Dear Colleagues:

At Pfizer, we are committed to upholding the highest standards when we interact with physicians, healthcare organizations, patients and other stakeholders. The Orange Guide (also known as the Field Guide) provides an overview of the laws, regulations, Pfizer policies and guidelines that govern our U.S. field colleagues in the biopharmaceutical business. A revised edition of the Orange Guide is now available on PfieldNet. It is essential that you familiarize yourself with the Orange Guide.

Every colleague is accountable for understanding and meeting our company’s compliance requirements. Do not hesitate to consult with your team attorney or the Orange Guide team at OrangeGuide@pfizer.com if you have any questions.

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

Rady A. Johnson  Douglas M. Lankler

integrity is...
HOW TO USE THE ORANGE GUIDE

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

For ease of navigation, the Orange Guide is embedded with “bookmarks” for each chapter topic and subheading. When you are reviewing the Orange Guide, make sure you keep the “Bookmark” pane on the left side of the page open and accessible as shown below:
To expand the bookmarks for a chapter, simply click on the + and you will see the topics covered listed and accessible by hyperlinks as shown below.

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

Sincerely,

The Orange Guide Team
Integrity is a core Pfizer value and a foundation of our business. Our commitment to integrity is demonstrated by our compliance with healthcare laws and the rules governing our interactions with customers and patients.
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# Chapter 1: OVERVIEW AND KEY PRINCIPLES

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Chapter 1: OVERVIEW AND KEY PRINCIPLES

Introduction

Integrity is a core Pfizer value and a foundation of our business. Our commitment to integrity is demonstrated by our compliance with laws and the rules governing our business. Compliance with these laws builds trust with patients, healthcare professionals (HCPs), institutions, purchasers, and the government, as well as supports our Imperative 3: Earn Greater Respect from Society.

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

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**Anti-Kickback Laws:** Prohibit improper influence on healthcare decisions by making it a crime to knowingly and willfully give or receive anything of value in order to influence or obtain government healthcare business.

**Best Price Law:** Prohibits charging Medicaid more than the lowest price (i.e., “best price”) at which Pfizer offers a product to any other customer. Pfizer must calculate and report to the federal government our “best price” for each product.

**False Claims Act:** Prohibits making or inducing someone else to make a false claim for reimbursement from the federal government.

This Chapter provides an overview of some of the key laws, regulations, guidance, and industry codes that apply to our business. The policies contained in this Guide are designed to help ensure that your activities comply with these laws, regulations, guidance, industry codes, and our State Attorneys General Agreements. Alternative approaches may be permissible in particular circumstances if approved by Legal.

Non-compliance with these policies can subject Pfizer colleagues to disciplinary action up to and including termination of employment. Further, improper activities that violate one or more of these laws and regulations could result in criminal and civil penalties for you and the Company.

If the application of any policy is unclear to you, discuss the issue with your manager or team attorney.

**Field Commercial Colleague Roles**

While integrity is required of, and the laws discussed in this Chapter apply to, all Pfizer colleagues, the Orange Guide is designed specifically for U.S. field commercial colleagues ("Field Commercial Colleagues"). Field Commercial Colleagues are Pfizer colleagues in the commercial organization whose primary responsibility is to interact with Pfizer customers. Field Commercial Colleagues include, but are not limited to, Pfizer Healthcare Representatives, District Business Managers (DBMs), Regional Managers (RMs), Regional Business Directors (RBDs), Key Account Managers (KAMs), Vaccines Account Managers (VAMs), Biosimilars Account Managers (BAMs), Vaccines Account Directors (VADs), Oncology Account Specialists (OASs), Hematology Account Specialists (HASs), National and Regional Account Directors (ADs), New Channel Directors (NCDs) and Regional Channel Directors (RCDs), and
other titles with comparable roles and responsibilities. Field Commercial Colleagues can further be broken down into Sales Colleagues and Account Managers.

**Sales Colleagues**

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

**Account Managers**

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

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

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<td><strong>Engagements</strong></td>
<td>Face-to-face product detail to educate HCPs about the benefits and risks Pfizer products may have for individual patients</td>
<td>Generally, C-Suite level interactions to discuss population health, Collaborations (see Orange Guide Chapter 5: Interactions with Health Systems and Medical Groups), Contracting (see Orange Guide Chapter 12: Discount and Rebate Contracting), and Quality Engagements (see Orange Guide Chapter 14: Organized Customer and Payer Tools and Resources)</td>
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In addition, the differences between the Sales Colleague and Account Manager roles require that they interact with internal Pfizer colleagues, and particularly with Field Medical Colleagues, differently. For

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purposes of this guide, “Field Medical Colleagues” include Field-Based Medical Directors (FMDs), Medical Outcome Specialists (MOSs), and Outcomes Research Scientists (ORS). Interactions between Field Commercial Colleagues and Field Medical Colleagues must be limited so as to preserve the independence of Field Medical Colleagues. Field Commercial Colleagues may not, nor should they appear to, direct the activities of Field Medical Colleagues. For this reason, internal interactions between Field Commercial Colleagues and Field Medical Colleagues and external interactions between such colleagues and Pfizer customers must be carefully considered to ensure the content and context of the medical activity is appropriate. Further distinctions in how Sales Colleagues and Account Managers may interact with Field Medical Colleagues are discussed throughout the Orange Guide.

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

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

Overview of Key Healthcare Laws and Regulations

Anti-Kickback Laws

An HCP’s treatment decisions should not be tainted by motives of personal gain or enrichment. The anti-kickback laws seek to eliminate improper influences on healthcare decisions by making it a criminal and/or civil offense to solicit, receive, pay, offer to pay, or provide anything of value knowingly and willfully in order to influence or obtain government healthcare business. These laws prohibit
payments intended to induce someone to purchase, prescribe, endorse, or recommend a product that is reimbursed under federal or state healthcare programs. For example, the anti-kickback laws prohibit such activities as:

- Providing a gift or payment to an HCP (including a pharmacist) intended to influence the prescribing, dispensing, or recommending of pharmaceutical products;
- Providing a gift to a retail or wholesale customer to influence the purchase of pharmaceutical products;
- Providing an educational or research grant to a managed care organization to influence the formulary position of a product; and
- Paying for the services (e.g., consulting services) of an HCP or other customer at a fee above the reasonable, “fair market value” for such services in exchange for prescribing or giving favorable treatment to a Pfizer drug.

**Fair Market Value:** Price at which an asset or service passes from a willing seller to a willing buyer based on market demand and supply. Pfizer is required to pay any person or entity in a position to purchase, prescribe, endorse, or recommend our products fair market value for the good or service Pfizer receives in return. For example, Pfizer is required to pay HCPs fair market value compensation for speaking and consulting services. Similarly, Pfizer must pay a Specialty Pharmacy fair market value compensation for any prescribing data Pfizer wishes to purchase from it.

Pfizer treats all HCPs and other customers as if they are subject to the anti-kickback laws, even though they may not participate in government healthcare programs.

**Safe Harbors from the Federal Anti-Kickback Statute**

The federal Anti-Kickback Statute is so broad that, if read literally, it could restrict many otherwise legitimate marketing activities and even some non-promotional activities. Recognizing this, the U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG) has defined certain “safe harbors.” Activities that fall entirely within a safe harbor, such as legitimate service arrangements, do not violate the Anti-Kickback Statute.
A number of safe harbors are relevant to our business activities, but three are especially important:

- **Discount safe harbor**: allows Pfizer to discount the price of a product to make it competitive with other products, provided that the discount is properly reported to the government and complies with other safe harbor requirements.
- **Managed Care safe harbor**: permits Pfizer to provide a wide array of discounted items or services to certain eligible managed care organizations under specified circumstances.
- **Personal Services safe harbor**: protects legitimate service arrangements recorded in a written agreement where the compensation is determined in advance and on a fair market value basis. This safe harbor is applicable in Pfizer’s dealings with healthcare professionals for consulting services and speaking agreements 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.

**Medicaid and Medicare**

Federal healthcare programs, such as Medicaid and Medicare, are large purchasers of prescription drug products. Under Medicaid, the government covers the cost of prescription medicines for low income and disabled patients. Since 2006, Medicare coverage has included outpatient prescription medicines purchased by eligible senior citizens through a pharmacy. The government’s increased role as a purchaser of pharmaceuticals has heightened its attention to certain federal laws, including the False Claims Act (further described below), to ensure that entities are not submitting false claims to the government for reimbursement.

**Medicaid Best Price Law**

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

A failure to account for discounts or other price concessions accurately could result in inaccurate price reporting to the federal government. This could occur if, for example, Pfizer mischaracterizes discounts provided to a managed care or retail customer, such as through a rebate disguised as an educational grant or by paying more than fair market value for a service that Pfizer purchases from a Specialty Pharmacy in order to reduce the net cost of the Pfizer products that organization purchases. If Pfizer reduces the net cost in this way without accurately reporting such discounts to the federal government, Medicaid could end up paying more for the Pfizer products than the managed care or retail customer, a violation of the Medicaid Best Price Law. Violating this law could result in a company having to pay significant penalties and being subjected to operating restrictions. For more information on issues pertaining to discounting and price reporting, see Orange Guide Chapter 12: Discount and Rebate Contracting and White Guide Chapter 6: Government Healthcare Programs.

**Medicare Part D Regulations**

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

MA-PDs and PDPs are private health plans that contract with the Centers for Medicare and Medicaid Services (CMS), the federal agency that administers Medicare and Medicaid. CMS regulates these health plans closely and has become increasingly vigilant in monitoring their interactions with manufacturers. In particular, CMS has expressed concern that Medicare health plans not be overcharged for prescription drugs and that all formulary placement and prescribing decisions be made based on appropriate considerations. As a result, MA-PDs and PDPs are required to report their costs to the government and, in so doing, must disclose any “direct or indirect remuneration” that they receive from pharmaceutical companies. Accordingly, Pfizer must be vigilant in monitoring the payments that it makes to MA-PDs and PDPs, as well as in its general relationship with these plans.
FDA Laws and Regulations

The Food and Drug Administration (FDA) regulates almost every aspect of our business, from research and development to sales and marketing. FDA regulation of product advertising and promotional labeling directly affects our customer relationships. Therefore, all colleagues must understand the basic rules we must follow to ensure compliance with FDA laws and regulations.

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

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 information on a drug’s package or label, prescribing information contained in the package insert, and any other written, printed, or graphic material “accompanying” the drug, including sales materials in the Veeva CRM system and other promotional materials.

Advertising

The FDA also strictly regulates the “advertising” of all prescription drug products that Pfizer markets in the United States.

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

Promotional labeling and advertising are often collectively referred to as promotion or promotional materials. Any promotional materials (whether in print or electronic form) used to promote our products – including all visual aids, brochures, journal advertising, promotional programs, and other sales aids – may include only claims about the product that are consistent with that product’s FDA-approved label. In addition, these materials must contain balanced statements about the product’s attributes.
benefits as well as risks. All promotional materials, unless they meet the requirements of exempted “reminders,” must also include the product’s **prescribing information (PI)**. For certain advertisements, a brief summary relating to side effects, contraindications, and effectiveness may be used in lieu of the full PI.


**Starters (Samples)**

The **Prescription Drug Marketing Act of 1987 (PDMA)** prohibits the sale, purchase, or trade of drug samples (called “starters” at Pfizer). It is illegal for any individual (including physicians) to sell or seek reimbursement for a free sample. Individuals who engage in or encourage such conduct are subject to criminal prosecution. Drug samples could be considered “remuneration” under the anti-kickback laws if given 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, as prescription decisions should be based solely on patient need.

In addition, several states have laws that affect whether and to whom starters may be distributed. For example, some states have particular limitations on distributing starters for controlled substances and some have requirements on when starters that were lost or stolen must be reported. Moreover, states have various approaches to which HCPs (e.g., nurse practitioners, physician assistants) may prescribe drugs and therefore are authorized to accept starters. For more information on how to develop a compliant starter strategy, see the Starters chapter in this Guide.

**Federal and State Pharmaceutical Disclosure and Compliance Laws**

Pharmaceutical manufacturers operating in the United States are required to submit reports to the government regarding payments and other transfers of value made to U.S.-licensed physicians and teaching hospitals under the transparency provisions of the federal Patient Protection and Affordable Health Care Act. These reports are made publicly available, and Pfizer is committed to complying with all applicable laws and regulations related to pharmaceutical sales and marketing.
Care Act (often referred to as “Open Payments” or “Sunshine Act”). In addition, a growing number of states regulate pharmaceutical companies’ interactions with HCPs. These state laws and regulations include disclosure of payments made to HCPs, restrictions or prohibitions on gifts and meals, and reporting of data such as Average Manufacturing Price and Best Price. Some of these restrictions may even extend to interactions that occur outside of the geographic boundaries of the state that enacted the law or regulation.

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

**Overview of Other Key Laws and Regulations**

**False Claims Act**

The False Claims Act (FCA) prohibits entities and individuals from submitting, or inducing another to submit a false claim for reimbursement from the federal government. The federal government has used the FCA to investigate and prosecute pharmaceutical companies for falsely reporting best price, paying kickbacks to healthcare providers, and encouraging physicians to seek reimbursement from the government for free samples of prescription drug products.

