflow. Along with the Field Medical Colleague, we plan to conduct the assessment for patients with atrial fibrillation, a therapeutic area for which Pfizer has approved HIT educational resources. The customer has also asked that we provide feedback on the workflow for obesity as well as interoperability across the sites of the Integrated Delivery Network (IDN). Can I provide the customer the information it seeks?</p>
	<p>Without an approved collaboration or other unique arrangement approved by management and Legal for the proposed purpose, an HIT Account Director/Field Medical Colleague should not provide the requested feedback on obesity and interoperability. The workflow assessment should be confined to the topic of atrial fibrillation, where Pfizer has an appropriate interest in patient care and also has approved tools and resources.</p> <p>A workflow assessment for obesity would likely be inappropriate, as it is not a therapeutic area currently aligned to Pfizer interests, nor do approved tools and resources exist. Workflow assessments should focus on opportunities to implement approved resources. Similarly, addressing general interoperability is neither aligned to Pfizer strategy nor tailored to improving patient care. Instead, assessments in those areas could be construed as inappropriate HIT consulting services that could expose Pfizer and the HIT Account Director/Field Medical Colleague to liability under the anti-kickback laws.</p>

FAQ: HIT Engagements and Federal Requirements	
	<p>I'm a KAM and I'd like to work with a customer to develop an improved workflow for identifying patients and improving care in a therapeutic area where Pfizer has a public health goal. I've consulted with my HIT Account Director and would like to engage the customer on the HIT-related aspects of this project. The customer is unsure if they want to work with us on this. In explaining why this might be of interest, can I or the HIT Account Director explain how Pfizer can help the customer improve its ability to satisfy federal requirements, such as meaningful use?</p>
	<p>No. Engaging in HIT Initiatives with customers with the express or implied purpose of aiding the customer in satisfying MIPS/MACRA requirements could expose Pfizer to liability under the anti-kickback laws and should be avoided. The purpose and focus of engaging with a customer on an HIT Initiative and/or providing HIT resources should be to provide clinical/disease education to help improve patient care or population health.</p>

FAQ: HIT Engagements and Federal Requirements	
	I understand that I cannot proactively initiate that discussion, but what if the customer asks about how Pfizer can help it satisfy MIPS/MACRA requirements? At that point, can we discuss MIPS/MACRA strategies?
	No, this would not be an appropriate activity. Whether proactive or reactive, Pfizer cannot provide assistance for the purpose of aiding customers in achieving any financial incentives, including MIPS/MACRA. Although the appropriate use of some Pfizer resources could potentially affect whether a customer meets some MIPS/MACRA criteria, Pfizer should never deliver these resources with the purpose of helping the customer to increase its revenue, reimbursements, or eligibility for financial incentives. See Chapter 3 for additional details on collaborations that could positively impact a customer's reimbursement.

Post-Workflow Assessment Engagement

Once completed, the workflow assessment readback report will be delivered to the customer by the HIT Account Director and appropriate Field Medical Colleague in accordance with the Workflow Assessment Implementation Guide. The report will help assist the Account Team and customer in identifying next steps in the population health engagement. As always, Account Team coordination is key.

Here are some possible scenarios that may arise after a workflow assessment:

- Delivery of one or more RC-approved HIT resources available on [PROMOSprime](#) is recommended
 - When this occurs, the HIT Account Director, in consultation the other Account Team members, may provide those HIT Tools to the customer consistent with the associated implementation guidance
- Implementation of an RC- or MRC-approved HIT resource that requires discussion of clinical or disease concepts is recommended
 - When this occurs, a Field Medical Colleague with clinical informatics expertise should deploy the resource with the HIT Account Director or without any commercial involvement if it is a Medical-only HIT resource
 - Refer to the implementation guidance for the resource to determine what role is approved to use the resource with customers
- Broader opportunities for customer engagement are identified
 - When the workflow assessment suggests a more complex arrangement, requiring customization of existing tools, or significant time investment from both Pfizer and the customer, the Account Team should consider a collaboration

A collaboration, including one with an HIT component, is an activity or project undertaken by Pfizer with an organization to advance public health goals of interest to both Pfizer and the organization.

Account teams should consult with their Product Attorney and read the guidance on collaborations in this section to determine if an HIT Initiative would be a collaboration, and if so, the process for ensuring compliance.

Chapter 6: Additional Resources for More Information

Privacy

- For more information about HIPAA, the appropriate use of patient information, and Pfizer's policies for protecting patient privacy, see Section 1 of *The Orange Guide*

State Laws

- For information on relevant state law restrictions, see Section 7 of *The Orange Guide*

Organized Customer and Payer Tools and Resources

- General questions should be referred to your manager, appropriate Marketing teams and/or the Pricing and Access 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 Orange Guide*

Non-Discount/Discount Arrangements and Contracting

- General questions should be referred to your manager and/or a member of the Pricing and Access Legal team
- Discount Arrangements and Contracting questions may be referred to your manager, Pricing and Access Legal, Product Attorney, or Contracting Development
- For Questions regarding FMV, please refer to a member of the Pricing and Access Legal team and/or aligned contact within PCA Customer Marketing, Regional Customer Marketing or Brand Marketing
- For any questions about expanded access for a Pfizer investigational product, refer the inquiry promptly to Pfizer Medical Information or direct them to [PfizerCAREs](#) (Pfizer's Expanded Access Request system) or the PfizerCAREs mailbox at PfizerCAREs@pfizer.com
- For any questions about Clinical Research Collaborations, direct them to the CR-Collaborations@pfizer.com mailbox
- Questions may be referred to a Medical colleague, your manager, or Legal
- For more information about collaborations and Collaboration Agreements involving KAMs, including how to get them approved and prepared, see the [Organized Customer Collaborations Process Guidelines](#)

HIT

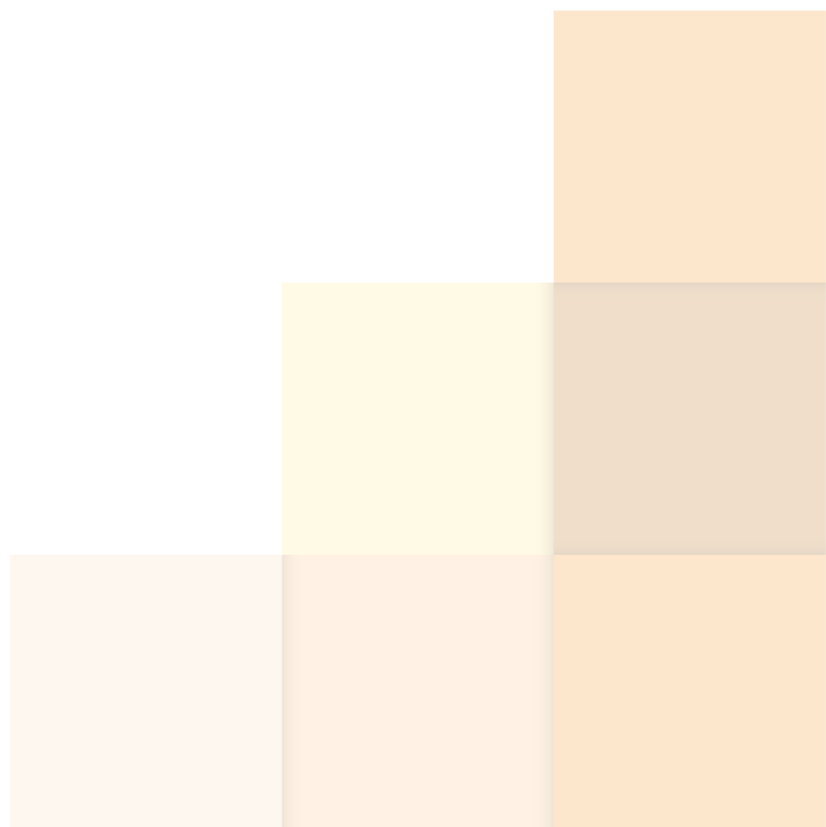
- For more information about HIT, see the [HIT CoE website](#)



The Orange Guide

Section 5

Guidelines for Patient Support and Consumer Interactions



Section 5

Guidelines for Patient Support and 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:

7. Facilitating patient access to Pfizer medicines and associated patient support programs after a Pfizer medicine is prescribed by a patient's HCP.
8. Providing non-promotional education on relevant disease states and/or products for patients, caregivers, and patient advocacy groups (PAGs)

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

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 key Pfizer policies regarding Pfizer's donations to Independent Charity Patient Assistance Programs (ICPAPs).

And finally, Pfizer policies regarding Field Commercial Colleagues and PSRs' interactions with patients and consumers will be reviewed.

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

Pfizer is committed to supporting patient access to the medicines prescribed by HCPs in a manner consistent with all applicable laws and regulations. As part of this commitment, some Pfizer brands may offer brand-specific reimbursement and patient support activities that are carried out by field-based colleagues 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 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.