The government has also used the FCA to combat instances of off-label promotion. Under the government’s reasoning, when a pharmaceutical company engages in off-label marketing, the company puts into motion a series of events in which a prescription will be reimbursed by a government program even though it was not eligible for reimbursement (e.g., physician writes a prescription for an off-label use, pharmacist fills the prescription, pharmacist then seeks reimbursement for the off-label prescription). In so doing, it has been argued by the government that the pharmaceutical company has “induced” another party to submit a false claim, resulting in an alleged violation by the pharmaceutical company. Sales Colleagues must ensure that all HCP interactions comply with Orange Guide Chapter 2: Detailing to HCPs, and all other colleagues must ensure that marketing materials and other commercial activities comply with White Guide Chapter 2: Advertising and Promotional Labeling and White Guide Chapter 3: Promotional Interactions with Healthcare Professionals, and any other relevant policies and guidance.
Privacy Laws

Pfizer and firms engaged by us to perform various services (e.g., advertising and promotion agencies) might collect and process various types of personal information (e.g., healthcare data), and colleagues may encounter sensitive personal information in the course of their visits to meet with HCPs. Colleagues are responsible for ensuring that the data is handled carefully and in compliance with Pfizer’s policies and applicable federal and state privacy laws and regulations.

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

State Consumer Protection Laws

Many states have laws that seek to protect consumers from inappropriate marketing and sales practices. For example, virtually all states have broad laws prohibiting “unfair” or “deceptive” trade practices. Some state Attorneys General further contend that state consumer protection laws encompass off-label promotion. You should direct any questions regarding state consumer protection laws and their impact on your activities to your team attorney.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act (FCPA) is a federal law that prohibits corrupt or improper payments to government officials outside the United States. The FCPA consists of two primary sections: (1) the anti-bribery provision; and (2) the record keeping provision. Violations of the FCPA may subject Pfizer and its individual employees to criminal and civil penalties.

The anti-bribery section of the FCPA prohibits U.S.-based companies from offering, paying, promising to pay, or authorizing payment of anything of value to a foreign official with the intent of influencing the official or gaining improper advantage. The statute broadly includes “anything of value,” which includes cash payments, gifts, meals, and any other item that may have value to the recipient. Further, the definition of “foreign official” includes any officer or employee of a non-U.S. government (any department, agency, or instrumentality) or public international organization. HCPs at foreign government-owned hospitals, for example, may qualify as foreign officials under the FCPA.
Under the record keeping requirements of the FCPA, Pfizer and its employees must “keep books, records and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets and maintain a system of internal accounting controls...”

Pfizer colleagues who are permitted to engage a non-U.S. HCP as a consultant (or enter into any other interaction in which a payment or other benefit may be given to the individual), must follow My Anti-Corruption Policy and Procedures (MAPP). For more information, see White Guide Chapter 5: HCP and Government Official Consulting Engagements and MAPP.

**Industry Codes, Guidance, and Our Government Agreements**

**PhRMA Code**

The **Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals (PhRMA Code)** was developed and adopted by many of the country's leading research-based pharmaceutical and biotechnology companies. It applies to relationships with physicians and other HCPs. Pfizer is committed to following its principles.

The PhRMA Code is intended to protect patients from undue influences on healthcare decision-making and reaffirms that interactions between company representatives and HCPs should be focused on informing HCPs about the benefits and risks of medicines to help enhance patient care. The PhRMA Code principles are embedded in the policies throughout this Guide.

The PhRMA Code, as well as “Frequently Asked Questions,” can be viewed under the Compliance tab on PfieldNet at [http://pfieldnet.pfizer.com/Compliance/Pages/Home.aspx](http://pfieldnet.pfizer.com/Compliance/Pages/Home.aspx) and on OpSource at [http://opsource.pfizer.com/Pages/PhRMAHCPHome.aspx](http://opsource.pfizer.com/Pages/PhRMAHCPHome.aspx).

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

In 2009, PhRMA adopted its updated **PhRMA Guiding Principles – Direct to Consumer Advertisements About Prescription Medicines**. These Principles guide the industry's use of DTC advertising to communicate information about disease states and potential treatments so that patients can make informed choices. PhRMA’s Guiding DTC Principles help enable DTC communications that serve to educate patients and consumers and encourage them to seek guidance from their healthcare professionals. Pfizer has adopted its own **Guidance for the Implementation of the Updated PhRMA**
DTC Principles, which must be followed when developing DTC advertising. When developing DTC advertising, Marketing colleagues must also adhere to the policies set forth in White Guide Chapter 2: Advertising and Promotional Labeling.

OIG Compliance Program Guidance for Pharmaceutical Manufacturers

In 2003, the OIG issued its Compliance Program Guidance for Pharmaceutical Manufacturers, which sets forth its general views on the value and fundamental principles of compliance programs for pharmaceutical companies and the specific elements that pharmaceutical companies should consider when developing and implementing effective compliance programs. The Guidance states that the following seven elements are recognized as fundamental to an effective compliance program:

1. implementing written policies and procedures;
2. designating a compliance officer and compliance committee;
3. conducting effective training and education;
4. developing effective lines of communication;
5. conducting internal monitoring and auditing;
6. enforcing standards through well-publicized disciplinary guidelines; and
7. responding promptly to detected problems and undertaking corrective action.

All seven elements are embedded in Pfizer’s compliance program.

Pfizer’s Government Agreements and Post-CIA Compliance

A Corporate Integrity Agreement (CIA) is a written agreement with the OIG that typically imposes upon a company certain integrity obligations (e.g., training, reporting, or audits) for a specified period of time, typically five years from the date the CIA is executed.

A State Attorney General Agreement is a written agreement with one or more state Attorneys General that imposes certain integrity obligations, which can be for a specified period of time or indefinite.

Pfizer’s Corporate Integrity Agreements

Pfizer has previously entered into CIAs as part of three settlements with the U.S. government for alleged violations of federal healthcare program requirements.

- **Lipitor CIA (2002):** In 2002, Pfizer paid a $49 million fine and entered into a CIA for a term of five years. The case involved a qui tam lawsuit (a whistleblower suit filed by a private individual on behalf of the government) filed by a Warner-Lambert employee alleging that Pfizer
provided $250,000 in undisclosed cash discounts (concealed as “unrestricted educational grants”) to a managed care customer to get Lipitor on the plan’s formulary. The government alleged that Pfizer underpaid Medicaid rebates as a result of failing to properly calculate the “best price” for Lipitor.

- **Neurontin CIA (2004):** In 2004, Pfizer paid a $429 million fine and entered into its second five-year CIA. The case was also based upon a whistleblower suit filed by a former Warner-Lambert employee alleging that Pfizer had engaged in off-label marketing to promote Neurontin.

- **Bextra CIA (2009):** In 2009, Pfizer entered into a five-year CIA as part of a settlement for alleged violations of federal health care program requirements. As part of the settlement, Pfizer paid $2.3 billion in fines. The case originated with eleven separate whistleblower lawsuits that included allegations that Pfizer promoted Bextra for uses and in dosages that the FDA did not approve. The CIA also settled alleged off-label promotional activities concerning several other Pfizer products.

The Bextra CIA expired on December 31, 2014. While the Company no longer is obligated under the Bextra CIA to maintain certain specific requirements or reporting obligations, many of those requirements still remain as part of our compliance program and all colleagues must continue to conduct their activities in accordance with applicable policies and procedures, including those set forth in this Guide.

**Pfizer’s State Attorneys General Agreements**

Pfizer has entered into written agreements directly with several state Attorneys General, which impose certain integrity obligations upon Pfizer. Because these agreements are entered into with individual states, 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, many of the obligations do not expire. As applicable, obligations impacting Pfizer colleague activities are implemented through policies and procedures governing the relevant activities.

For additional information regarding Pfizer’s State Attorneys General settlement agreements, please visit the [State AG Agreements](#) page on the Corporate Compliance Division website.
Violations and Penalties

The OIG, the U.S. Department of Justice, the FDA, and state Attorneys General aggressively enforce the anti-kickback and other laws and regulations discussed in this Overview. In addition to violating our obligations under our government agreements, any violation of law is subject to prosecution and potentially punishable by a fine and/or imprisonment, as well as civil monetary penalties. Conviction under these laws can also result in Pfizer’s exclusion from participation in federal and state healthcare programs, as well as imprisonment of officers and/or employees responsible for each violation.

Failure to adhere to FDA advertising and promotion regulations, in particular, can result in the need to run corrective advertising or to “pre-clear” future promotional materials. Violations of the PDMA, which can include failing to follow starter management requirements, may result in criminal sanctions, including imprisonment.

Pfizer’s Compliance Program

Pfizer takes compliance with these laws and regulations very seriously and expects every colleague to do the same. Pfizer’s commitment to integrity is a fundamental value, and your personal commitment to owning compliance is critical to Pfizer’s success. Acting with integrity requires that colleagues promptly disclose potential violations and cooperate with investigations of possible violations. Each colleague has a Duty to Act by reporting suspected compliance violations to Pfizer Human Resources, Legal, or Compliance via the Compliance Helpline (1-866-866-7349 or online at https://pfizer.alertline.com), via e-mail at corporate.compliance@pfizer.com, or by phone (1-212-733-3026).

If you are involved in a compliance investigation in any capacity (for example, as a witness or complaining party), you are expected to keep the details of the investigation confidential. Maintaining confidentiality helps to preserve the integrity of the process and protects the individuals participating in the investigation. Unless prohibited by local law, any exceptions to confidentiality must first be discussed with the Compliance Division.
Duty to Act: If you reasonably believe that an employee has violated the law or Pfizer policy, you have a duty to report that information immediately to your supervisor, Human Resources, Legal, or the Compliance Division. Pfizer has open door, anti-retaliation, and confidentiality policies to encourage and protect all Pfizer colleagues who raise valid concerns.

FOR MORE INFORMATION

- Colleagues must be familiar with and abide by all of the policies and guidance in this Guide.
- Questions may be referred to your manager or team attorney.
Chapter 2: INTERACTIONS WITH HCPs

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Chapter 2: INTERACTIONS WITH HCPS

Introduction

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

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

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

Non-compliance with these policies can subject Pfizer colleagues to disciplinary actions up to and including termination of employment. Further, improper activities that violate one or more of these laws and regulations could result in criminal and civil penalties for you and the Company.

If any policy is unclear to you, discuss the issue with your manager or your team attorney.
Key Points to Ensure Compliance

- All items provided or shown to HCPs must be RC-approved. Do not use materials that you have created or altered in any way, or materials meant for internal use only.

- All statements regarding a Pfizer product must be on-label (consistent with the product’s package insert), truthful, and not misleading. Only use promotional statements that are consistent with RC-approved materials and guidance (including any Implementation Guides).

- When discussing a product, always give a fair and balanced presentation of the benefits and risks.

- Field Commercial Colleagues and Sales Colleagues are required to record all promotional interactions with their customers in Veeva CRM and synchronize Veeva CRM daily.

- All inquiries about off-label information, unapproved uses or unapproved clinical data must be unsolicited and referred to Pfizer Medical Information using Veeva CRM or another approved process.

- Unless the brand team, Legal, or Compliance provide guidance otherwise, Sales Colleagues on Veeva CRM are expected to use materials on their approved device (i.e., tablet or iPad) whenever possible when engaging in detailing. Furthermore, under no circumstances are non-RC approved applications, e.g., MMIT (formulary coverage app), to be used in detailing.

- Sales Colleagues may only discuss approved products and indications. They may not discuss new products or indications until they have received RC-approved materials and messaging for promotion.

- Disease state and other unbranded discussions should not imply an off-label use for a Pfizer product and should be executed in accordance with RC guidance on the use of the materials.

- Sales Colleagues may not detail, provide co-pay cards, vouchers, educational materials, meals, or starters, invite to a speaker program, or otherwise promote a product to, any HCP who is considered to practice in an excluded specialty for the specified product. Excluded specialties by product are available for reference on PfieldNet or may be verified in the HCP Lookup Tool. Similarly, Sales Colleagues should not engage in these activities with any HCP whom they believe is unlikely to prescribe the product on-label.
Key Points to Ensure Compliance

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

Core Compliance Principles

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

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

Use Only RC-Approved Materials and Selling Statements

Using RC-Approved Materials in Details

Pfizer may be held responsible for anything that you say or show to customers. The guidance below must be followed when presenting information to customers and/or engaging in detailing: Show only materials that have been approved by the relevant Review Committee (RC) for promoting to HCPs. Colleagues are prohibited from altering these materials in any way.
• In general, if a promotional item or material is not available for ordering through Pfizer’s online ordering system (PROMOS or CRC, depending on the role), or not available on Veeva CRM, it is not approved for use with customers. Certain other RC-approved content may be approved for use with customers (e.g., certain content may be approved for use outside of Veeva CRM).

• Unless the brand team, Legal, or Compliance provide guidance otherwise, Veeva CRM should be used as the primary resource for sharing promotional materials when detailing customers. When using materials in Veeva CRM, you are using materials that are up to date, compliant, and RC-approved. Furthermore, under no circumstances are non-RC approved applications, e.g., MMIT (formulary coverage app), to be used in detailing.

• “Do Not Detail” pieces or materials marked “For Internal Use Only”, must not be shown to or discussed with customers or any other third parties.

• In limited circumstances, Account Managers may be permitted to use materials that have not been subject to RC review. Account Managers must always check with their team attorney before using such materials.
# Key Points: Permitted vs. Prohibited Activities

<table>
<thead>
<tr>
<th>Permitted</th>
<th>Prohibited</th>
</tr>
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<tbody>
<tr>
<td>Using promotional materials that have been approved by the relevant RC.</td>
<td>Showing a chart put together based on two RC-approved pieces.</td>
</tr>
<tr>
<td></td>
<td>Using any RC unapproved item as a visual aid to illustrate a point or concept (e.g., pill bottles, money, food, candy, water bottles, and software applications).</td>
</tr>
<tr>
<td>Marking a training copy of your clinical reprint (that you don’t show to HCPs) to help you learn key points.</td>
<td>Showing a HCP any promotional material that has been marked or altered in any way (e.g., highlighting, sticky notes, handwritten notes, check marks, arrows, etc.).</td>
</tr>
<tr>
<td>Leaving a handwritten thank you note that includes the name of the product but does not make any direct or indirect product claim.</td>
<td>Leaving a thank you note that contains more than the name of a product, including any direct or indirect product claim (e.g., mentioning indications or disease state information).</td>
</tr>
<tr>
<td>Using or disseminating Pfizer training materials and other “Do Not Detail” pieces internally for educational purposes only, ensuring that the materials and the e-mail transmitting those materials are clearly marked as “Do Not Detail.”</td>
<td>Showing Pfizer training materials, information from web-based or mobile applications not RC-approved for detailing, or other “Do Not Detail” pieces to customers.</td>
</tr>
<tr>
<td>Sending a very brief e-mail/text to a customer (using your Pfizer device) asking if you can schedule an appointment to discuss a specific product (e.g., “Dr., I’d like to set up an appointment to discuss Lyrica with you.”).</td>
<td>Sending an e-mail/text to a customer asking if you can schedule an appointment to discuss a product and including anything at all in the subject, body, or signature line of an e-mail/text that makes or implies a product claim, including mentioning indications or therapeutic areas (e.g., “Dr., I’d like to set up an appointment to discuss Lyrica and fibromyalgia with you.”).</td>
</tr>
</tbody>
</table>
Modifying a Pfizer Approved Patient Survey

Q. A medical practice that I am working with wants to modify one of Pfizer’s RC-approved patient surveys to better meet their needs. The change does not alter the substance of the survey. Can I make the change and return it to the practice?

A. No. If you make any alteration to RC-approved material, it results an impermissible homemade promotional piece.

Communicating Formulary Status

Q. 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?

A. In some circumstances, it might be appropriate to discuss the formulary status of Pfizer and competitor products with HCPs provided that all statements are accurate, non-misleading, and are RC-approved. For example, 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.

Q. What materials are available to me to help discuss formulary status?

A. The Payer and Channel Access (PCA) group provides RC-approved access grids (generated in the Fingertip Formulary System) that depict the formulary status of certain Pfizer products. Contact the relevant PCA Account Manager if information is not available in the Fingertip Formulary System or if you need to request a copy of up-to-date formulary access grids. Non-RC approved formulary applications, e.g., MMIT, are not permitted for use in detailing.

Mailing RC-Approved Pieces to HCPs

Q. Am I permitted to mail an RC-approved promotional piece to an HCP?

A. No, unless there is explicit guidance and RC permission to do so.
Discussing Prior Authorizations

Q. Can I engage in discussions with HCPs about Prior Authorizations?
A. You should follow any applicable RC-approved guidance when engaging in a discussion about specific Prior Authorization ("PA") criteria or forms. In order for you to give or show a specific PA form, it must be RC-approved or you must first obtain written approval from an appropriate PCA representative. If a PA form has been approved for distribution, you may discuss the relevant factual prior authorization criteria with an HCP. If the approved PA form contains a Pfizer product name, the applicable package insert must be left behind with it.

You should never assist HCPs or staff in filling out a prior authorization form, and you may not coach anyone on fulfilling or evading a prior authorization form’s requirements in order to obtain approval for either a specific patient or a type of patient.

Selling Statements

It is critical that you only make selling statements (including openers, closers, and probing questions) that are consistent with RC-approved materials and follow all guidance and direction contained in any relevant product Implementation Guide(s) or other RC-approved guidance. These materials are prepared in accordance with FDA-approved product labeling and are designed to ensure appropriate execution.

Sometimes colleagues share suggested selling statements internally, often by e-mail or before or after internal meetings. Although sharing recommended selling statements can sometimes help improve selling skills, it is critical that these statements be consistent with RC-approved selling messages and any documents (including e-mails) sharing such statements be marked as “DO NOT DETAIL.”

Suggesting inappropriate selling statements or statements that are not consistent with claims contained in RC-approved materials can carry significant risks for Pfizer. Thus, if you determine that it might be beneficial to discuss a proposed selling statement, either by preparing a document or sending an e-mail about it, you must carefully review the statement to make sure it is consistent with RC-approved materials, including any relevant Implementation Guide(s). If you make a change to an approved selling statement (even if minimal), you must obtain your manager’s approval prior to disseminating any document containing the selling statement (including, for example, e-mails, PowerPoint presentations, and summaries of district meetings or workshops).
Each colleague is responsible for appropriate promotion in a manner consistent with RC-approved materials and messaging as well as FDA-approved labeling. Using inappropriate selling statements, whether intentional or not, can have far-reaching consequences for Pfizer, and may result in disciplinary action.

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

- Do not make selling statements (including openers, closers and probing questions) that are inconsistent with RC-approved materials and messaging, including any relevant Implementation Guides.

- Before you make any change to an approved selling statement, even if minimal, you must carefully review the statement to ensure it is consistent with RC-approved materials (including relevant Implementation Guides) and consult with your manager to ensure it is compliant.

- Making changes to approved selling statements is discouraged and should be the exception – not the rule.

- Do not disseminate suggested selling statements that differ from RC-approved selling statements, internally or externally, without obtaining your manager’s approval.

- Do not make or imply comparative claims of any kind, especially superiority claims, unless the claim is specifically made in RC-approved promotional materials.
E-mailing/Texting HCPs

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

A. Generally, yes, but only in the limited circumstances set forth here. You may use e-mail/texting to communicate logistical and non-substantive information (e.g., time, date, place of appointment). You may not use e-mail or texts to discuss substantive business matters unless RC-approved, e.g., by sending a rep-triggered e-mail (RTE) or, for Account Managers, sending a message through CRC.

You may use a product name in these e-mails/texts only if necessary to give the recipient context for why you would like to meet. However, you may not make any claims about a product in the subject, body, or signature line of any e-mail/text—this includes mentioning indications or therapeutic areas. E-mails/texts that do not follow this strict rule are considered “homemade” and are prohibited.

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

It is a best practice to start a new e-mail thread when e-mailing a customer. Using an old e-mail thread requires additional review to ensure prior communications are void of any information that might be seen as a “homemade” claim.

Q. What should I do if I receive an inappropriate text or e-mail from a customer?

A. It depends. Receipt of inappropriate communications may require action on your part to ensure the communication is not improperly attributed to you or Pfizer. Consult your team attorney if you are unsure if a response is necessary or if you need assistance in developing an appropriate response.
E-mailing/Texting HCPs (continued)

Q. Am I permitted to use a non-Pfizer e-mail account, or a non-Pfizer device with texting capabilities or other social networking tool (e.g., Google®, Yahoo® or Facebook®), to interact with HCPs or other customers regarding Pfizer business? Am I permitted to communicate with Pfizer colleagues about Pfizer business using one of these platforms?

A. No. You may only use your Pfizer e-mail account or a Pfizer-issued device to communicate with customers or colleagues regarding Pfizer business. Furthermore, you may not use any unapproved cloud-sharing/storage applications, e.g., Google Docs, SharePoint, Dropbox, Evernote, etc. to communicate or share, with either customers or internally with colleagues, business information or to store any business data. See Corporate Policy 403 – Acceptable Use of Information Systems for additional information.

Texting Internally

Q. Is it appropriate to have internal discussions about selling statements or other substantive business topics over text message?

A. No. You should not use text messages to communicate with customers about selling statements or other substantive business topics. Communications with Pfizer colleagues via text message should also be limited to logistical information. E-mail should be used when discussing any substantive topics. As noted below, any information about detailing interactions must be entered as a Call Note in Veeva CRM before it can be shared internally via e-mail.

Stay On-Label and Discuss Only Approved Products and Indications

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

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

If an HCP asks an unsolicited question about an unapproved product or unapproved indication, you must refer the question to Pfizer's U.S. Medical Information Department (USMI). Colleagues using Veeva CRM must submit any such questions using their tablet or other approved device. You may also provide HCPs with a copy of the approved Medical Resources brochure, which is intended to inform them about various Pfizer Medical Resources and how to access them. This brochure includes contact information to enable the HCP to contact USMI or an FMD directly. You may not otherwise facilitate any USMI/FMD request or referral.

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

**Do Not Engage in Promotional Interactions with HCPs in Excluded Specialties**

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

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

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

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<tr>
<th>On-Label Claims (Appropriate)</th>
<th>Off-Label Claims (Inappropriate)</th>
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<tbody>
<tr>
<td>Statements about a product's efficacy for the approved indication.</td>
<td>Statements about a product's efficacy for an unapproved use.</td>
</tr>
<tr>
<td>e.g.: Lyrica can help your patients with insomnia to sleep better.</td>
<td></td>
</tr>
<tr>
<td>Statements about a product's efficacy within a population of patients specifically identified in the package insert.</td>
<td>Statements about a product's efficacy within a population of patients who are not included in the product labeling.</td>
</tr>
<tr>
<td>e.g.: Pristiq can be used in pediatric patients.</td>
<td></td>
</tr>
<tr>
<td>Statements about the safety of a product that are consistent with the information in the package insert.</td>
<td>Statements about the safety of a product that are overly broad or minimize risk.</td>
</tr>
<tr>
<td>e.g.: Toviaz is well tolerated and patients do not really experience side effects.</td>
<td></td>
</tr>
<tr>
<td>Statements that accurately reflect an approved indication.</td>
<td>Statements that inappropriately broaden an indication.</td>
</tr>
<tr>
<td>e.g.: Lyrica is effective therapy across the full spectrum of painful neuropathic conditions.</td>
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</table>

### Comparative Claims

You can only make comparative claims when there are RC-approved promotional materials (including Veeva CRM slides and any applicable product Implementation Guides) that expressly make such claims. The FDA considers promotional materials or claims to be false and misleading if they state or imply that a drug's safety or efficacy is comparable or superior to that of another drug's without “substantial evidence” to support such statements or implications. It is not appropriate to make comparative claims based on the data in products' respective package inserts. Similarly, because of the differences in clinical trial designs, inclusion criteria, and other factors, it is not permissible to...
compare results from two separate trials. In addition, it is not appropriate to detail two or more Pfizer products in a manner that falsely or misleadingly conflates the properties of the respective products. It is also not appropriate for field commercial colleagues to make or allude to inappropriate comparative claims in internal communications, because it may create the perception that these statements are being used with customers.

**Comparative Claim:** Comparing any attribute of a product to an attribute of another product. The FDA requires “substantial evidence” to make these claims, which generally means two adequate, well-controlled studies comparing the two drugs head-to-head using comparable dosage regimens or a single, large, well-controlled study.

**Superlative Claims**

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

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

**Comparing Product Package Inserts**

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

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

**Provide an Accurate and Balanced Presentation**

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

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

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

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

**Fair Balance and Accurate and Not Misleading Claims**

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

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

**Never Engage in Actual or Perceived Quid Pro Quo**

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

You should never tie giving something of value—even something of nominal value—to induce, directly or indirectly, an HCP’s prescribing or recommendation of a product.
KAM Resources and Inappropriate Quid Pro Quo

Q. I am a KAM, and a Quality Director at one of my customers is looking for ways to improve metrics around patients who smoke. He told me that if Pfizer can help drive up quit rates and reduce readmissions among patients who identify as smokers, then he would encourage the P&T Committee to position Chantix more favorably on their formulary.

A. This offer is an inappropriate quid pro quo. Pfizer should not offer its quality programs or any other resource or item of value as an inducement (or reward) for formulary placement or increased prescribing.