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

	<p>Patient Support Role Offerings <i>MUST</i>:</p> <ul style="list-style-type: none">• Be made available in a non-discriminatory fashion to all appropriate HCPs and eligible patients• Be unrelated to the volume or value of business generated by any HCP or healthcare facility or to any decision by a patient to use a Pfizer medicine
	<p>Patient Support Role Offerings <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Provide substantial, independent value to HCPs, HCP practices, patients, or their caregivers

Additional guidance specific to each role is presented below, along with guidance around PSRs and Privacy Laws. Activity-specific guidance is addressed later in this section. For more information, please also see the [General Principles and Guidance for Patient Support Role Activities](#) on PolicyPoint.


Field Reimbursement Managers (FRMs)

FRMs are subject-matter experts on reimbursement, access, and coverage issues affecting Pfizer products.

	<p>FRMs MAY:</p> <ul style="list-style-type: none">• Educate HCPs and their staff on matters relating to reimbursement, access, and coverage to facilitate appropriate patient access to prescribed Pfizer products• 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• Coordinate with Pfizer hubs, where approved, concerning individual patient cases when the patient is receiving reimbursement support services or is requesting information about the Patient Assistance Program (PAP) or co-pay assistance• Engage commercial and government payers, including Medicare Administrative Contractors and Medicare Carrier Advisory Committees, to discuss systemic obstacles to and support policy-level decisions about patient access to Pfizer products• Attend relevant state and regional society and association meetings to keep apprised of reimbursement and coverage developments that may affect Pfizer products
	<p>FRMs MUST NOT:</p> <ul style="list-style-type: none">• Provide services that a customer would ordinarily pay a third party to perform or otherwise substitute for the HCP's general staff functions, such as general coding and/or claims submission training• Provide any routine business operating services, such as filling out forms for Physician Assistants (PAs), appeal documentation, or a Letter of Medical Necessity (LOMN), submitting claims, or processing bills• Provide support for the appeal of a denied claim, such as compiling documentation and/or submitting a written appeal on behalf of a patient• Speak directly to a patient

Field Access Specialists (FASs)



The FAS role generally functions like the FRM.

	<p>In addition to the direction above for FRMs, FASs MAY:</p> <ul style="list-style-type: none">• Have additional approved permissions supported by considerations such as the uniqueness of the disease state, patient population, therapeutic class, and current challenges to access<ul style="list-style-type: none">– For example, FASs may <i>proactively</i> reach out to hubs and HCPs related to individual case support, whereas FRMs typically only provide <i>reactive</i> support• Work with PACs
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Patient Access Coordinators (PACs)



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

In carrying out their activities, PACs may have the need to interact with FASs. These interactions must follow the direction below.

	<p>FASs and PACs MUST:</p> <ul style="list-style-type: none">• Only communicate with hub associates to review hub enrollments and identify pending actions for cases, including outlining missing information and who will conduct any needed outreach• Communicate with the hub only in regard to patients with a signed PAC opt-in<ul style="list-style-type: none">– For patients who have opted-in to receive PAC support, PACs MAY:<ul style="list-style-type: none">▪ Make a proactive welcome call to explain the hub enrollment process and timing▪ Follow up on missing case information, as approved▪ Reactively address patient questions either by sharing information approved for inclusion in their Customer Relationship Management (CRM) platform or transferring patients to the hub• Ensure that the data and information they require for communications with customers and patients only reside on a secure, Legal-approved platform
	<p>FASs and PACs MUST NOT:</p> <ul style="list-style-type: none">• Share case notes with other colleagues, unless designated as a back-up in the CRM to cover for a counterpart's leave or vacation

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

	<p>PALs MAY:</p> <ul style="list-style-type: none">• Staff approved exhibits and displays at patient meetings and conferences• Educate patients and their caregivers on disease awareness and management
	<p>PALs MUST NOT:</p> <ul style="list-style-type: none">• Provide off-label information• Proactively discuss specific treatment options• Act as a case manager or advocate for consumers with respect to reimbursement, access, or affordability issues

	<ul style="list-style-type: none">Engage in consumer interactions that are not specifically described in <i>The Orange Guide</i> without additional specific guidanceCollect 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 that they 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 LegalFor a detailed discussion of privacy issues and the appropriate handling of Personal Information, refer to Section 1 of <i>The Orange Guide</i>Offer any medical opinions, advice, or consultation even if they have a license to practice medicine or are any other type of HCP
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For more 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: <ul style="list-style-type: none">Provide education in a manner that is non-promotional, fair and balanced, and consistent with the relevant product's Prescribing Information
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✗	HCP-Facing CEs MUST NOT: <ul style="list-style-type: none">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: <ul style="list-style-type: none">Educate on disease awareness and management, and provide basic information on proper use and administration of Pfizer medicines and related devicesMeet individually or in group settings, depending on the guidance developed by the Brand Team in partnership with Compliance
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✗	Patient-Facing CEs MUST NOT: <ul style="list-style-type: none">Promote Pfizer products to patients or caregivers
---	---

Patient Support Roles 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 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 laws, refer to Section 1 of *The Orange Guide*.

Privacy and Individual Patient Support Activities

FRM, FAS, PAC, and PAL engagements with respect to individual patients will necessitate those colleagues having access to at least some PHI. These colleagues must safeguard any PHI they may receive.

Furthermore, FRMs, FASs, and PACs should avoid conducting reimbursement support activities over e-mail and text. In the event it is necessary, these Pfizer Colleagues should ensure that the appropriate authorizations have been received and that they do not disclose patient information to individuals other than those authorized to receive it.

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 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.

Chapter 3: Patient Support Programs

Aligned with the goal of supporting patient access to medicines, Pfizer has also established Patient Support Programs, such as Pfizer RxPathways and hubs, so that eligible patients may access resources designed to help with:

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

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

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

Pfizer RxPathways is not brand-specific and is run by the Pfizer Global Health and Social Impact (GHSI) Team.

Hubs are third-party vendors contracted 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 programs.

Hubs are jointly managed by the Specialty Access Solutions Center of Excellence (SAS CoE) and GHSI 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:

- GHSI 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

Guidance for Field Commercial Colleagues Regarding Pfizer RxPathways and Hubs

It is Pfizer's policy to establish and implement Pfizer RxPathways and the hubs consistent with all applicable laws and regulations. To that end, Pfizer RxPathways and the hubs provide no more than limited reimbursement support to patients who are prescribed a Pfizer medicine.



RxPathways and the hubs are intended to support patient access to independently prescribed Pfizer medicines and are not intended to reward or induce an HCP for past, present, or future prescribing of products, or to reduce economic or administrative burdens for an HCP or related practice or office staff.

Section 5: Guidelines for Patient Support and Consumer Interactions

Pfizer offers its RxPathways and hub activities in a non-discriminatory fashion to all eligible patients after they are prescribed an applicable Pfizer product by their HCP. The availability of RxPathways and hub support is unrelated to the volume or value of business generated by any HCP or healthcare facility.

To ensure that Pfizer meets these obligations, the Pfizer Pricing and Access Legal (P&A Legal) Team must review and provide guidance for RxPathways and each hub operating in the United States. Additionally, Pfizer annually re-evaluates the need for specific hub activities on a product-by-product basis to substantiate the need for their continued offering.

Field Commercial Colleagues must follow the guidance summarized below when engaging their HCP customers in discussions regarding RxPathways or the hubs.

	<p>Field Commercial Colleagues <i>MUST</i>:</p> <ul style="list-style-type: none">• Limit communications about the availability of RxPathways and hub activities to Review Committee (RC)-approved information about RxPathways and any hub program• 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 hub
	<p>Field Commercial Colleagues <i>MUST NOT</i>:</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 RxPathways or hub programs and activities to induce HCPs to prescribe products or discourage HCPs from prescribing alternative therapies

Additional information regarding hub processes and procedures is available in the *Pfizer Standard Operating Procedure for Patient and Reimbursement Support Hubs* (Hubs SOP).

Chapter 4: Patient Assistance Programs

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 play an important role in assisting patients with accessing medically necessary products that are prescribed by their HCPs.

However, several federal and state laws and other regulatory guidance are implicated in connection with the operation of these programs. These include federal and state [anti-kickback statutes](#), the federal Beneficiary Inducement Statute, the federal False Claims Act, government price reporting obligations, federal and state privacy laws, and [U.S. Department of Health and Human Services \(HHS\) Office of Inspector General \(OIG\)](#) guidance.

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

These programs and activities are intended to support appropriate patient access to independently prescribed Pfizer medicines or 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 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, 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. This program is referred to as the Pfizer PAP or the Free Drug Program.

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 hub as long as a hub is available for the prescribed product and includes the PAP.

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 (GHSI) 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.

All Pfizer Colleagues that conduct business related to the Pfizer PAP work on behalf of PPAF and must fulfill the independent charitable objectives of PPAF.

Institutional Patient Assistance Program (IPAP)



The IPAP, which is part of the Pfizer PAP, provides select products to financially eligible, uninsured patients through nearly 300 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 PAP

Communications with patients and/or HCPs regarding the Pfizer PAP must be factual and non-promotional. If a colleague's role allows them to engage with HCPs or patients in proactive or reactive discussions 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 PolicyPoint.