Interacting with C-Suite Administrators

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

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

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

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

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

**Interacting with Employer Representatives**

Pfizer also calls on employers that make decisions regarding the access their employees have to medicine. To best leverage existing relationships and avoid providing inconsistent messages, consult a PCA representative and the Director of National Employer Accounts (“DE”) in your region to ensure proper coordination of activities with employers. DEs are Pfizer PCA Colleagues who are dedicated to working with employers. The DEs understand the regional employer market, develop clear plans, and coordinate implementation of those plans with the regional colleagues. In many cases, the DE may already have established relationships with employers in your area or have clear guidance on areas to avoid.

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

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

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

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

- Only PCA Colleagues (and certain other authorized colleagues who have received appropriate training) are permitted to engage in discussions regarding health screenings. In addition, depending on the resource, only PCA Colleagues and Account Managers may engage in discussions regarding quality programs.

- Certain interactions with unions are subject to federal reporting obligations and possibly other limitations. Check with your team attorney before interacting with any union.
Hospital Protocols

Q. May I detail an HCP who is involved in the development of a hospital clinical protocol or who is in a position to influence which products are included in a hospital clinical protocol?
A. Yes. You may detail any such HCP if your detailing is otherwise done in accordance with all applicable Orange Guide principles, including the four Core Compliance Principles discussed in this Chapter.

Q. May I detail an HCP in order to ask the HCP to consider inclusion of a Pfizer product in a hospital’s clinical protocol?
A. Yes. Pfizer colleagues may encourage an HCP to consider including a Pfizer product in a hospital protocol or standing order provided that such use would be consistent with labeling and promotion is strictly limited to approved, on-label messaging of the Pfizer product, and all Orange Guide principles are followed.

Q. May I participate in the development of a hospital clinical protocol?
A. No. Pfizer colleagues are not permitted to assist hospitals with drafting or otherwise developing hospital clinical protocols or treatment standing orders. In certain circumstances, if available, Pfizer colleagues may utilize RC-approved materials to engage with HCP about the importance of developing a protocol in a certain disease area.

Q. May I use a hospital protocol in detailing sessions?
A. Only if the Review Committee has approved the use of such hospital protocol. You may not distribute a protocol and it may not be used or discussed outside of the originating institution.

Other Things You Need to Know

Educational Items to HCPs

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

### Out-of-Pocket Gifts for HCPs

<table>
<thead>
<tr>
<th>Q.</th>
<th>Can I pay for a gift for an HCP out of my own pocket if I do not expense it?</th>
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<tr>
<td>A.</td>
<td>It is not appropriate to purchase personal gifts of any kind for HCPs in the course of doing business, even if you pay out of pocket and do not seek reimbursement from Pfizer. The gesture can too easily appear to be an attempt to illegally influence prescribing in violation of the Anti-Kickback Statutes. 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.</td>
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### Interactions with Field Medical Colleagues

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

Field Medical Directors (FMDs) are field-based medical colleagues who are part of the Business Unit medical team. These colleagues have therapeutic area expertise and primarily serve the medical needs of individual HCPs, including investigators and other experts, within an assigned geography. Their communications with these HCPs include engaging in Pfizer-initiated medical communications using Medical Review Committee (MRC) – approved materials, responding to unsolicited medical requests they receive or that are escalated to them by the Medical Information department, and discussing service-based activities such as Pfizer sponsored/collaborative research, IIRs, and/or consultancies. In addition, FMDs may give payer value proposition/formulary presentations in coordination with Medical Outcomes Specialist (MOS) or Outcomes Research Scientist (ORS) Colleagues. The FMD role is governed by the “Green Guide.”
Principles Governing FMD and Field Commercial Colleague Interactions

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

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

Internal Interactions between FMDs and Field Commercial Colleagues

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

Medical Objectives and Customer Insights

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

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

The FMDs are permitted to share the names of HCPs on their contact list with Field Commercial Colleagues. However, FMDs and Field Commercial Colleagues must call on HCPs separately independently unless otherwise permitted to hold a joint meeting, as described in this Chapter. Field Commercial Colleagues may offer suggestions to FMDs about adding HCPs to their contact list; however, the FMDs will apply pre-determined medical criteria and make an independent determination regarding whether any HCPs are appropriate to add to the list.

**FMD Attendance at Field Commercial Meetings**

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

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

- Conduct product or disease training, using RC-approved materials;

- Provide general information about medical objectives or an overview of Medical Review Committee (MRC) approved topic(s) or materials:
  - FMDs are not permitted to discuss the details of MRC-approved content or share actual MRC-approved materials with Field Commercial Colleagues. Field Commercial Colleagues must not ask for this information or seek to influence the way in which medical content is developed or delivered to HCPs or other customers.

- Share aggregated customer insights, information about geography or regional level dynamics, or to seek feedback. For example, information can be shared about gaps in HCP understanding about a disease or treatment. Customer information discussed must be in aggregate and not specific to any particular HCP or other customer’s prescribing/utilization of Pfizer products or medical inquiries.
  - Field Commercial Colleagues are not permitted to ask FMDs to share any type of off-
label information about a Pfizer product or information about unapproved Pfizer products.

- Field Commercial Colleagues are not permitted to share customer-specific prescribing habits and to seek assistance from FMDs with overcoming barriers to customer prescribing/utilization of Pfizer products.

- Field Commercial Colleagues are not permitted to request information from FMDs about the substance of responses provided to customers who have made unsolicited medical requests for information.

- FMD may seek to understand the business goals and objectives for an organized customer account so that they can develop fully-informed medical strategies, but they must not take directions from account management colleagues regarding medical activities.

**Organized Customer Planning and Coordination**

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

**Unsolicited Medical Requests (UMRs)**

Field Commercial Colleagues must refer all UMRs to Pfizer’s Medical Information department, as described in this Chapter, and must not contact FMDs to respond to UMRs. Field Commercial colleagues are permitted to provide, an approved Medical Resources brochure to HCPs, which is intended to inform them about Pfizer Medical Resources and how to access them. This brochure includes contact information for the Medical Information department as well as particular FMDs. FMDs may e-mail a PDF of their individualized brochure to the relevant field sales manager or field commercial colleague.
If an HCP informs a Field Commercial Colleague that (s)he has not received a response to a previously submitted UMR or is not satisfied with a response received by Pfizer’s Medical Information department, the colleague may provide the appropriate FMD’s contact information to the HCP so that the HCP can contact the FMD directly.

**HCP Requests to Discuss Research**

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

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

Field Commercial Colleagues are permitted to contact an FMD if approved contracted promotional speaker asks to meet with a Pfizer Medical Colleague to discuss RC-approved speaker program content or a question related to the content. If the speaker has a UMR related to a product more generally (not specifically related to his/her role as a promotional speaker), the Field Commercial Colleague must refer the question to Pfizer’s Medical Information department, as described in this Chapter.

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

**Planning for Joint External Meetings**

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

External Interactions between FMDs, Field Commercial Colleagues, and HCPs

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

Insight Meals

Insight Meals are out-of-office meals with unpaid HCP attendees that meet the following requirements;

1. Are hosted by Field Commercial Colleagues authorized to host out-of-office meals, and

2. Are either co-hosted by or planned with the input of Headquarters Marketing colleagues and/or Medical (HQ or field-based) colleagues, or

3. Hosted by HQ Marketing where Field Commercial Colleagues and/or Medical (HQ or field-based) are included. Attendance by Medical (HQ or field-based) colleagues may be appropriate only if a demonstrated business rationale can be shown. This includes, for example, meals arranged to gather input from the attendees regarding products, disease states or local market conditions and share that input with brand teams.

   This does not apply to meals hosted by Senior Field Commercial Colleagues without attendance of or planning by Headquarters Marketing or Medical colleagues.

   - For each Insight Meal held, the host must have an agenda, list of topics and questions, or other presentation to facilitate the legitimate business discussion with the attendees. The materials should be reviewed, prior to the Insight Meal, by the team attorney as well as the GPC and brand medical (as needed).
   - The materials and questions to be utilized to facilitate the discussion must be on-label, consistent with overall brand strategy, and approved by the team attorney as well as the GPC and brand medical (as needed).

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• Prior to hosting an Insight Meal, the Pfizer host should consult the team attorney to ensure the materials are reviewed as indicated on the prior slide and:
  o There is a legitimate business purpose to host the meeting, e.g. information to be gathered is needed and not duplicative of information already available.
  o An Insight Meal is an appropriate way to obtain the information.

• To the extent that multiple Pfizer colleagues (e.g. RMs from different geographies or colleagues from both Marketing and Sales) wish to discuss the same topic or use the same materials with different HCPs, the colleagues must all coordinate with the team attorney to ensure that the overall number of events and HCP attendees is appropriate to achieve the business need.

• The host must discuss with the team attorney and appropriate GPC, as necessary:
  o previous Insights Meals on related topics;
  o previous attendance at Insight Meals by the invited HCPs;
  o proposed questions and content;
  o appropriate number of events to host;
  o the number of HCPs to attend each event;
  o the proposed Pfizer attendees to ensure that the events are limited to those necessary to achieve the informational need and the discussion is appropriate for all Pfizer colleagues who may attend; and
  o Any other relevant consideration given the circumstances/need.

Consider the meeting purpose and materials when determining Pfizer and HCP attendees

• Ratio of Pfizer colleagues to HCP attendees must be appropriate and conducive to the business discussion.
• Materials shared must be by reviewed and approved by the team attorney (as well as the GPC and brand medical, if needed) and discussion topics must be appropriate for all proposed Pfizer attendees.

• Sales Representatives and District Managers may participate if there is a legitimate business need and the discussion topics are appropriate for their participation. However, sales colleagues must not engage in detailing during an Insight Meal.

• Medical colleagues (HQ or field-based) may attend if there is a legitimate business need and if their participation is appropriate given the objectives of the Insight Meal and topics to be discussed. Medical participation is subject to review and approval by the team attorney as well as the GPC (if needed).
  
  o Any attendance by medical colleagues should be consistent with guidance on joint commercial-medical activities in the Orange Guide and Green Guide.

• Hosts must capture and track HCP attendees to ensure the HCPs do not attend more than one Insight Meal on the same topic (i.e. with the same questions, discussion points, etc.) within a reasonable timeframe (to be evaluated by the team attorney during the review process).

• Identify these meals as “Insight Meal” within PTE to facilitate manager tracking of the attendees.

• Following the Customer Insight Meal, the Pfizer Sales colleague must share the information gathered with the Brand Team or other Pfizer teams, as appropriate, to determine how the information will be utilized to further Pfizer’s business.

• Potential hosts should use these deliverables and insights to assess need for future Insights Meals for the same geography, disease state or product.

Introductory Meetings

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

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

**Organized Customer Meetings and Formulary Committee Presentations**

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

Pfizer-initiated Formulary Committee presentations are primarily conducted by Field Medical Outcomes Colleagues. However, when specific product and/or therapeutic area expertise is needed, the Medical Outcomes Colleague may contact an FMD to deliver the presentation. If no Medical Outcomes Colleague is assigned to the customer, Field Commercial Colleagues are permitted to work directly with the FMD to arrange these Formulary Committee presentations.

**Interacting with Medical Outcomes Colleagues**

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

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

A. No. No colleague, including FMD and MOS Colleagues, can 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 Colleague can provide off-label information to a customer in response to a specific unsolicited question seeking such information, as set forth in the Green Guide. Any unsolicited request for off-label information received by a commercial colleague must be referred to USMI and follow the process as explained in this Chapter.

Exhibits and Displays

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

All exhibit and display requests must be reviewed and approved by your Manager and submitted to your designated Program Activity Coordinator (PAC) for processing and approval through Ariba. You should submit requests to the PAC at least four weeks prior to the date of the event. It is not permissible to participate in an exhibit or display if you have not received prior approval. In evaluating an exhibit or display request, Pfizer will ensure it is paying fair market value for the opportunity. If other companies are displaying their products, you should confirm whether such other exhibitors are being charged comparable amounts for the same type of space (it is also acceptable if all exhibitors are being charged the same fee but Pfizer has negotiated to pay a discounted rate). Often the event brochure will list the levels of exhibit and display opportunities and describe the space and services that are being purchased at each level. This type of brochure should accompany your exhibit or display request because it helps to validate the fair market value of the exhibit opportunity. Some factors to consider
when evaluating whether there is fair market value for an exhibit or display opportunity include the following:

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

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

**Q.** 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?

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

**Call Notes**

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

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

**Reporting Adverse Events and Other Product Safety Information**

Safety reporting is an important responsibility at Pfizer. As Field Commercial Colleagues, you may become aware of Product Safety Information. Please ensure that you follow Pfizer’s corporate policy on safety reporting, Corporate Policy 903, Your Responsibility to Report Information about the Safety, Quality, and Performance of Pfizer Products. Product Safety Information includes any information about the safety, quality, and performance of Pfizer products. There are four categories of Product Safety Information, listed below:

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### TYPES OF INFORMATION THAT SHOULD BE REPORTED

<table>
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<th>Description</th>
<th>Examples*</th>
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<tbody>
<tr>
<td>1. Adverse Events</td>
<td>Any untoward medical occurrence in an individual administered a Pfizer product, which includes any non-prescription or prescription drug, biologic, biosimilar, medical device, vaccine, cosmetic, or nutritional product.</td>
</tr>
</tbody>
</table>
|                                                                            | • 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 had been given. |
|                                                                            | Patient takes a product for high cholesterol and notices decreased insomnia. |
| 3. Product/Device Complaints                                                | Product: any written, electronic, or oral expression of dissatisfaction relative to the physical properties, condition, package insert, and/or packaging of a product. |
|                                                                            | Device: any written, electronic, or oral communication of dissatisfaction relative to the appearance, identity, quality, durability, reliability, safety, effectiveness, instructions for use, or performance of a medical device or a product with a medical device component, including software products that are regulated as medical devices (e.g. mobile apps, website functionality, etc.). |
|                                                                            | A product complaint associated with any Pfizer-sponsored medical software (including websites and mobile apps) should also be reported. |
|                                                                            | • Blister pack arrived empty  
|                                                                            | • Vial is leaking liquid  
|                                                                            | • Syringe is jammed  
|                                                                            | • Product is/may be counterfeit                                                                 |
| 4. Circumstances That May Lead To Adverse Events                            | Certain situations should also be forwarded whether or not there are any associated adverse events. They include: drug misuse; drug overdose; exposure during pregnancy or breastfeeding; medication errors; occupational exposure; and off-label use. |
|                                                                            | • Occupational Exposure: Splashing of oral/injectable solution in the eye  
|                                                                            | • Off-label use: Prescribed Revatio for a child with hypertension (only approved for adults) |

* The above are examples only. Please refer to Corporate Policy 903 for a complete list of reportable information.