General Guidance

	<p>Field Commercial Colleagues <i>MUST</i>:</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
	<p>Field Commercial Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Position the Pfizer PAP as a tool to promote products, differentiate products from competitor products, or influence HCP prescribing habits• Promote the availability of the Pfizer PAP for any off-label product uses, even though the Pfizer PAP may be available to all eligible patients irrespective of their diagnosis• 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

Section 5: Guidelines for Patient Support and Consumer Interactions

- Fill out or submit PAP applications on behalf of patients or HCPs



Role-Specific Guidance

In addition to the general guidance described above, the following guidance applies to specific Pfizer roles.

	Field Sales	FRMs	FASs	PACs	PALs	CEs
MAY						
Discuss the Pfizer PAP with HCPs when describing all applicable Pfizer patient support offerings, as long as the discussions are in line with the general guidance above	x	x	x			
Answer patient-specific questions about the Pfizer PAP within the scope of their roles		x	x	x		
Provide HCPs with copies of a PAP application and/or explain the application		x	x			
Discuss the Pfizer PAP, as part of all applicable patient support offerings, with patients as permitted within the scope of their role, as long as the discussions are in line with the general guidance above and occur after the product has been prescribed to the patient				x	x	
Direct patients to the applicable hub/RxPathways				x	x	
Provide interested patients with copies of a PAP application and/or explain the application, if permitted for the relevant product				x	x	
Refer HCP and patient questions regarding the Pfizer PAP to the hub or other applicable resources, such as Pfizer RxPathways or its toll-free number (844-989-PATH), for more information	x	x	x	x	x	x
MUST NOT						
Answer patient-specific questions regarding the Pfizer PAP	x				x	x
Proactively involve themselves in patient cases by acting as a contact for the HCP in lieu of the hub	x	x	x	x	x	x
Contact a hub/RxPathways for any reason, including to inquire about the status of a PAP application or PAP product order	x				x	x
Act as a liaison between the HCP and the hub/RxPathways regarding PAP application questions	x			x	x	x



Interactions and Communications with Pfizer Hubs

The guidance on interactions and communications with Pfizer hubs differs by role.

	<p>Field Commercial Colleagues <i>MUST</i>:</p> <ul style="list-style-type: none">• Refer all questions or concerns regarding hubs' operation of the Pfizer PAP to GHSI
	<p>Field Commercial Colleagues <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Communicate with hubs for any PAP-related reason• 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

PSR Requests for PAP Data

GHSI must review and approve all requests for PAP data elements in collaboration with P&A Legal. PSR leadership may request access to PAP data elements as necessary to address patient cases within the scope of their approved roles using the template attached to the [General Principles and Guidance for Patient Support Role Activities](#) on PolicyPoint. Other than such formal requests, PSRs should never request or share PAP data beyond what has been approved by GHSI and P&A Legal.

FAQ: Referring Patients to the Pfizer PAP	
	<p>I am a Sales Colleague and an HCP told me that he has Product X patients who are uninsured. He asked me whether Pfizer can provide these patients with free product. Product X is included in the Pfizer PAP. What can I do in response to his request?</p>
	<p>You may inform the HCP that he can refer patients to the applicable hub or to the Pfizer RxPathways website or its toll-free number (844-989-PATH) for information about the Pfizer PAP and other available assistance programs.</p> <p>Sales Colleagues must not imply or guarantee that Pfizer will provide any specific assistance to patients. Sales Colleagues also must not answer patient-specific questions regarding the Pfizer PAP and should direct HCPs with such questions to the applicable hub or other resource, such as the applicable Pfizer website, for additional information.</p>

Independent Charity Patient Assistance Programs (ICPAPs)

Overview

ICPAPs are independent, U.S. 501(c)(3) non-profit organizations that operate patient assistance programs 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 GHSI. 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](#).

ICPAP Guidance for Field Commercial Colleagues

Pfizer policy places strict limitations on Pfizer Field Commercial Colleagues and other Commercial Colleagues’ ability to discuss ICPAP donations or the availability of ICPAP assistance with HCPs or patients.



Field Commercial Colleagues *MUST NOT*:

- Discuss with HCPs or patients:
 - Specific ICPAPs
 - The availability of funding in relevant disease states from ICPAPs
 - That ICPAPs can overcome co-pay barriers
- Assist HCPs, customers, or patients in communicating with, or applying to, ICPAPs
- Direct HCPs, customers, or patients to particular ICPAPs
- Inform HCPs, customers, or patients to which ICPAPs Pfizer donated, to which disease state fund(s), or amount of donations
- Be involved in any activities related to donations to ICPAPs
- Communicate with GHSI about ICPAPs or funding decisions for the purpose of influencing donations to ICPAPs
- Communicate with any ICPAP about co-pay donations
 - If a colleague receives funding requests or other communications from an ICPAP, they should refer the requestor to the [Pfizer ICPAP Request Mailbox](#)

- Seek to obtain ICPAP-related data from any source
 - [Corporate Policy 803](#) places strict limitations on the receipt and sharing of data received from third parties related to ICPAP donations
- Attempt to correlate or calculate the amount or frequency of ICPAP donations with the ICPAP's support of patients prescribed Pfizer products

ICPAP Guidance and Patient Support Roles



Field Reimbursement Manager (FRM) and Field Access Specialist (FAS) Colleagues MAY:

- Provide to HCPs materials approved by the relevant Review Committee (RC) that discuss the range of patient support programs and resources to which the relevant hub or RxPathways connects patients, including information about ICPAPs
- If asked by an office for a status update on a patient, confirm with the hub whether the patient has been referred to an alternate funding source and relay that information to the office
- Upon request, share a complete list of all ICPAPs with available funding with HCPs and their offices



Patient Support Role Colleagues MUST NOT:

- Track, provide the name of any specific ICPAP (other than as part of the full list, as noted above), or request or document if ICPAP assistance was approved or denied
- Conference in a patient/HCP on a call to an ICPAP for a warm transfer to the ICPAP

If a colleague has any questions regarding any of this guidance, they should contact P&A Legal.

Chapter 5: Patient and 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)
- All other non-HCPs
- Employees of patient associations or customer organizations, regardless as to whether they hold a professional healthcare degree

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.

Similar to interactions with HCPs, however, interactions with consumers can involve risks, including the following:

- 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 the federal anti-kickback laws
- Some state attorneys general have interpreted state consumer protection laws to encompass off-label promotion
- The [Food and Drug Administration \(FDA\)](#) has established stringent requirements regarding direct-to-consumer (DTC) communications

Furthermore, 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’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 Interactions

Field Commercial Colleagues and Patient Support Roles (PSRs) are permitted to provide consumers with disease state and limited 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
- 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

Section 5: Guidelines for Patient Support and Consumer Interactions

- Upon request by a consumer, and after execution of the approved Opt-In form, PALs may engage in individual patient and caregiver interactions
 - Consumer interactions may occur in-person, via e-mail, or phone
 - Any in-person meeting with consumers must be in public settings
 - PALs may not meet with consumers in their homes or during their appointments for medical evaluation/treatment

Field Commercial Colleagues and PSRs must follow these general guidelines when interacting with patients and consumers.



Field Commercial Colleagues and PSRs MUST:

- Use only RC-approved messaging and materials, with 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 events and other reportable safety information set forth in Section 1 of *The Orange Guide*



Field Commercial Colleagues and PSRs MUST NOT:

- Provide off-label information
- Proactively discuss specific treatment options
- 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 *The Orange Guide* without additional specific guidance
 - Before engaging in any consumer interaction other than those outlined here, Field Commercial Colleagues and PSRs 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
 - In the event Field Commercial Colleagues and PSRs 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 *The Orange Guide*
- Offer any medical opinions, advice, or consultation even if they have a license to practice medicine or are any other type of HCP

Exhibits and Displays



Pfizer is committed to providing information to consumers about their health and Pfizer treatment options. Field Commercial Colleagues and PSRs are sometimes provided with opportunities to interact directly with consumers by

Section 5: Guidelines for Patient Support and Consumer Interactions

working at Pfizer exhibits or displays at consumer events such as health fairs, patient advocacy events, and health screenings.

The goal of these interactions is to foster more informed conversations between patients, caregivers, and their HCPs about the patients' health and treatment options.

Review the guidance below specific to exhibits and displays.