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

Preceptorships and Other Training for Field Commercial Colleagues

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

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

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

Colleagues must be aware that patient privacy issues are often implicated when Pfizer employees are permitted to observe treatment or consultation sessions with patients and HCPs. Pfizer’s policies for protecting patient privacy in these circumstances are discussed in Orange Guide Chapter 8: Privacy: Protecting Personal Information. Colleagues must obtain all required permissions and fully comply with Pfizer policies and the rules of any institution where a program occurs.
Preceptorships may only be organized by colleagues who are District Manager level and above ("Project Managers"). Project Managers must complete the appropriate documentation located under the “HCP Engagements” tab at http://OpSource.Pfizer.com. Project Managers are required to obtain Legal approval for preceptorship engagements and must document the key learnings from the engagement and how the learnings will be incorporated into future business activities.

Occasionally, Sales Colleagues (Regional Manager level and higher) may engage HCPs to provide educational presentations at Pfizer meetings for the purpose of training colleagues. These training sessions should not be product-specific but rather should focus on the treatment of disease states in patient populations relevant to Pfizer.

The following conditions must be met when any HCP is engaged to train colleagues:

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

The organizer of the training must review the content of the presentation in advance to make sure that it is appropriate, addresses an unmet training need, and is not product-specific. The organizer must also remind all colleagues in attendance that the training is being provided for internal educational purposes only and that any information inconsistent with RC-approved promotional materials and in-context training cannot be used in detailing.
Refer to the HCP Engagement tab on OpSource for the procedures and policies that apply to these types of arrangements. You should always consult with your manager and obtain the approval of your team attorney before engaging in these activities.

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

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

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

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

- A representative may only provide a meal at an in-office or in-hospital setting,* unless a Centris speaker program is being conducted, in which case the program must comply with the rules set forth in Orange Guide Chapter 9: Speaker Programs for HCPs.

- All Pfizer policies and processes regarding detailing must be adhered to—for example, you should use Veeva CRM to record all attendees at a product detail (regardless of whether a meal was provided).

- You must make a good faith effort to avoid presenting product information to HCPs who are excluded for the product you are promoting.

- You must make it clear to the customer or organization that Pfizer is not a “sponsor” of its business meeting. Explain that Pfizer is engaging in a separate promotional activity with attendees of the meeting. Identify to the audience a clear start and end to the Pfizer promotional activities to avoid the misperception that Pfizer is supporting any part of the meeting itself.
• You must not distribute invitations or any other written material created by the host organization unless the material has been RC-approved.

• If you provide a meal,* it must be offered as part of the detail and incidental to the program. It is improper to provide frequent, regular, or recurring meals. For additional information on appropriate provision of meals, see Orange Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure.

• Pfizer cannot split the cost of a meal with the host of a third party meeting. However, you may engage in promotion during a meal that is provided and paid for entirely by a third party, as long as you make clear that Pfizer is not responsible for providing the meal. Meals provided by third parties will not be reported as part of Pfizer's payment disclosure policy.

• You must avoid being present during any discussion of any Pfizer product that you anticipate will be inconsistent with that product's labeling. In the context of journal club meetings or similar presentations, a Sales Colleague must make every effort to identify the agenda topics. Colleagues may detail before or after such a presentation only if the agenda topics for the program do not appear to contain off-label information respective to a product supported by the Sales Colleague.

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

* Remember that you cannot provide any food or other support in connection with an accredited continuing medical education activity (ACCME, ACPE, or ANCC). Even if you are offered time to promote while providing a meal to attendees at an accredited medical education conference, you must decline that opportunity since any type of financial support for accredited continuing education, including payment for event expenses or meals, can only be funded through an independent professional education grant. Requests for these grants should be sent by the requestor through Pfizer's Independent Grants for Learning & Change website. For more information, see Orange Guide Chapter 3: Support of External Organizations.
Q. 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?

A. Sales Colleagues may provide a promotional presentation. However, you should not attend or provide content or logistical support for any portions of a third-party meeting that are accredited for CME. Additional information about Pfizer’s policies for attending CME-accredited events is located in the below section (Attendance at Continuing Medical Education Events – Grand Rounds/Tumor Boards) and on the PfizerNet Compliance page.

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:

1. Ensuring that the audience is appropriate and does not contain HCPs who practice in excluded specialties;
2. Ensuring that you have a legitimate opportunity to present information about Pfizer products;
3. Ensuring that any meals are offered during the presentation and are incidental to the program;
4. Appropriately recording all attendees in Veeva CRM and all expenditures in PT&E;
5. Segregating the Pfizer promotional presentation from the rest of the meeting; and
6. Ensuring that all relevant state restrictions on the provision of meals and other items are followed (see Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions).

If you are unsure whether the promotional opportunity is appropriate, contact your manager or team attorney.

Attendance at Continuing Medical Education Events

Grand Rounds/Tumor Boards

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

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

Each Sales Colleague may attend no more than twenty four (24) grand rounds/tumor board programs per year. In addition, of those twenty four (24) maximum allowed grand rounds/tumor board programs, no more than eight (8) of them may occur with an individual institution within a calendar year.

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

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

- 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;
Orange Guide – Chapter 2: Interactions with HCPs

- Sales Colleagues must not engage in sales or promotional activities while in the space or place of the grand rounds program or in conjunction with such program.

- Sales Colleagues may not provide any meals at the host facility or in connection with the grand rounds program during the day of the event.

- Attending Sales Colleagues must comply with rules of the sponsoring institution.

- No Pfizer ID badges are to be worn unless required by the institution.

- Sales Colleagues must provide written certification of attendance to their manager within seven days following the event (via the Grand Rounds/Tumor Board SharePoint site).

- Regarding patient data, Sales Colleagues must avoid accessing protected health information (PHI), such as a patient's name, date of birth, or social security number, during their attendance at Grand Rounds programs. Sales Colleagues must avoid attending any program where they know that PHI will be made accessible. If a Sales Colleagues comes into contact with PHI at any program: (1) he or she must inform his or her manager promptly, and the manager must notify the RBD and team attorney promptly to set up a discussion as to whether any additional action is warranted; (2) he or she must not document or reproduce the PHI in any media or form; and (3) he or she must strictly maintain the confidentiality of such information in accordance with Pfizer's policy of safeguarding the privacy of PHI. Unless approved by the RBD, the manager should not approve further attendance by any Sales Colleague at a program at which PHI has been made available to attendees.

- Within three calendar days after attending a program, the Sales Colleague must inform his or her manager if there were any areas of non-compliance with this policy. In such case, the manager must notify the RBD, and either the BU Compliance Counsel or team attorney promptly to set up a discussion as to whether any additional action is warranted. For more information on Pfizer's policies for protecting patient privacy, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.

- Sales Colleagues must not discuss or utilize any off-label information learned during their attendance at the grand rounds program; and
• Sales Colleagues must ensure that any promotional efforts following their attendance at a grand rounds event will be consistent with all RC-approved messaging regarding their responsible Pfizer products.

• Safety reporting: Sales Colleagues are responsible for reporting any reportable safety information learned during the Grand Rounds programs as discussed in this Chapter and in Corporate Policy 903.

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

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

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

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

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

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

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

FOR MORE INFORMATION

• For more information on the acceptable use of information systems, see Corporate Policy 403, Acceptable Use of Information Systems.

• For more information on safety reporting, see Corporate Policy 903, Your Responsibility to Report Information about the Safety, Quality, and Performance of Pfizer Products.

• For more information on Pfizer’s policies for protecting patient privacy, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.

• For more information on interacting with consumers and employees, see Orange Guide Chapter 16: Consumer and Employee Interactions.

• For information on relevant state law restrictions, see Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions.

• For more information on providing meals to HCPs and on Pfizer’s HCP Disclosure Policy, see Orange Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure.

• For more information on interactions related to Greenstone and Pfizer Injectables, see Orange Guide Chapter 19: Sales Activities: Greenstone and Pfizer Injectables.

• For Q&A on the PhRMA Code, see the Compliance Tab on PfieldNet.

• For more information on interacting with MOS and/or FMD Colleagues, see the Green Guide: Governance for Medical Activities.
• For more information on documentation to be completed for preceptorships, see the HCP Engagements Tab at [http://OpSource.Pfizer.com/Pages/Home.aspx](http://OpSource.Pfizer.com/Pages/Home.aspx). Refer any questions to your manager or team attorney.
Chapter 3: SUPPORT OF EXTERNAL ORGANIZATIONS

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Chapter 3: SUPPORT OF EXTERNAL ORGANIZATIONS

Introduction

Pfizer is often asked to provide funding or other support to external organizations, including for-profit and not-for-profit entities. Pfizer provides external funding through medical education grants, sponsorships, and charitable contributions. Pfizer also supports joint collaborations with external organizations to advance shared objectives. Pfizer additionally sponsors awards, scholarships, fellowships, and similar funding in support or recognition of the education and professional accomplishments of healthcare professionals and students. Such Pfizer funding and support is a demonstration of the commitment to fund programs and initiatives that have broad public benefit, advance medical care, and improve patient outcomes.

As with any other interactions between Pfizer and entities involved in healthcare-related industries, providing funding or other support to external organizations can present legal risks if applicable laws, regulations, and Pfizer policies are not followed. All such interactions and the provision of financial support must be conducted appropriately to ensure that payments will not be perceived as an attempt to inappropriately influence the prescribing or recommendation of Pfizer products and to ensure the preservation of external organizations’ independence. In addition, Pfizer’s policy requires that promotional materials, and certain other materials provided by colleagues through collaborations with external organizations, be reviewed and approved by the applicable Review Committee.

In addition to existing payment disclosure obligations, Pfizer must comply with certain reporting and disclosure requirements of the Sunshine Act. Included in scope for reporting are any payments or transfers of value that are made directly or indirectly to a covered recipient defined as a U.S. physician or teaching hospital. A payment or transfer of value is considered indirect if it is known that the organization receiving the funding will be conveying a benefit to a covered recipient even if Pfizer does not direct or influence the selection of the recipient or have knowledge of the identity of the recipient.
If Pfizer has agreed to an organization’s use of funds that includes a payment or transfer of value to covered recipients in any form of direct, indirect, or in-kind payment or transfer of value, then the Pfizer project manager is responsible to collect all relevant information for each physician and/or teaching hospital required for disclosure using the Sunshine Data Template available at http://ecfd.pfizer.com/sites/sunshinetracker/default.aspx.

The reporting provisions of the Sunshine Act became effective August 1, 2013. The Centers for Medicare and Medicaid Services (CMS) disclose the data on a publicly available website located at http://www.cms.gov/OpenPayments/index.html. The first disclosure covering the period August 1 through December 31, 2013, was made public on September 30, 2014. Since 2015, CMS discloses calendar year data on June 30th of each year. Please refer to Orange Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure for more information on our disclosure obligations under the Sunshine Act.