	<p>Field Commercial Colleagues and PSRs 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 promote 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">– If only unbranded consumer materials have been RC-approved, they may not discuss or provide product information to consumers at the event• Follow any accompanying instructions on use of the materials, such as those found in implementation guides• Only provide a very modest snack, 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
	<p>Field Commercial Colleagues and PSRs 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 solicit business or in a manner that might suggest that the recipient is being bribed or improperly influenced

Health Screenings

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

Section 5: Guidelines for Patient Support and Consumer Interactions

These screenings often take place as part of larger health fairs and Field Commercial Colleagues working with Organized Customers or certain specialty markets may 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, non-profit organization, managed care organization, or other third party

Pfizer's office of Global Medical Grants (GMG) can support a screening organized by a third party through an unrestricted educational grant, provided that the event meets Pfizer's requirements for unrestricted educational grants. Pfizer Colleagues may not participate 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><i>Field Commercial Colleagues and PSRs MUST:</i></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• Contract with an approved third-party vendor that routinely conducts such screenings to perform the disease screening customer program• 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
	<p><i>Field Commercial Colleagues and PSRs MUST NOT:</i></p> <ul style="list-style-type: none">• Design their own 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<ul style="list-style-type: none">– Field Commercial Colleagues and PSRs may, under some circumstances, only after consultation with and approval by their Product Attorney, seek information about products or programs used by those participating in the screenings, but they may not use such information to promote the use of Pfizer products

- Choose customers to receive screenings based on their likelihood to prescribe Pfizer products or in return for previous prescribing
- Use a screening to drive or attempt to generate patient referrals to any HCP
- 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 their Product Attorney and/or Pricing and Access Legal (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 sales representatives 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 Orange Guide*.

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 and all content presented at Pfizer speaker programs for consumers, whether branded or unbranded.





Field Commercial Colleagues and PSRs MUST:

- Always disclose that they are a Pfizer employee or representative when interacting with consumers, including wearing a Pfizer name tag at all times
- Adhere strictly to Pfizer policies regarding consumer presentations and CentrisDirect™ procedures
- Ensure the consumer speaker program and the chosen speaker follow all applicable CentrisDirect™ requirements
- Review the important policies regarding the content of the planned program with the speaker, as outlined below
- Ensure that the consumer speaker program lasts a minimum of 45 minutes, inclusive of Q&A, for venue programs, and a minimum of 30 minutes for in-office or virtual programs
- Make a good faith effort to broadly advertise a consumer speaker program they are holding, such that it will result in an audience of at least 3 consumers
 - There must be three consumer RSVPs in order to move forward with a consumer speaker program
 - The three required attendees may not be composed of a mix of patients, caregivers, and family members from the same family
 - It is not permissible to hire a speaker to address a group of their own patients, or patients of a health system or practice for which they work
- Complete a roster in CentrisDirect™ for every consumer speaker program held
 - Only the total number of consumer attendees may be listed in the Consumer Attendance field
 - Read below for specifics around recording HCP attendance
 - The rosters must not include the names of any consumer attendees
- Confirm electronically in CentrisDirect™ that the consumer speaker program was held and that speaking services were provided
 - The speaker must confirm this as well
 - For Rare Disease consumer speaker programs only, PALs have the responsibility to enter, monitor and close out the program in CentrisDirect™
 - PALs can also serve as the speaker
- Be sure to follow any additional specific guidelines provided by the Brand Team
- Recognize that virtual consumer speaker programs without the provision of a meal are preferred
 - If a meal is provided, only provide a modest meal at a consumer speaker program where a Pfizer Colleague is in attendance
 - A modest consumer meal is defined as not exceeding \$50 per person, including food, beverages, tax, and tip
 - Where there is a mixed HCP and consumer audience, the meal limit remains at \$50 per attendee, for both HCP and consumer attendees
- Only hold consumer speaker programs at:
 - In-office locations, such as in connection with a hospital patient support group meeting
 - Modest out-of-office locations

	<p>If the audience contains a mix of consumers and HCPs, Field Commercial Colleagues and PSRs MUST:</p> <ul style="list-style-type: none">• Use only consumer-directed invitations<ul style="list-style-type: none">– These are available from their Program Planner or available in CentrisDirect™• Use only an RC-approved consumer slide kit<ul style="list-style-type: none">– Pfizer must comply with existing FDA requirements and the PhRMA Code on Direct To Consumer Advertising Principles when interacting with consumers<ul style="list-style-type: none">▪ This ensures Pfizer product information, particularly safety information, is presented in a way that consumers can understand• Be aware that HCPs attending the consumer speaker program are subject to Pfizer's HCP Payment Disclosure policy<ul style="list-style-type: none">– If an HCP is a patient or a family member of a patient, or if the HCP does not have a specialty in the disease state and is attending the consumer speaker program as a consumer or caregiver for a patient, then Field Commercial Colleagues do not have to capture their name in the Consumer Attendance field of the roster in CentrisDirect™– If the HCP has a specialty in the disease state and would be someone a representative would potentially call on or would be able to attend one of our HCP peer-to-peer speaker programs due to their specialty in that disease state, then Field Commercial Colleagues and PSRs must record their names in the Consumer Attendance field of the roster in CentrisDirect™ for disclosure purposes
	<p>Field Commercial Colleagues and PSRs 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• Provide or pay for alcohol in connection with consumer speaker programs• Hold consumer speaker programs at high-end restaurants• Provide entertainment or recreation<ul style="list-style-type: none">– Field Commercial Colleagues and PSRs should make a good faith effort to avoid using venues that provide entertainment, such as hotels with casinos, golf courses, and resorts


Content

Before holding a consumer speaker program, Field Commercial Colleagues and PSRs must review these important policies regarding the content of the planned program with the speaker.

	<p>Speakers <i>MUST</i>:</p> <ul style="list-style-type: none">• Use only RC-approved consumer slide decks, and these slide decks must be used in their entirety and slides cannot be deleted or inserted by the speaker, unless otherwise directed, such as certain PAL-led Community Connections Program decks that are modular in nature• Remain on-label when providing information about Pfizer products, even if the speaker receives a question from the audience about an off-label use of the product<ul style="list-style-type: none">– Consumers are not trained medical professionals and, therefore, the dialogue between an HCP speaker and consumers is not considered scientific exchange– The speaker should explain that the product is not indicated for the use described, and the speaker should refer the consumers to their HCPs for further information– If the speaker does not appropriately respond to the question, the Pfizer Colleague is obligated to make a corrective statement and refer the consumers to their HCPs
	<p>Speakers <i>MUST NOT</i>:</p> <ul style="list-style-type: none">• Discuss information about Pfizer products if they are presenting an unbranded consumer slide deck<ul style="list-style-type: none">– The exception is if they are responding to an unsolicited question about the on-label use of a Pfizer product• Provide specific medical advice to a consumer attendee, even when the individual requests it, and should instead refer the consumer to their HCP• Discuss competitor products at branded or unbranded talks unless specifically contained in the RC-approved consumer materials or slide deck• Use the consumer speaker program as an opportunity to promote their medical services or practice or to recruit new patients

Providing Materials for Non-Pfizer Patient Education Events

There are also situations in which Field Commercial Colleagues and PSRs may provide RC-approved consumer materials to third parties such as HCPs or patient groups for use in their own patient education efforts.

	<p>Field Commercial Colleagues and PSRs <i>MAY</i>:</p> <ul style="list-style-type: none">• Provide RC-approved consumer materials for use at patient education programs that are organized and conducted by third parties
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Field Commercial Colleagues and PSRs MUST NOT:

- Share slide decks unless the relevant RC has specifically authorized dissemination of the slide deck in this manner
- Offer any speaker payment or other financial support for these non-Pfizer patient education programs, including, but not limited to, providing food or equipment for these programs

Chapter 6: Additional Resources for More Information

Privacy

- For more information about HIPAA, the appropriate use of patient information, and Pfizer's policies for protecting patient privacy, see Section 1 of *The Orange Guide*

State Laws

- For information on relevant state law restrictions, see Section 7 of *The Orange Guide*

Patient Support Programs and Patient Assistance Programs

- For more information about Pfizer RxPathways, including the Pfizer PAP, IPAP, Savings Program, or Reimbursement Support Services, please contact the RxPathways Team at PfizerRxPathways@pfizer.com
- For more information about hub fee-for-service activities, please contact the [SAS CoE team](#)
- For RC-approved FAQs and Talking Points, visit [MyPfieldNet](#)
- If you have additional questions about the information covered in this Section, please contact Pricing & Access Legal or Compliance

Patient and Consumer Interactions

- For more information on handling suspected adverse events, see Section 1 of *The Orange Guide* or [Corporate Policy 903, Your Responsibility to Report Information about the Safety, Quality, and Performance of Pfizer Products](#)
- For more information on speaker programs and additional speaker program resources, please refer to the [Speaker Program \(Centris\) Resources](#) page on Biopharma Ops on Demand
- Additional questions may be referred to your manager, Legal, or Compliance

Health Screenings

- For more information on requests for educational grants to support health screenings, see Section 6 of *The Orange Guide*
- Additional questions may be referred to your manager, Compliance, or the Payer and Channel Access (PCA) Legal Team



The Orange Guide

Section 6

Guidelines for Funding and Other Support of External Organizations

Section 6

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

This section provides a high-level summary of key Pfizer policies regarding specific types of funding and support of external organizations, mainly found in the [Funding Requests For Not-for-Profit Organizations SOP \(External Funding SOP\)](#). General information related to funding and support is reviewed below. For more details for each type of support opportunity, colleagues should consult the *External Funding SOP*.

In particular, this section does not comprehensively address the activities that may be funded by Business Unit (BU) Leadership and the Medical Lead for each BU. Those activities are also addressed in the *External Funding SOP*.

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.

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 Field Commercial Colleagues do not make any sort of commitment until the funding request is fully approved.



Field Commercial Colleagues *MUST*:

- Understand the types of activities their role and group are permitted to fund as outlined in this section
 - While Field Commercial Colleagues are limited in the funding they can provide, it is important to understand each type of request they may receive from customers and how these requests should be handled
- Follow the policy and procedures described in the [External Funding SOP](#)
 - Additional resources that can help colleagues determine whether a proposed funding activity is permissible to support are available at [Policy Xchange](#)
 - Colleagues can also direct any questions about the process to the U.S. External Funding Team at USFundingRequest@Pfizer.com



Field Commercial Colleagues *MUST NOT*:

- 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, 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

Chapter 2: Common Funding Requests Received by Field Commercial Colleagues

This chapter provides a high-level summary of key Pfizer policies regarding common funding requests received by Field Commercial Colleagues, including:

- Sponsorships
- Charitable Contributions
- Collaborations
- Awards, Scholarships, and Fellowships
- Independent Medical Grants (IMGs)

General information related to funding and support is reviewed below. For more details for each type of support opportunity, colleagues should consult the [External Funding SOP](#) and the [Independent Medical Grants SOP](#). Furthermore, if colleagues receive a funding request, they should not make a verbal or written commitment until the funding request is fully approved.

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 Field Commercial Colleagues in accordance with the processes and requirements described in the *External Funding 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 <i>As long as it meets all relevant Review Committee (RC) approval requirements</i>	Fair Recognition <i>NOT considered a tangible benefit</i>
Promotional placement of product logos on a podium or in literature aimed at 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

Section 6: Guidelines for Funding and Other Support of External Organizations


Fair Recognition vs. Tangible Benefit		
Examples	Tangible Benefit <i>As long as it meets all relevant Review Committee (RC) approval requirements</i>	Fair Recognition <i>NOT considered a tangible benefit</i>
Opportunity to promote Pfizer products, such as via branded materials or a booth at an exhibition	x	
Tickets to an event		x
Opportunity to promote 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 smoking cessation, which may have related branded or unbranded materials	x	
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>Field Commercial 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"> For Sales Colleagues specifically, sponsorships may be funded only at the Area Business Manager (ABM) level or higher
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Section 6: Guidelines for Funding and Other Support of External Organizations

	<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 Unit (BU)/Division/Function, unless otherwise noted
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	<p>Field Commercial Colleagues <i>MUST NOT</i>:</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 above• Make a verbal or written commitment until the funding request is fully approved
---	---

Furthermore, it is important to note that the purchase of exhibit and display space by U.S. Sales Colleagues is covered by the [Exhibits and Displays SOP](#) and is processed in Ariba. However, if an exhibit and display request is part of a larger promotional sponsorship package that includes other tangible benefits in addition to the exhibit and display space, then the [External Funding SOP](#) should be followed.

FAQ: Evaluating the Substantive Nature of a Funding Request	
	Can a Field Commercial Colleague, ABM level or higher, fund a sponsorship as long as the tangible benefit criteria are met?
	<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, Field Sales Colleagues are not permitted to fund medical education, as 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>

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 SOP* further distinguishes between four categories of charitable contribution:

- Non-Healthcare
- Healthcare (Non-Policy Focused)
- Policy-Focused Healthcare
- Special Events

Charitable contributions are not permitted to be funded by Field Commercial Colleagues. If approached with an opportunity to fund a charitable contribution, Field 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 see the [External Funding SOP](#) for more details.



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 HCP or private practice group?	No	No



Sponsorship vs. Charitable Contribution		
Characteristic	Sponsorship	Charitable Contribution
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: Purchase of a Single Ticket to a Gala/Fundraiser

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

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>

Collaborations

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.

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. If the organization creates materials that are published, this must occur in conjunction with Pfizer.

For Field Commercial Colleagues, all materials developed for distribution must go through a Pfizer RC evaluation to check the content for factual accuracy and compliance with applicable laws, regulations, and Pfizer policies. 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.

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

Collaborations involving research are out of scope of the [External Funding SOP](#). Such research collaborations must follow the [Research Collaborations SOP \(SOP RC01\)](#).

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 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

Awards, scholarships, and fellowships are permitted to be funded only by Worldwide Medical & Safety (WMS) and BU Medical Colleagues. Furthermore, Patient and Health Impact (PHI) Colleagues involved in designing and conducting research related to health economics and real-world data are the only Chief Business Office (CBO) colleagues permitted to fund fellowships.

Field Commercial Colleagues approached with an opportunity to fund an award, scholarship, or fellowship should immediately triage the request to the appropriate colleague who will follow the [External Funding SOP](#) approval process.

Independent Medical Grants (IMGs)

IMGs must only be used to support bona fide independent initiatives, such as research, quality improvement, 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 Field Commercial Colleagues. If approached with an opportunity to fund an IMG, Field Commercial Colleagues should refer organizations to the externally-facing [Independent Medical Education \(IME\) page](#) on the Pfizer website.

IMG types include:

Investigator-Sponsored Research (ISR) Grants support ISR studies that expand therapeutic area and product knowledge, including safety information, by identifying new ways of using existing treatments or investigational compounds, or by focusing on under-studied patient populations

Section 6: Guidelines for Funding and Other Support of External Organizations

General Research Grants support the development or refinement of specific and defined medical knowledge based upon medical and scientific merit and are used to support research that would otherwise not be defined as an ISR, including support for an institution's general research fund, Health Services Research, Registry Development, Outcomes Research, and Research Fellowships

- Includes interventional, non-interventional, outcomes, registry, and other types of research

Quality Improvement (QI) Grants are given to a third-party entity for QI which consists of systematic and continuous actions that lead to measurable improvement in healthcare services and the health status of targeted patient groups

- Examples include a hospital looking to improve patient outcomes and reduce cost by leveraging their analytics system to demonstrate the impact of their pharmacist-led medication therapy management in reducing the total cost of care, or a Health System looking to implement standing orders to increase access to quality immunization health care and to reduce missed opportunities for immunizations in both children and adults

Independent Medical Education (IME) Grants are given to a third-party entity to support an activity or initiative that serves to maintain, develop, or increase the knowledge, skills, and/or professional performance of HCPs

- Includes, but not limited to, activities like certified Continuing Medical Education (CME)/Continuing Education (CE)/Continuing Professional Development (CPD) for HCPs

IMG requests are managed by the GMG group in Pfizer's WMS organization. These grant types are covered by the [Independent Medical Grants SOP](#).

Each request is evaluated based on objective criteria including the 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.

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

IMGs must be conducted in accordance with all applicable local laws and regulations, applicable Pfizer policies and Standard Operating Procedures (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.



Field 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
 - 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](#)



Field Commercial Colleagues MUST NOT:

- 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, and 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:
 - 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 CME/CE provider, program sponsor, or speaker at a CME/CE activity
 - 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

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, **Field Commercial 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, **Field Commercial 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

Section 6: Guidelines for Funding and Other Support of External Organizations

- 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, **Field Commercial Colleagues MAY:**

- Pay for placement of an exhibit or display at [fair market value](#)
- 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

FAQ: Investigator-Sponsored Research (ISR) Grant

Q

I am a Commercial Colleague developing a relationship with an HCP customer who is an expert in her field and who does a significant amount of clinical research involving a Pfizer drug. She told me that she is seeking funding for a research proposal. Is it OK for me to suggest she submit a proposal to Pfizer for an ISR grant?

A

Yes, if an HCP independently expresses interest in applying for research funding, you may suggest submitting a proposal for an ISR grant. If you do speak with the HCP about Pfizer's ISR program, do not make any promise or suggestion that the ISR proposal will be supported, nor assist in any way in drafting the ISR proposal or submitting it through the [GMG website](#). The HCP can access information about the requirements and application process for ISR grants at www.pfizer.com/isr. Note, Pfizer Colleagues must not proactively solicit the submission of ISR proposals by Pfizer customers. In addition, you may have no other involvement in the request or funding decision, and you must not attempt to influence, or foster the impression that you can influence, the funding decision. It is your responsibility to ensure that the HCP understands that all funding decisions are made without your input, based upon assessment of the medical and scientific merits of the proposal as well as the investigator's eligibility to conduct the research.





FAQ: Colleague Roles in Grant Process

Q

May a Field Commercial Colleague communicate with grant requestors regarding the status of grant requests?

A

No. These colleagues must not be part of the submission, review, or approval process. Requestors must communicate only with members of the GMG team regarding grant requests, funding, or denials. Colleagues must direct requestors to the [GMG website](#), or the dedicated e-mail address GMG@pfizer.com, without any commentary on the merits of the submission.

FAQ: Colleagues' Role in Preserving Independence	
	May a colleague provide input on the content of an activity funded through GMG, even non-CME/CE? Similarly, can a colleague provide logistical assistance for any 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 Field Commercial Colleagues attend educational sessions as a learner or observer at a MedEd event that was funded through GMG?
	No. However, Field Commercial Colleagues may staff an exhibit and display or participate in a non-CME portion of the event, such as product theaters, as long as they are appropriately conducted apart from any CME sessions and otherwise follow Pfizer policy for such activities. If there is a question about whether an event is supported by a grant from Pfizer, contact GMG@pfizer.com .