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

- Understand the Policies that Apply to Your Group
- Funding to not-for-profit organizations by U.S.-based colleagues within the Pfizer Innovative Health (PIH), Pfizer Essential Health (PEH) (excluding PEH R&D colleagues), collectively Business Units or BUs, Pfizer Medical, and Corporate Affairs groups must follow the policy and procedures outlined in the [SOP on Funding Requests for Not-for-Profit Organizations](#). For questions relating to this SOP, e-mail [USFundingRequest@Pfizer.com](mailto:USFundingRequest@Pfizer.com). For specific questions relating to funding by Corporate Affairs, e-mail [PolicyFRC@Pfizer.com](mailto:PolicyFRC@Pfizer.com).
- Funding to external organizations by colleagues in WRD, GPD and PEH R&D must follow the [WRD SOP 201](#).
- Funding under this Chapter is not intended to provide support for research activities such as Investigator Initiated Research (IIR) and Clinical and Research Collaborations (CRCs).
- Pfizer colleagues in other divisions must follow [Corporate Procedure 801](#) and also the review, approval and documentation requirements applicable to their division.
- Understand the Types of Activities Your Group Is Permitted to Fund.
- For U.S.-based colleagues in the BUs, Pfizer Medical, and Corporate Affairs groups, the following table summarizes permitted funding by group:

<table>
<thead>
<tr>
<th>Type of Funding</th>
<th>Sales</th>
<th>Non-Sales (including PCA)*</th>
<th>Corporate Affairs</th>
<th>Pfizer Medical and BU Medical</th>
<th>Independent Grants for Learning &amp; Change (IGLC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Healthcare Charitable Contribution</td>
<td></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Healthcare Charitable Contribution</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
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</tbody>
</table>

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### Key Points to Ensure Compliance

<table>
<thead>
<tr>
<th>Type of Funding</th>
<th>Sales</th>
<th>Non-Sales (including PCA and GH&amp;V)*</th>
<th>Corporate Affairs</th>
<th>Pfizer Medical and BU Medical</th>
<th>Independent Grants for Learning &amp; Change (IGLC)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy Focused Healthcare Charitable Contribution</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Special Event</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Sponsorship</td>
<td>Yes, but DBM and above only</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Collaboration</td>
<td>Yes, but DBM and above only</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Fellowship</td>
<td>Only certain GH&amp;V Colleagues</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical Education Grant</td>
<td></td>
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<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>

* To remain consistent with, and for purposes of this chart found in the SOP on Funding Requests for Not-for-Profit Organizations, “PCA” shall include, Account Managers, including but not limited to Account Directors, Key Account Managers (KAMs), HIT Specialists and Vaccine Account Managers (VAMs).
Key Points to Ensure Compliance

- Field Commercial Colleagues, as defined in Chapter 1 of this Guide, may fund sponsorships that provide an appropriate “tangible benefit” (as defined later in this Chapter) to Pfizer. For Sales Colleagues, these sponsorships may be pursued only at the DBM level or higher.

- A funding request that does not include a “tangible benefit” will not be treated as a sponsorship but rather as a charitable contribution. Charitable contributions are not eligible for funding by Sales Colleagues.

- External organizations will often submit funding requests using key terms (e.g., “charitable contribution,” “grant,” and “sponsorship”) interchangeably and inconsistently. Pfizer colleagues must identify the substantive nature of each request based on Pfizer definitions to ensure that it is a type of request they are permitted to fund. Refer to the SOP on Funding Requests for Not-for-Profit Organizations.

- Never offer or provide funding: (i) as a “quid pro quo” to inappropriately influence the formulary positioning, recommendation, or increased prescribing of a Pfizer product; or (ii) to gain improper favor with a healthcare professional, government official, or any other individual or organization.

- Never provide individual HCPs or group practices with grant funding or donations unless approved in advance by Legal.

- Never link charitable funding to a commercial transaction or interaction.

- Never provide funding to an organization in a manner that undermines the organization’s independence or mission or for capital support or “start-up” costs.

- Never provide funding for any activity that may result in inappropriate promotion of Pfizer products or where there is a likelihood that treatment options will not be presented in a fair and balanced manner.
Medical Education Grants

Overview

Pfizer provides non-promotional funding to third-party organizations in the form of independent medical education grants. An independent medical education grant refers to funding given to a third-party entity for a healthcare quality improvement (QI) or health services initiative or to support a specific educational or professional development activity directed at healthcare professionals (HCPs) that will benefit the public and improve patient health.

Legitimate professional and educational initiatives that can be supported with medical education grants include, but are not limited to, activities like continuing medical education (CME)/continuing education (CE) for HCPs. Medical education grants are permissible only if they are “independent,” which means that colleagues may not influence the content of the supported activity or how it is conducted. For example, colleagues cannot choose nor have any input on the topic, or the speakers who participate in the activity. Additionally, if Pfizer colleagues are solicited by external organizations to serve as faculty, colleagues are required to ascertain whether funding has been provided by Pfizer for the specific medical education activity. Any independent CME/CE activity supported by Pfizer precludes Pfizer colleagues from serving as faculty for that CME activity.

The review and approval of requests for education grants in the U.S. (and Puerto Rico) is managed by the office of Independent Grants for Learning & Change (IGLC). IGLC, a part of Pfizer Medical, works with therapeutic area representatives from BU Medical and Legal to develop medical educational strategies for clinical areas of interest. To be considered for funding, a grant request should align with these medical educational strategies and must meet all of the criteria of an appropriate educational activity or QI/health services initiative, including that it is independent and information provided is balanced, accurate, and not misleading, delivered to a broad audience, and reasonable in cost. Additional criteria must be met when responding to a request for proposal (RFP) prepared by IGLC in collaboration with External Review Panels and/or in partnership with other third party organizations.

Under no circumstances does Pfizer condition grant funding upon past, present, or future prescribing, purchasing, or recommending of Pfizer products, nor will Pfizer accept any benefits in return for providing a medical education grant. IGLC also does not provide medical education grants in support of an individual’s career advancement or development. (The review and approval process for

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such activities is covered below in the section titled “Awards, Scholarships and Fellowships.”) By requiring the review and approval of these requests by IGLC (or when applicable, by External Review Panels), Pfizer seeks to minimize the risk that a medical education grant could be approved, or perceived to have been approved, for an improper purpose.

Commercial support of medical education grants has been under increasing scrutiny by Congress and the U.S. Department of Health and Human Services Office of Inspector General (OIG). In an effort to be more transparent, Pfizer publicly reports grants and charitable contributions provided to medical, scientific, and patient organizations in the United States, on the Pfizer website.

Application Submission

All requests for U.S. medical education grants must be submitted by the external organization directly to IGLC via Pfizer’s online Grant Management System (GMS) at www.pfizer.com/independentgrants. All submissions, required documentation, and decisions are recorded and archived in GMS.

Types of organizations eligible to apply for grants include hospitals, academic medical centers, schools of nursing or pharmacy, professional societies and associations, and other institutions specializing in specific healthcare-related disciplines (e.g., public health, quality improvement). Eligible organizations may submit a request for support of QI/health services initiatives and independent accredited or non-accredited professional educational programs and activities. Requests for accredited independent professional education must be submitted by accredited organizations. Examples of qualified accreditations include ACCME, AAFP, and AOA, ACPE, ANCC, AANP, AAPA, and NCOA. Providers must be in compliance with Pfizer standards as well as the guidelines of the OIG, ACCME, and other relevant bodies, as applicable. Pfizer does not support requests from individual physicians, private practice groups, or institutions that appear to have significant conflicts of interest. For example, organizations where practicing healthcare providers have a proprietary or ownership interest in the organization will not be eligible to apply for medical education grants from Pfizer. Additionally, funding from IGLC may not be used to support food and beverage for learners or audience participants.
International Grant Activity

Q. May Pfizer Country Offices outside the U.S. fund independent medical education programs occurring in the U.S.?

A. No. All such requests must be submitted by the external organization directly to IGLC via GMS. Under strictly limited conditions, exceptions may be permitted with approval from IGLC and Legal.

Application Review, Notification, and Payment

IGLC will review application submissions for completeness, alignment with medical educational goals, compliance with Pfizer policies, and other requirements. For those requests submitted in response to an RFP, final decisions will be rendered by External Review Panels. Due to limited funding, not all grant requests will be approved. Requestors will receive an e-mail notification when a grant is approved or denied. Funds are sent directly to the requesting organization.

Colleague Roles in Grant Process

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 IGLC team regarding grant requests, funding, or denials. Colleagues must direct requestors to the IGLC website at www.pfizer.com/independentgrants, or the dedicated e-mail address IGLC@pfizer.com.

Pfizer May Not Influence Grant-Funded Activities

Colleagues may not offer suggestions regarding topics, content, or speakers to a CME/CE provider, program sponsor, or speaker at a CME/CE medical education activity. Even if you are asked to provide input on topics or speakers, you must decline. If a provider or speaker were to implement Pfizer suggestions, the independence of that medical education program could be compromised. Similarly, a grant request for an independent medical education activity that includes faculty who have spoken on similar topics in a promotional capacity for Pfizer in the 12 months prior to the date of submission of the grant request will be declined. Additionally, colleagues must not provide logistical support at an independent medical education activity.

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On occasion, Pfizer may be offered promotional opportunities in connection with an independent medical education activity, such as exhibit space or time to conduct a speaker program. Such opportunities may be accepted only under strictly limited conditions. For information on promotional opportunities at CME/CE activities, see the section below.

### Colleagues’ Role in Preserving Independence

**Q.** May a colleague provide input on the content of a CME/CE activity in order to inform the accredited provider that the information is inaccurate or unreasonably favors Pfizer products?

**A.** No. To preserve independence, colleagues, including those in IGLC, must not provide input or in any way influence the content of a CME/CE activity.

**Q.** May a colleague provide input on the content of a non-CME/CE activity funded through IGLC? Similarly, can a colleague provide logistical assistance for a non-CE event funded through IGLC?

**A.** No. Pfizer considers all grant-funded activities, even non-CME/CE activities, to be independent. Colleagues may not influence any grant-funded activity in any way.

### Promotional Opportunities at Medical Education Conferences

You may not under any circumstances fund or provide a meal or any other type of expense associated with a third party’s medical education conference or activity where CME/CE credit is being offered.

If Pfizer is offered the opportunity to conduct a speaker program in connection with an accredited medical education activity (ACCME, AAFP, or AOA), this may be done only under the following conditions:

- The Pfizer program must be conducted in a room physically separated from the space where CME/CE content is being provided.
- At the start of the program, the speaker must clearly communicate to attendees that it is a separate Pfizer promotional presentation not certified for CME/CE credit.
- Pfizer cannot provide meals or beverages in connection with the Pfizer program. Any meals provided by a CME/CE provider must be made available to all CME/CE event attendees, including those not attending the Pfizer presentation.
• No advice or guidance may be provided regarding the content of the medical education activity.

• No financial or other support, including payment for event expenses or meals, setting up logistics, or handling non-Pfizer speaker arrangements, may be provided in connection with the Pfizer program (subject to vary narrow exceptions for logistical expenses discussed in Orange Guide Chapter 9: Speaker Programs for HCP). As discussed above, financial support may only be funded by an independent medical education grant approved by IGLC.

If colleagues are offered an opportunity to conduct a speaker program at an event where CME/CE is not being provided, the above restrictions do not apply; however, Sales Colleagues must still follow all applicable Pfizer policies for promotional speaker programs (including the policies outlined in Orange Guide Chapter 9: Speaker Programs for HCPs).

Complimentary Exhibit or Display Space

If exhibit opportunities are available at an event—whether or not CME/CE credit is being offered – Pfizer may pay for placement of an exhibit or display at fair market value. From time to time event organizers may offer Pfizer complimentary exhibit and display space. If such complimentary offerings are tied to an IGLC-approved grant, then Pfizer may only accept complimentary exhibit space when it is offered to all potential exhibitors equally.

Sponsorships and Charitable Contributions: All Divisions

General

Not-for-profit organizations, including but not limited to qualified 501(c)(3) charitable organizations, may offer Pfizer the opportunity to provide funding for sponsorships or charitable contributions. Colleagues must follow the review, approval, and documentation requirements applicable to their division.
**Sponsorships and Charitable Contributions: WRD, GPD, and PEH R&D**

Funding to external organizations by Worldwide R&D (WRD), Global Product Development (GPD), and PEH R&D colleagues must follow Worldwide R&D SOP 201. Any charitable contributions initiated by WRD, GPD or PEH R&D colleagues must be submitted using the Charitable Contributions Request Form located in Ariba SAP, Funding Request Project. A letter of request from the organization on its letterhead, or alternative documentation that is approved in advance by the WRD Compliance Team is also required. Charitable contributions greater than $10,000 are subject to relevant Authorized Signatory List (ASL). WRD, GPD and PEH R&D colleagues should consult Worldwide R&D SOP 201 for additional guidelines and requirements.

**Sponsorships and Charitable Contributions: U.S. BUs, Pfizer Medical, and Corporate Affairs**

The remainder of this section describes the policy that applies to the U.S. BUs, including Field Commercial Colleagues, Pfizer Medical (formerly called the CMO division), and Corporate Affairs Groups. Colleagues in these divisions should refer to the SOP on Funding Requests for Not-for-Profit Organizations ("External Funding SOP") to determine whether a funding opportunity is a sponsorship or a charitable contribution. This Chapter does not comprehensively address the activities that may be funded by BU Leadership and the Medical Lead for each BU. Those activities are addressed in the External Funding SOP.