Chapter 3: 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.

Each colleague 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 BU and PCA Account Management Colleagues) ¹	Corporate Affairs	BU Medical and Worldwide Medical & Safety (WMS)	CBO	Global Medical Grants (GMG)
	Sponsorship	Yes, but ABM and above only	Yes	Yes	Yes	Yes	Yes
Charitable Contributions	Healthcare CC (non-policy focused)						Yes
	Policy-Focused Healthcare CC			Yes			
	Non-Healthcare CC		Yes ²	Yes	Yes	Yes	
	Special Event			Yes			
	Collaborations	Yes, but ABM and above only	Yes	Yes	Yes	Yes	Yes
	Awards				Yes		
	Scholarships				Yes		
	Fellowships				Yes	Yes ³	

Section 6: Guidelines for Funding and Other Support of External Organizations

Permitted Funding by Group							
		Field Commercial Colleagues					
	Type of Funding	Sales	Non-Sales (including BU and PCA Account Management Colleagues) ¹	Corporate Affairs	BU Medical and Worldwide Medical & Safety (WMS)	CBO	Global Medical Grants (GMG)
	Independent Medical Grants (IMGs)			Yes	Yes		Yes
<p>1. To remain consistent with the External Funding SOP, Business Unit (BU) and Payer and Channel Access (PCA) 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</p> <p>2. BU and PCA Account Management Colleagues must consult Legal before proceeding to support a Non-Healthcare Charitable Contribution (CC)</p> <p>3. Patient and Health Impact (PHI) colleagues involved in designing and conducting research related to health economics and real-world data are the only Chief Business Office (CBO) colleagues permitted to fund Fellowships</p>							

As the above table depicts, Field Commercial Colleagues, in general, 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 PolicyPoint.

Remember, the *External Funding SOP* focuses on funding requests from not-for-profit entities, and Field Commercial Colleagues should not commit to or provide funding to any such entity until the Standard Operating Procedure's (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 Field Commercial Colleagues should consult with Legal before committing to or providing funding for these entities.

Chapter 4: 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 Unit (BU) or division that are undertaken with organizations to promote Pfizer's products or advance Pfizer's business interests appropriately. For example, an Account Manager can join an employer coalition for the purpose of advocating for Pfizer's position on formulary benefit design, assuming necessary approvals are obtained.

Regular Membership and Board Membership

Colleagues should exercise caution when participating as a regular member, officer, trustee, or board member of an external organization, particularly if the organization is likely to request funding from Pfizer.


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 6: Guidelines for Funding and Other Support of External Organizations

	<ul style="list-style-type: none">– Limited exceptions to the requirement are described in Corporate Policy 203, Conflicts of Interest
	<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 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

Chapter 5: Additional Resources for More Information

General Funding Request Information

- For more information regarding the majority of information in this section, please refer to the [ExterCribatlenal Funding SOP](#), which applies to U.S.-based (and non-U.S.-based when using U.S. cost centers) colleagues in the BUs, WMS, CBO, and Corporate Affairs
- For questions relating to the *External Funding SOP*, e-mail the U.S. External Funding Team at USFundingRequest@pfizer.com
- 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

- Sales Colleagues who need information about policies for funding exhibit and display opportunities can refer to Section 3 of *The Orange Guide* and [ED SOP2-01 – Exhibits and Displays Standard Operating Procedure](#) 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

- 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 7 of *The Orange Guide*
- For information about Pfizer’s disclosure of external funding activities, please visit the [Transparency in Grants](#) page of the Pfizer website



The Orange Guide

Section 7

State Healthcare Laws and Interactions With State and Federal Employees

Section 7

State Healthcare Laws and Interactions With State and 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 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:

- The important rules Field Commercial Colleagues must understand and follow when engaging in promotional and non-promotional activities with U.S. federal government agencies and their employees, including the Department of Veterans Affairs (VA), the Department of Defense (DoD), the Department of Health & Human Services (HHS)
- Certain key Pfizer policies regarding lobbying registration and disclosure
- 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 Field Commercial Colleagues, and particularly 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: Interactions With Federal Employees

As Pfizer's sales to the federal government continue to increase, interactions with government officials, 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 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 \(DHA\)](#)
- [Department of Health & 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"

Field Commercial Colleagues may interact with HCPs and other employees who work for these government agencies and institutions on a full- or part-time basis or otherwise qualify as federal government employees. Account Managers may also interact with federal government employees who make decisions on formularies and purchasing.

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.

Impact of Formulary Status on Ability to Promote

Before engaging in promotional activities, Field Commercial Colleagues need to understand the impact of formulary status on their ability to promote.

Field Commercial Colleagues must comply with federal agency, institution, and local site policies regarding drug promotion, including those that regulate promotion based on formulary status. In some cases, local regulations will prohibit any discussion of products that are either not on the institution's formulary or are on formulary with

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restrictions. Therefore, the formulary status of the product being discussed must be clearly and accurately represented.

VA-Specific Promotional Rules

At VA facilities and other VA points of care, promotion of formulary and non-formulary drugs, including those with established [Criteria-For-Use \(CFU\)](#), is permitted only in limited circumstances. CFU are clinical criteria developed by the VA at a national level that describe how certain drugs may be used—however, exceptions may be applied at the local level for operational reasons.

In all cases, the Veterans Integrated Services Network (VISN) Director, the facility Chief of Pharmacy, or their designee must provide approval of the promotional activity.


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

- The promotion has been approved by the VA medical facility's Chief of Pharmacy Services, or designee
- The promotion is consistent with the existing Pharmacy Benefits Management (PBM) CFU guidance
 - Please note that Sales Representatives may access information regarding VA CFU from the [PBM Services Website](#)
- The drugs or drug-related supplies are discussed, displayed, and represented accurately
- The promotion has significant educational value and does not inappropriately divert VA staff from other activities they would otherwise perform during duty hours, including patient care and other educational activities
- The drug or drug-related supply has not been classified by VA as non-promotable

Non-VANF drugs and drug-related supplies, where PBM CFU have not been developed, may be promoted in VA medical centers, including CBOCs and other VA medical facilities, if all of the following conditions are met:



- The promotion is specifically permitted by the VA medical facility's Chief of Pharmacy Services, or designee
- The drugs or drug-related supplies are discussed, displayed, and represented accurately
- The promotion has significant educational value and does not inappropriately divert VA staff from other activities they would otherwise perform during duty hours, including patient care and other educational activities
- The drug or drug-related supply has not been classified by VA as non-promotable
 - Please note that the PBM maintains a national listing of formulary medications that are not to be promoted or detailed by Sales Representatives on the [PBM Services Website](#)

Products with CFU:

	<p>It is possible that product-specific information and recommendations in the CFU may be inconsistent with product labeling. Therefore, Sales Colleagues MAY:</p> <ul style="list-style-type: none">• Discuss CFU product-specific recommendations and clinical recommendations only if approved by the relevant Brand Review Committee (RC)<ul style="list-style-type: none">– It is important to highlight, when having such discussions, that the CFU were independently developed by the VA and that Pfizer does not necessarily endorse them– In the event that the CFU are inconsistent with product labeling, for example, when they recommend use of a Pfizer product over a competitor when there is no head-to-head data, or when the use is recommended in a patient population that is different from that in the label, the
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	<p>Brand RC may consider allowing Sales Colleagues to refer HCPs to the VA website for review of the CFU, or leaving a copy behind, without discussing them</p> <ul style="list-style-type: none"> • If copies of CFU are approved by the Brand RC as a leave-behind, they should be distributed separately from any promotional materials, a copy of the approved product labeling should be attached, and these prominent disclaimers should be included: <ul style="list-style-type: none"> – The CFU were independently developed by the VA – Pfizer does not endorse the CFU or recommend using the product as described in the CFU
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In all cases where there is any question as to whether promotional materials are consistent with Pfizer policies, the colleague must consult their Product Attorney before providing those promotional materials to the customer.

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

Site Visits, Promotional Materials, and Educational Materials

In general, when visiting a federal institution, it is important to be aware of rules regarding site visits, promotional materials, and educational materials. Some of these rules may be driven by facility-specific policies and colleagues should follow the process of each facility regarding appointments and activity.

	<p>VA policy requires:</p> <ul style="list-style-type: none"> • Colleagues to make an appointment prior to visiting VA Facilities for the purpose of promotional activity • Promotional materials referenced on a VA site be approved by the VA medical facility's Chief of Pharmacy Services or their designee <ul style="list-style-type: none"> – Any promotional programs or educational materials that Field Commercial Colleagues wish to use or circulate at VA facilities must be RC-approved and submitted to the Facility Chief of Pharmacy Services for review and approval at least 60 days prior to the educational program or meeting <ul style="list-style-type: none"> ▪ No materials may be used without obtaining such approval • Any patient education materials with a product name or logo of the manufacturer must receive permission from the VA PBM Service before distributing
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VA policy does NOT permit:

- Company representatives to leave promotional materials in patient areas
- Marketing to students, including residents
- Waiting in patient-care areas or paging employees via a public address/paging system

Starters

Many federal government institutions, such as VA and DoD clinics and hospitals, may prohibit pharmaceutical companies from leaving starters, samples, or free goods. Colleagues must always learn the sample policies and procedures of any institution that they call on and follow those rules.

If there is any question as to whether these policies and procedures might conflict with Pfizer policy or the Prescription Drug Marketing Act (PDMA), colleagues must consult Compliance before leaving starters with that customer.

FAQ: Providing Starters to the VA

Q

I've been told by an HCP at a VA facility that pharmaceutical companies cannot leave starters with the VA. Is this correct?

A

Yes, starters are typically not allowed in VA facilities. However, VA national policy permits pharmaceutical companies to provide samples/starters to VA medical facilities in certain cases upon approval by the VA Medical Facility Director. If the facility allows, the samples/starters must be delivered to the Office of the Chief of Pharmacy Services for proper storage, documentation, and dispensing. The distribution of samples/starters directly to VA HCPs is inconsistent with the VA's policy. Moreover, if the products are intended to be used solely to allow VA clinicians to gain familiarity with the product, such use must be pre-approved by the VISN Pharmacist Executive and/or VISN Formulary Committee.

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.



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

Section 7: State Healthcare Laws and Interactions With State and Federal Employees

- 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:

- 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
- Any gifts, including meals and refreshments, provided to federal government employees will be subject to Pfizer's HCP Payment Disclosure Policy
- All HCPs, including those employed by the VA and DoD, may opt out of receiving these items by notifying 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.

FAQ: Leaving Educational Items with federal government employees	
	If I leave educational items that are 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 HCP Payment Disclosure Policy, 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.

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.

Inviting Government Employees to Speak or Present at Events

Field Commercial Colleagues must contact Compliance for more information before scheduling an event or meeting at which a full- or part-time federal employee will speak or extending an invitation to any federal employee to attend an event.

Speaker/Free Attendance

Full- or part-time federal government employees, including HCPs, may accept an offer of free attendance to speak at a Pfizer-sponsored event and may accept meals provided at the event that are provided to all participating speakers on the same day.

Pfizer policy requires approval in writing by the DAEO of any such engagement as federal government employees are generally prohibited from accepting compensation for speaking engagements that relate to their official duties, including receiving compensation to speak to other government employees on Pfizer's behalf.

Speaker/Paid

In limited circumstances, full- or part-time federal government employees may be compensated to speak on matters that are not related to their official duties. The conflict-of-interest regulations require that any such engagement be pre-approved in writing by the federal government employee's DAEO.

In assessing such an engagement, the DAEO will consider whether the federal government employee:

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

Pfizer policy requires receipt of DAEO approval in writing prior to such speaking engagement or confirmation from the government employee, in writing, that they received approval from the DAEO. Approval from other federal government employees who are not the DAEO is not sufficient.

Inviting Government Employees to Attend Events



On occasion, Pfizer may wish to invite federal government employees to events, including off-site educational speaker programs, as non-speakers. Under those circumstances, free attendance is considered a gift.



Free attendance and meals provided to all attendees in a group setting may be allowed under an exception to the gift restriction that applies for widely attended gatherings.



Importantly, to qualify for this exception, the federal government employee must receive prior written approval from their DAEO before accepting the invitation to attend. Furthermore, all invitations must be contingent upon receiving this approval.

Pfizer policy requires:

- Receipt of DAEO approval in writing
 - It is also acceptable to receive confirmation from the federal government employee, in writing, that they received approval from the DAEO
 - Approval from other federal government employees who are not the DAEO is not sufficient
- Any meal being provided is in connection with a legitimate educational speaker program that satisfies Pfizer's standards for a speaker program as described in Section 3 of *The Orange Guide*
 - Meals are not offered on a regular or repeated basis to a federal government-employed HCP

FAQ: Speaker Program Meals	
	<p>A Sales Colleague has invited a DoD HCP to a speaker program that qualifies as a widely attended gathering. If the DoD HCP attends the speaker program after confirming in writing with her employer that attendance is permitted, is it permissible for the DoD HCP to receive the same meal as the other attendees in the group setting if it's more than \$20 in value? Or is Pfizer required to provide a meal of \$20 or less in value?</p>
	<p>The Pfizer Colleague needs to confirm that the federal government employee has received DAEO approval in writing. Approval by others within the agency will not be sufficient. If DAEO written approval has been obtained, the exception will be met, and the meal provided at the event will not be considered a gift. Thus, the HCP can have the same meal as the other event attendees.</p>

FAQ: Part-Time VA Employees	
	<p>One of my customers works three days a week at his private practice and two days a week at a VA hospital. When I provide him meals at his private office, am I required to follow all of the VA/DoD policies?</p>
	<p>Yes. HCPs who work part-time for the VA are still required to follow the policies of the VA as if they are full-time employees.</p>

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

	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.
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Supporting Independent Medical Education

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 SOP \(SOP GNT01\)*](#) for further details.

Chapter 3: Federal and State Lobbying Activities

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 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 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](#) 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 HCPs, rules around lobbying, ethics, and gifts regulate specific interactions with federal government officials 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, as well as any expenses incurred in connection with any lobbying contact or supporting activity, such as travel, lodging, and meals.

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

Section 7: State Healthcare Laws and Interactions With State and Federal Employees

- Preparing for and providing on the record testimony in a congressional or agency hearing
- Communicating with government officials 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 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 government officials	Discuss Pfizer products or specific Pfizer activities
Coordinate any lobbying activities with government officials 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 section 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 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.

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.

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

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 and 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 4: Key State/City 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.

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 Orange 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 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 Orange 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 HCP-Related Healthcare Compliance Laws

State	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 are required as of July 1, 2017 Licenses must be renewed every year and CE requirements must be satisfied Licensees will also be required to record certain information about interactions with HCPs
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 Advise Colorado Prescribers that this is the landing page where they can get the most up to date information on WAC prices and any generic information relating to our products
Connecticut	<ul style="list-style-type: none"> The Connecticut Compliance Program Law requires companies to adopt a marketing code of conduct—the PhRMA Code is acceptable Starting in 2016, companies must begin tracking payments or other transfers of value provided to Advanced Practice Registered Nurses (APRN) authorized to practice independently (not in collaboration with a physician) for reporting 	<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
District of Columbia	<ul style="list-style-type: none"> Individuals engaged in the practice of "pharmaceutical detailing" must secure a license to detail in person in 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

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State	Important Provisions of the State Law	Requirements
Massachusetts	<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 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 Massachusetts 	<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 <i>The Orange Guide</i>, 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 CRM, which flags most, but not all, MA HCPs • You must make a good faith effort to determine if an HCP is licensed in Massachusetts
Michigan	<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 and Advanced Practice Registered Nurses (NP, CNS, CRNA, CNM) 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 Registered Nurses in Michigan, therefore, we must record the supervising physician’s name for all nurses that request starters • When starters for controlled substances are included, the supervising physician’s name and their DEA registration number must also be added to the transaction’s call notes in Veeva • Michigan state law now permits a Physician’s 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 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 	<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

Section 7: State Healthcare Laws and Interactions With State and Federal Employees

State	Important Provisions of the State Law	Requirements
	<ul style="list-style-type: none"> 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"> 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 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 five (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 NV HCPs
New Jersey	<ul style="list-style-type: none"> Meals to a New Jersey 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 a New Jersey 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 A New Jersey prescriber shall not accept more than \$10,000 in the aggregate from all pharmaceutical manufacturers in a calendar year for certain Bona Fide Services <ul style="list-style-type: none"> Bona Fide Services impacted by the cap include promotional activities (does not include 	<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 New Jersey 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

Section 7: State Healthcare Laws and Interactions With State and Federal Employees

State	Important Provisions of the State Law	Requirements
	<p>Speaker Programs), participation on advisory boards, and consulting arrangements</p> <ul style="list-style-type: none"> – 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 	
Oregon	<ul style="list-style-type: none"> • Individuals who market or promote prescription drugs to HCPs in Oregon must obtain a license <ul style="list-style-type: none"> – Individuals who promote prescription drugs 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
Vermont	<ul style="list-style-type: none"> • Vermont 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, and in connection with a job interview for prospective employment • Vermont 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 • Pfizer must report certain HCP expenditures, as well as samples, copay cards, coupons, and vouchers, to Vermont • Price Disclosure Forms must be provided to HCPs when detailing and posted on Pfizer's website 	<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 • 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 www.pfizer.com/vtprescribers, 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 Vermont

California

Definition of a Healthcare Professional

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 PhRMA's Code on Interactions with Health Care Professionals
- Set an annual aggregate limit for spending on meals, promotional items, and other activities provided to covered HCPs
- 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
- Pfizer Review Committee (RC)-approved educational items, such as textbooks, anatomical models etc.