**Determining the appropriate funding type will determine which colleague groups are permitted to fund them.** How a third party defines or describes the funding request does not determine Pfizer’s classification. In fact, external organizations will often submit funding requests using key terms interchangeably and inconsistently (e.g., “charitable contributions,” “grants,” and “sponsorships”). Each colleague must identify the substantive nature of each request, based on Pfizer’s standard definitions summarized below, to ensure that a request represents the type of opportunity that they can appropriately fund. Such guidance can be found in the External Funding SOP.
“Not-for-Profit” Defined

A “not-for-profit” (also referred to as a “non-profit”) organization is an organization that does not distribute its profits to its owners and is typically organized for educational, charitable, or scientific purposes. The External Funding SOP applies to entities that have been designated as not-for-profit by appropriate state and federal agencies, including but not limited to: 1) certain charities and patient advocacy groups designated by a 501(c)(3) status; 2) professional medical associations or chambers of commerce (501(c)(6) status); and 3) cultural and civic organizations (501(c)(4) status).

Sponsorships

Sponsorships are funding opportunities provided by either for-profit or not-for-profit organizations that present a “tangible benefit” to Pfizer. They can be funded by all Pfizer groups in accordance with the processes and requirements described in this Chapter. A tangible benefit is any legitimate, appropriate, and business-oriented benefit to the proprietary interests, business, or public policy goals of Pfizer or its products, services, or programs. The receipt of general recognition or incidental goods or services that do not directly promote Pfizer business goals in and of itself does not constitute a tangible benefit. A tangible benefit must provide the opportunity to truly advertise or advance Pfizer business interests, e.g., to educate customers and/or prescribers about the specific attributes of our products and/or services.

A funding request characterized as a sponsorship that does not include a tangible benefit in return for funding will not be treated as a sponsorship but rather as a charitable contribution. As discussed in the next section, Sales Colleagues are not permitted to make any charitable contributions. All other colleagues (including PCA*) are not permitted to make healthcare charitable contributions but are permitted to make appropriate non-healthcare charitable contributions. Colleagues may not ask a requesting organization to change the associated benefits being offered for funding in order to impact the classification or source of funding within Pfizer.

* To remain consistent with the SOP on Funding Requests for Not-for-Profit Organizations, “PCA” includes Account Managers, including but not limited to Account Directors, Key Account Managers (KAMs), Oncology KAMs, HIT Specialists, and Vaccine Account Managers.
<table>
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<th>Tangible Benefit Examples*</th>
<th>Fair Recognition Examples (Not Considered A Tangible Benefit)</th>
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| • An activity provides a Tangible Benefit where Pfizer is a direct recipient of the activity output (e.g., funding the development of literature that will then be used by Pfizer) or where Pfizer has any input with respect to the execution or content of the activity (e.g., providing strategic direction or message development).  
• Distribution of branded materials or dissemination of information on specific products.  
• Promotional placement of product logos on a podium or in literature aimed at HCPs or patients.  
• Opportunity to promote Pfizer products (e.g., via branded materials or a booth at an exhibition).  
• Opportunity to promote Pfizer's programs or services (e.g., Pfizer RxPathways).  
• Providing or selecting a speaker (including for a policy topic).  
• Opportunity to promote Pfizer unbranded programs (such as smoking cessation which may have related branded or unbranded materials).  
• Opportunity to promote specific businesses, portfolios, or franchises within Pfizer (e.g., Pfizer Oncology, Pfizer Women’s Health, Pfizer Vaccines), provided that such promotion involves activities beyond mere promotional placement of its name/logo, such as the ability to distribute materials or information related to such business, portfolio, or franchise and/or products within such business, portfolio, or franchise. | • Placement of a Pfizer corporate logo by itself on a podium, in literature, or on a purchased table at an event.  
• Honorable mentions and announcement of thanks, written or verbal.  
• Tickets to an event.  
• Recognition in conference brochure/program (such as listing as Gold Sponsor). |

* Subject to meeting all relevant review committee approval requirements.
If a not-for-profit sponsorship opportunity satisfies the above key characteristics, U.S.-based colleagues in BUs, Pfizer Medical, and Corporate Affairs may submit a funding request using the Funding Request Form (FRF) available at https://aribaprime.pfizer.com/Sourcing/Main. Sponsorship opportunities involving for-profit organizations are evaluated under similar rules but must be submitted for Legal approval directly and not through the Ariba ACM /FRF system.

Evaluate Substantive Nature of Funding Request

Q. Can a colleague in a BU, Pfizer Medical, or Corporate Affairs fund a sponsorship as long as the tangible benefit criteria is met?

A. Not necessarily. When evaluating the substantive nature of a funding request for a sponsorship, colleagues must differentiate the tangible benefit offered from the activity/event. For example, at times organizations may offer exhibit space in return for providing support for a medical education conference. While the exhibit space is considered a tangible benefit, only IGLC is permitted to support the medical education conference through a medical education grant. In order to fund a sponsorship for the exhibit space, the funding request must clearly outline support is being provided for the exhibit space and not for the medical education conference.

Submission of Funding Requests by Sales Colleagues

Sponsorships may be funded only by Sales Colleagues at the District Business Manager (DBM) level or higher. The purchase of exhibit and display space by U.S. Sales Colleagues is covered by the Exhibit and Displays SOP (ED SOP2-01) and is processed through Ariba ACM. However, if a U.S. Sales Colleague funds a sponsorship that provides for a package of benefits (i.e., in addition to the exhibit and display space) then the SOP on Funding Requests for Not-for-Profit Organizations should be followed.

Before submitting any requests using the FRF (including applicable charitable contributions described below), colleagues should review the training materials located under the Funding Request tab at Funding Request Project in Ariba-ACM. Completion of the Funding Request training module is a prerequisite for having access to the FRF. All such funding requests are subject to review and approval by the appropriate Legal Division colleague, unless otherwise noted. Contact USFundingRequest@Pfizer.com to gain access to the training module.
Charitable Contributions

Generally, charitable contributions are expenditures that are intended to fund a qualified 501(c)(3) organization in the United States (or non-U.S.-based not-for-profit entity equivalently recognized by the respective country’s local government) for its broad charitable purpose or mission. As described above, any funding opportunity that does not include a direct tangible benefit to Pfizer will be treated as a charitable contribution (for purposes of determining whether specified colleagues can fund it). When permitted, charitable contributions must be made for a bona fide charitable purpose and without any ulterior commercial motive. Charitable contributions may include some benefit to Pfizer but any benefit given to Pfizer must be incidental to the donation itself. Pfizer may not provide input into the content or strategic direction of the activity being funded, nor receive rights to use the results of the activity being funded. Due to limited funding, not all charitable contribution requests will be approved.

Pfizer broadly distinguishes between four categories of charitable contributions: non-healthcare, healthcare, policy-focused healthcare, and Special Events. This section contains definitions and examples of each type of charitable contribution, a description of the groups that may provide funding and an overview of the relevant approval process.

Non-healthcare charitable contributions are the donation of money, goods, or services to organizations or programs that exist for broad public benefit not related to products or healthcare topics.

- **Examples:** Contribution for disaster relief; contribution for a school fundraiser.

- **Colleagues who May Provide Funding:** U.S.-based colleagues in the following Pfizer divisions: U.S. Business Unit non-Sales Functions (including PCA), Corporate Affairs, and Pfizer Medical. For purposes of the External Funding SOP, PCA includes Account Managers, as defined above.

- **Approval Process:** Requests for non-healthcare charitable contributions may be submitted using the Funding Request Form at https://aribaprimelpfizer.com/Sourcing/Main. All such requests are subject to review and approval by Legal.

Healthcare charitable contributions (non-policy focused) are charitable contributions to healthcare-related organizations or non-healthcare related organizations for healthcare-related programs. Field
Commercial Colleagues may not fund healthcare charitable contributions. The office of Independent Grants for Learning & Change (IGLC) funds charitable contributions related to the following: disease state focused patient or community education or advocacy; health screening and surveying; improved patient access to care (e.g., transportation costs); and/or organizations whose general mission is to benefit specific patient groups. If the target audience of a patient/community education program also includes HCPs, the request may not be supported as a charitable contribution—the request must be submitted as a medical education grant (refer to the section above titled “Medical Education Grants”).

- **Examples:** Contribution to the Arthritis Foundation for patient education on lifestyle changes that can help them manage their condition; contribution to CancerCare for improved access to care—transportation to/from medical appointments for patients with Gastrointestinal Tumors (GIST) and Renal Cell Carcinoma (RCC).

- **Colleagues who May Provide Funding:** IGLC only.

- **Approval Process:** Similar to medical education grant submissions, requests for (non-policy-focused) healthcare charitable contributions that meet the criteria above must be submitted directly by the 501(c)(3) not-for-profit organization to IGLC via Pfizer’s online Grant Management System (GMS) at [www.pfizer.com/healthcharitables](http://www.pfizer.com/healthcharitables). Colleagues may not submit requests to IGLC on an organization’s behalf. This website includes a list of criteria that any request must meet to be eligible for IGLC charitable funding. Funding from IGLC may not be used to support food or beverages for learners/participants. IGLC will review submissions for completeness, alignment with clinical areas of interest, compliance with Pfizer policies, and other requirements. Requestors will receive an e-mail notification when the request is approved or denied.

**Policy-focused healthcare charitable contributions** are contributions to organizations where the funds are to be used for the organization’s specific mission-related activities that align with Pfizer’s public policy goals. This includes, but is not limited to, patient education on public policy issues, policy-related access to healthcare issues, and support of charities whose general mission is to further healthcare policy (and does not include healthcare professionals’ continuing medical education or disease state, medical, or clinically-focused activities).

- **Example:** Charitable contribution to the Georgia Medical Society for education of members on healthcare reform.
• **Colleagues who May Provide Funding:** Corporate Affairs and Pfizer Medical (CMO division).

• **Approval Process:** Requests must be submitted by appropriate colleagues using the Funding Request Form at [https://aribaprime.pfizer.com/Sourcing/Main](https://aribaprime.pfizer.com/Sourcing/Main). All such requests are subject to review and approval by Legal.

“Special Events” are contributions to organizations whose goals align with Pfizer’s public policy goals to help fund their fundraising dinners, walks, biking and golf events, galas, awards ceremonies, and other similar events. Special Events are activities that do not present tangible benefits to Pfizer (and are therefore ineligible for sponsorship funding).

• **Examples:** Financial support of a Multiple Sclerosis Society walkathon.

• **Colleagues who May Provide Funding:** Corporate Affairs and Pfizer Medical (CMO division).

• **Approval Process:** All requests must be submitted by appropriate colleagues using the Funding Request Form through Ariba ACM at [https://aribaprime.pfizer.com/Sourcing/Main](https://aribaprime.pfizer.com/Sourcing/Main). All such requests are subject to review and approval by Legal.

**U.S.-based colleagues in the BU’s are prohibited from providing funding for Special Events but may refer organizations to the Special Events page on Pfizer’s website** [http://www.pfizer.com/specialevents](http://www.pfizer.com/specialevents).

• **Internal Coordination:** Involvement of Business Unit colleagues in policy-focused healthcare charitable contributions and Special Events must be strictly limited. Certain designated Business Unit colleagues are permitted to present therapeutic area strategies and priorities to Corporate Affairs so that the Corporate Affairs group has access to the most comprehensive information in determining how best to work with requesting organizations. These presentations may not focus on specific events or funding opportunities and may occur only during development of operating plans and strategic planning discussions.

• **Additional Assistance:** If a Special Event includes or requires Pfizer participation, such as volunteers to hand out materials or seats at a gala table, Corporate Affairs may invite colleagues to participate only if there is no branded or promotional interaction with the
organization, and discussions with attendees must not involve Pfizer brands or products. Colleagues are not permitted to invite HCPs to these events.

<table>
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<tr>
<th>Key Characteristics: Sponsorships vs. Charitable Contributions</th>
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<tr>
<td><strong>Characteristic</strong></td>
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<tr>
<td>Promotional in nature</td>
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<tr>
<td>Payee must be a not-for-profit organization (501(c)(3) or similar designation)</td>
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<tr>
<td>Pfizer must receive a “tangible benefit”</td>
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<tr>
<td>Payment can be made to an individual HCP or private practice group</td>
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<tr>
<td>Tickets or invitations received as a result can be offered to Healthcare Professionals</td>
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<tr>
<td>Agreement documenting terms and conditions of Pfizer funding</td>
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Information on Pfizer’s External Funding SOP

Q. Where can Pfizer colleagues in the BUs, Pfizer Medical and Corporate Affairs get help and information on Pfizer's policy regarding funding to not-for-profit organizations?

A. Funding requests must be initiated online using the Funding Request Form at [https://aribaprinme.pfizer.com/Sourcing/Main](https://aribaprinme.pfizer.com/Sourcing/Main) under the “BU/Pfizer Medical/Policy FRF” tab. Additional resources are also available at [http://OpSource.pfizer.com](http://OpSource.pfizer.com) under the “Funding Requests” tab. OpSource also includes a funding request “wizard” and other tools that can help you determine whether a proposed funding activity is permissible for you to support. You can direct any questions about the process to [USFundingRequest@Pfizer.com](mailto:USFundingRequest@Pfizer.com).
Purchase of a single ticket to a Gala/Fundraiser

Q. 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?

A. Yes. The SOP permits these colleagues to purchase single tickets to fundraising events for legitimate business purposes. The ticket fee may be submitted as an invoice and charged to your department’s payment process. However, remember that colleagues in these groups are not permitted to purchase entire tables at such events. Colleagues must operate within the spirit of these guidelines and not purchase individual tickets in a manner that result in the purchase of a whole table in order to circumvent the SOP.