The value of the following items is NOT included when calculating the annual aggregate limit:

- Starters
- [Fair market value](#) payments for services, such as speaking and consulting payments
- RC-approved promotional literature such as clinical reprints and slim jims
- Independent educational grants (financial support for Continuing Education [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. Licenses were required beginning July 1, 2017.

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 Continuing Education (CE) requirements. The initial professional education course and application are available on the [Chicago Department of Public Health \(CDPH\) website](#).

Licensees will be required to abide by a code of ethics 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
- \$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
- 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. Sales Representatives who obtain licenses as of October 15, 2017 and do not promote or market a Schedule II drug will not have to track any interactions for the next year until license renewal, at which point they must again see what drugs or drug categories are listed on the website. The Pfizer Global HCP Transparency Reporting team will submit any required disclosures on behalf of the Sales Representative.

Chicago can impose significant penalties on Pfizer Colleagues for failure to comply with this law, which may include fines of no less than \$1,000 and no more than \$3,000 per violation. If 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 Wholesale Acquisition Cost (WAC) price of their products, and at least 3 generic products in the same therapeutic class for any marketed product. Therapeutic class is defined as a group of similar drugs that have the same or similar mechanisms of action and are used to treat a specific condition.

As a result of this new law, 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 www.pfizer.com/coprescribers.

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 the most up-to-date information on WAC prices and any generic information relating to our products

If a colleague has any questions, they should contact Compliance.

Connecticut

The Law: Connecticut Compliance Program Law & 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
- Connecticut Department of Consumer Protection has authority to investigate alleged violations of the code-adoption requirement and alleged failures to conduct any training program or regular audit for compliance with the adopted code
 - Violations of the provisions would subject a company to a civil penalty of up to \$5,000
- Manufacturers to disclose payments and transfers of value provided to Connecticut-licensed Advanced Practice Registered Nurses (APRNs) who practice not in collaboration with a physician, that is, independently
 - Definition of Advanced Practice Registered Nurse below for purposes of the Connecticut disclosure law is defined as: an APRN who practices “not in collaboration with a physician,” that is, an APRN who practices independently
 - Who appears in the Connecticut Department of Public Health annual APRN list, 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.

District of Columbia

Definition of a Healthcare Professional

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 District of Columbia (D.C.) Prescription Drug Marketing Costs Disclosure Law requires Pfizer to report all marketing costs for prescription drugs to the D.C. Department of Health, including the value, nature, purpose, and recipient of all expenses associated with advertising, marketing, and direct promotion to D.C. residents through radio, television, magazine, newspaper, direct mail, and telephone.

Specifically, costs associated with the following activities are required to be reported:

- Direct-to-consumer advertisements targeting D.C. residents
- Educational or informational programs, materials, or seminars provided to 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, Pfizer Travel & Entertainment (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. Safe Rx 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 Continuing Education (CE) during the two-year period preceding the date the license expires. They must register for a *SafeRx Pharmaceutical Detail Licensing CE Program* through Power to 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 two months to complete each course offered, and Pfizer will pay directly for home study courses taken with the CMR *SafeRx Pharmaceutical Detail Licensing CE Program*.

If a colleague has completed a CMR Certification or CMR Flex course post-receipt of their pharmaceutical detailer's license, they should contact CMR by phone at **800-328-2615** or via email at program@cmrinstitute.org to determine if they already received renewal credit.

The District of Columbia can impose significant penalties on Pfizer Colleagues for failure to comply with this law, which may include a fine of up to \$10,000 as well as penalties and sanctions. If 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 D.C. Medication Advisory Committee Prohibited

D.C. law also prohibits offering a gift or remuneration of any kind to a member of the D.C. Medication Advisory Committee (DCMAC). Colleagues must not give anything of value to any DCMAC member, even if the item is Review Committee (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 FAQ](#).

Massachusetts

Definition of a Healthcare Professional

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, etc. of a Massachusetts-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 (MA). The law also requires Pfizer to disclose payments and items provided to "[Covered Recipients](#)," further defined below, that have a value of \$50 or more.

These 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 on 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 Customer Relationship Management (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
- 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 Pfizer Travel & Entertainment (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.

Therefore, even though pharmacists are not subject to the meal restrictions set forth above, because they are not included in the definition of HCP, they are subject to the disclosure requirements since they are considered Covered Recipients, so certain payments to pharmacists must be disclosed.

Expenditures that do not need to be disclosed include those associated with rebates and discounts, genuine research, clinical trials, demonstration units, and starters. Disclosed data will be made publicly available on the state’s website.

Co-pay cards, coupons and free trial vouchers may be provided to 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

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 (NP, CNS, CRNA, CNM)

- All starter requests recorded for Michigan Registered Nurses (RNs) and APRNs must include the supervising physician's name in the transaction's call notes in Customer Relationship Management (Veeva CRM)
 - The Veeva system does not allow us to distinguish between APRNs and Registered Nurses in Michigan, therefore, we must record the supervising physician's name for all nurses that request starters
- When starters for controlled substances are included, the supervising physician's name and their Drug Enforcement Administration (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.

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, Review Committee (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/congress exhibit booths are allowable and not considered banned gifts. All meals must, however, comply with all Pfizer policies on providing meals to HCPs, including the policy that meals should be modest and not exceed \$135 in value.

Consulting Engagements With Minnesota 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 or educational conference or meeting or performing bona fide services under one of the permitted consulting engagements, and who is receiving compensation for services pursuant to a contract with Pfizer. Refreshments and snacks provided at educational/scientific conventions/congress exhibit booths are also allowed. These types of meals are not considered a “gift” under the state statute.

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 Customer Relationship Management (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

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 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 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.

The law impacts the way Pfizer engages New Jersey Prescribers and restrict Pfizer's ability to provide meals to a New Jersey Prescriber. The law applies to all Pfizer Colleagues who interact with New Jersey Prescribers who practice in 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 Customer Relationship Management (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 or lunch and \$35 for dinner
 - The \$17 or \$35 excludes tax, tip, and any delivery charge
 - Colleagues must submit receipts in Concur/Pfizer Travel & Entertainment (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 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 Continuing Education (CE) requirements. License applications will require the following:

- The applicant's full name, social security number, email 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
- \$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 and 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

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)
- 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 on these expenditures are accurate and complete.

Section 7: State Healthcare Laws and Interactions With State and Federal Employees

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 Customer Relationship Management (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 Review Committee (RC)-approved
- Articles, journals, and other educational items
- Certain conference [sponsorships](#)
- Rebates and discounts
- Authorized expenditures related to clinical trials
- Compensation at fair market value (FMV) for bona fide consulting services, including research and product development meetings

Marketing Research

The Prescribed Products Gift Ban and Disclosure Law prohibits Pfizer from providing payments to Vermont-licensed HCPs in connection with marketing research surveys, including blinded surveys.

Paid market research surveys involving Vermont-licensed HCPs are banned. The restriction applies whether the survey is conducted directly by Pfizer or through an independent third-party survey research organization.

Disclosure of Expenditures to Vermont 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

Section 7: State Healthcare Laws and Interactions With State and Federal Employees

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 www.pfizer.com/vtprescribers.

The following table identifies which forms are required in connection with typical promotional activities.

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 5: Key State Employee Gift Laws

Summary of Key State Employee Gift Laws

Almost all states have restrictions on interactions with state employees, including HCPs employed by state institutions. A summary of the most significant state restrictions is provided below.

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 \$65 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 \$65 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

Colorado

Definition of Healthcare Professional 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 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 \$65 in any calendar year.

As with any other customer, colleagues may not provide any type of gift, regardless of value, to a Colorado state employee if the gift is intended or expected to influence or reward that employee in the performance of any activity related to 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 \$65 to a Colorado state employee in any calendar year. This means that colleagues must coordinate to ensure that no employee of the State of Colorado receives more than \$65 in items and meals from Pfizer as a company during any calendar year. The \$65 annual limit is not per Pfizer Colleague.

Pfizer 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 \$65 limit for Colorado state employees:

- Unsolicited 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 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
- 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, directly or indirectly, any gift.

“Gift” includes anything of value given in any form, including any money, service, loan, travel, entertainment, hospitality, or promise, unless an exception applies.

Colleagues may not provide any item to a New York State or local officer or employee if the item is intended or expected to influence or reward the New York State or local officer or employee in the performance of any activity related to 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 Review Committee (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 6: Additional Resources for More Information

Federal Employee Interactions and Lobbying

- Lobbying questions may be referred to the relevant 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

Educational Grants

- For more information on Pfizer's educational grant process refer to the [Independent Medical Grants SOP \(SOP GNT01\)](#)

State Laws

- For more information on state law restrictions, contact compliance or send questions to StateHealthcareLawCompliance@pfizer.com
- To determine whether an HCP is licensed in Massachusetts, Minnesota, New Jersey or Vermont, Sales Representatives should consult the physician profile within Veeva CRM, and other colleagues should consult the [HCP Lookup Tool](#)
- Additional information on state law restrictions and other tools is available under the State Healthcare Law Compliance tab on [Policy Xchange](#) or in the Compliance tab in [MyPfieldNet](#)

Disclosure/Transparency

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