Sponsorship Request related to For-Profit Organizations

Q. Does the External Funding SOP apply to funding requests from for-profit organizations?

A. No. These requests are evaluated under similar standards but are not covered by the External Funding SOP and should not be processed using the Funding Request Form (FRF) in Ariba-ACM. Field Commercial Colleagues should process these requests through their Regional Coordinator and obtain approval from their team attorney.

Sales-Funded Exhibit and Display Requests

Q. Are Exhibit and Display Fees made payable to not-for-profit organizations covered by the External Funding SOP?

A. Sales-funded Exhibits and Displays are subject to a different SOP – [ED SOP2-01](#) available on OpSource under the Funding Requests tab which is separate from the External Funding SOP. You should submit Exhibit and Display requests through Ariba ACM using the Funding Request Form (FRF) which will be routed to your program activity coordinator for review and follow the applicable policies (available in OpSource under the “Funding Requests” tab). However, if an Exhibit and Display request is part of a larger promotional sponsorship package that includes other benefits (in addition to an exhibit and display space), then the [External Funding SOP](#) should be followed.
Collaborations

Another way that Pfizer supports external organizations is by participating in collaborations or joining coalitions to advance shared objectives. Colleagues must follow the review, approval, and documentation requirements applicable to their division. The requirements for U.S. BUs, Pfizer Medical, and Corporate Affairs groups are described below.

Overview

A collaboration is an activity or project undertaken by Pfizer with one or more external organizations (either for-profit or not-for-profit) to advance specified shared objectives, where all parties participate as equal partners. Pfizer must not only support the organization with funding (in cash or in-kind resources or expertise), but must also make a substantial intellectual contribution to the project. “Substantial intellectual contribution” means conceiving and designing a project, acquiring data, or analyzing and interpreting data. If the organization creates materials that are published, this must occur in conjunction with Pfizer. In a Collaboration, Pfizer is involved with the creation of the output, provides feedback on suggested publications, and has the right to use the materials being created. For BU colleagues, all materials developed for distribution must go through a Pfizer RC evaluation to check the content for factual accuracy and compliance with applicable laws, regulations and Pfizer policies.
Pfizer’s involvement in a Collaboration must be disclosed clearly in all resulting materials in a manner that does not imply that the materials were funded through an unrestricted grant or Charitable Contribution. Such disclosure should state “Developed in collaboration with Pfizer” or similar terms.

- **Examples:** A brand team may collaborate with cancer survivor organizations on a pamphlet about effective patient–physician dialogue; “Campaign to Quit” conducted jointly with the American Lung Association.

- **Colleagues who May Provide Funding:** U.S.-based colleagues in the Business Units, Pfizer Medical, and Corporate Affairs groups.

- **Approval Process:** Colleagues should discuss all pertinent facts about a collaboration with Legal prior to submitting the Funding Request Project for approval. After consulting with Legal, requests to participate in a collaboration must be submitted by appropriate colleagues by creating a Funding Request Project in Ariba-ACM, which are subject to formal review and approval by Legal.

- One type of collaboration involves Pfizer working with two or more separate entities to achieve a common objective (e.g., public policy development). This type of collaboration is commonly known as a coalition. Pfizer’s membership in a coalition may involve monetary funding or a donation in-kind of resources or expertise, but must always include Pfizer’s involvement in the development of the mission and goals and the advancement of the aims of the collective group. Due to a high degree of legal risk in healthcare-related coalitions, the majority of the group’s members must be non-commercial, non-manufacturer organizations and they should be the partners who have ultimate control over the coalition and its messaging, subject to Pfizer’s rights to review the content for factual accuracy and to ensure compliance with applicable laws, regulations, and Pfizer policies.

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

Given the nature of Pfizer’s involvement in collaborations, including the provision of strategic input and often the rights to use the output of the activities, this category must provide Pfizer with a tangible benefit and should not be considered a charitable contribution even if the receiving organization is a not-for-profit entity.
Pfizer’s participation in collaborations must also be appropriately disclosed in all resulting materials in a manner that does not imply that funding was provided via an unrestricted grant or charitable contribution (e.g., “Developed in partnership with Pfizer” rather than “Funding support provided by Pfizer”).

**Awards, Scholarships, and Fellowships**

**Overview**

Pfizer sponsors awards, scholarships, fellowships, and similar funding in support or recognition of HCPs and students. Pfizer Medical and BU Medical are permitted to fund awards, fellowships, and scholarships. Certain GH&V colleagues are also permitted to fund fellowships.

**Awards** are programs developed with an independent professional group to provide funds or other recognition to an individual demonstrating professional excellence in the field of medical science or healthcare leadership or an outstanding commitment to public health or patient care. **Fellowships** are generally funds paid to medical schools; academic medical centers; teaching hospitals; schools of nursing, pharmacy, or public health; and other healthcare-related organizations to support junior faculty or emerging leaders in medical science for one or more years of research or study. **Scholarships** are funds awarded to students engaged in a full-time academic activity (normally a medical degree) to aid with education costs. Pfizer also sponsors awards, scholarships, fellowships, and similar funding that: (1) permit medical students, residents, fellows, and other healthcare professionals in training to attend carefully selected educational conferences; or (2) support clinical or research fellowships.

- **Colleagues who May Provide Funding:** Awards, scholarships, and fellowships are permitted to be funded only by Pfizer Medical and BU Medical colleagues. GH&V colleagues involved in designing and conducting research related to health economics and real world data are the only BU colleagues permitted to fund fellowships.

- **Approval Process:** All such funding requests are subject to review and approval by the Policy Funding Review Committee (PFRC).

- **Requirements:** Pfizer funding of awards, scholarships, and fellowships is permissible only under the following circumstances:
The selection of awardees is independent of direct and indirect Pfizer influence, which includes direct selection of awardees as well as choosing the selection committee that makes the ultimate decision about individual awardees;

The application is competitive and open to all relevant institutions and candidates in a given geographic area or therapeutic area;

Resulting programs are not related to any Pfizer product;

Pfizer receives an unsolicited request from an organization to fund a fellowship program that already exists, or is being developed, and will be operated by, the organization; and

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

In addition, awards, scholarships, and fellowships must be provided directly to requesting organizations (e.g., academic medical center; professional association) that independently select final individual awardees. It is permissible to assemble and retain a selection committee to evaluate requesting organizations when such expertise is required; provided that such requesting organizations independently select the individual student or HCP ultimately to receive the award, scholarship, or fellowship. Whenever possible, programs should be co-sponsored with non-profit medical societies, professional groups, or similar organizations.

Awarded funds must be used only for the direct expenses of the program and may not be used to subsidize the requesting organization’s existing, routine, or ordinary business expenses. Fellowships must be paid directly to the awardee’s institution and cannot be paid directly to the awardee. In addition, Pfizer can provide fellowships only to support the research activities of awardees who already have positions at academic institutions. Fellowship funds cannot be used to cover a salary for a position that bills services, or for that portion of a position that bills services. If a position includes both billable services and research or teaching, the award must be pro-rated based on the amount of time the awardee will devote to non-billable teaching and research. Also, funding cannot be used to cover the salaries of other individuals assisting the awardee.
Non-Financial Support

**Personal Volunteering**

With the exception of approved team building activities, personal volunteering activities by Pfizer colleagues must be done during a colleague’s personal time and not a Pfizer effort. Volunteering must be an individual choice and no managerial pressure or direction can be exerted to influence a colleague to volunteer. Personal volunteering must therefore not be linked to commercial goals or objectives or otherwise be part of promotional activities or business plans. An exception to this is that at certain Special Events (as described above), the Corporate Affairs group may seek assistance from colleagues to attend or help at the event.

This prohibition, however, does not apply to activities approved by the relevant BU or division that are undertaken with organizations to 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, or board member of an external organization, particularly if the organization is likely to request funding from Pfizer. Colleagues must always ensure that their participation in external organizations is consistent with this Chapter, the Summary of Pfizer Policies on Business Conduct (the “Blue Book”), Corporate Policy 203: Conflicts of Interest, and other applicable Pfizer policies that address conflicts of interest. Pfizer colleagues participating as officers or board members must recuse themselves from joining in any decisions or activities relating to Pfizer, Pfizer products, or competitor products.

The fact that a Pfizer colleague participates as a regular member, officer, or board member of an external organization does not necessarily preclude the organization from receiving funding from Pfizer. However, a colleague’s participation in any such organization must not affect Pfizer’s decision to approve or reject the funding request.
Accordingly, every colleague who participates as a regular member, officer, or board member of an external organization that requests funding from Pfizer (in the form of a sponsorship, charitable contribution, Special Event, or otherwise) must:

1. Make appropriate disclosures to the Legal reviewer responsible for reviewing the funding request. These disclosures must identify the colleague’s role in the organization and his or her involvement in the activity for which funding is being solicited (for example, participation on an event planning committee); and

2. Disclose to the organization, prior to the submission of a funding request that he or she is not participating in Pfizer’s review or approval of the request.

3. Where the funding request is principally based on the colleague’s relationship with the external organization, colleague must receive approval from Corporate Responsibility leadership in accordance with Corporate Policy #801a.

FOR MORE INFORMATION

- Sales Colleagues who need information about policies for funding Exhibit and Display opportunities can review Orange Guide Chapter 2: Interactions with HCPs and ED SOP2-01 – Exhibits and Displays Standard Operating Procedure available in OpSource under the “Funding Requests”.
- SOP on Funding Requests for Not-for-Profit Organizations (applies to U.S.-based colleagues in the Business Units, Pfizer Medical, and Corporate Affairs groups). For questions relating to this SOP, e-mail USFundingRequest@Pfizer.com. For specific questions relating to funding by Corporate Affairs, e-mail PolicyFRC@Pfizer.com.
- For other general information and training materials regarding Funding Requests, consult the Funding Requests tab on http://OpSource.Pfizer.com.
- For questions regarding medical education grants, e-mail IGLC@Pfizer.com or visit www.pfizer.com/independentgrants.
- For questions regarding (non-policy-focused) healthcare charitable contributions, e-mail healthcharitables@Pfizer.com or visit www.pfizer.com/healthcharitables.
• For questions regarding policy-focused healthcare charitable contributions, awards, scholarships, or fellowships, e-mail PolicyFRC@pfizer.com.

• For questions regarding “Special Events” funding (e.g., walk-a-thons, bike-a-thons, golf events, fundraising dinners, award ceremonies), e-mail publicaffairssupport@pfizer.com.

• Please refer to Orange Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure for more information on our funding disclosure obligations under the Sunshine Act.

• For more information on the Pfizer Foundation, refer to www.pfizer.com/responsibility.

• Refer other questions to your team attorney.
Chapter 4: FEDERAL EMPLOYEE INTERACTIONS
AND LOBBYING

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Chapter 4: FEDERAL EMPLOYEE INTERACTIONS AND LOBBYING

Introduction

This Chapter focuses on: (a) the important rules you must understand and follow when engaging in promotional and non-promotional activities with the Department of Veterans Affairs (VA), Department of Defense (DoD), and other federal employees; and (b) summarizes certain key Pfizer policies regarding lobbying registration and disclosure. This Chapter is relevant to any colleague who interacts with healthcare professionals (HCP) and formulary decision makers employed by the federal government (including interactions with any HCP employed by the VA or DoD) or who engages in lobbying activities with any elected or appointed state or federal government official or public employee (including state Medicaid agency employees and public hospital and government HCPs).

Each colleague is responsible for adhering to Pfizer's policies regarding interactions with federal employees and lobbying activities involving federal or state government officials and public employees. Non-compliance with these policies puts the Company at risk and can subject colleagues to disciplinary action up to and including termination of employment.

Federal Employee Interactions

As Pfizer’s sales to the federal government continue to increase, interactions with government officials (e.g., Director of Medicaid) and government employees (e.g., a physician at a federal institution or at a federal prison) are becoming common. Pfizer’s customers include federal government agencies and institutions, including the VA and its hospitals, the DoD and its medical facilities, and the Indian Health Service. Pfizer Sales Colleagues may interact with HCPs who work for these government agencies and institutions and who are employees of the federal government. Account Managers may interact with federal government employees who make decisions on formularies and purchasing.

Interactions with federal employees are governed by the Standards of Ethical Conduct established by the Office of Government Ethics (“Standards of Ethical Conduct”) as well as the local site policies of each institution. In the case of VA employees, your activities are even further restricted by the more
specific rules contained in Veterans Health Administration Handbook 1004.07 (“Financial Relationships Between VHA Healthcare Professionals and Industry”) and the update to Department of Veterans Affairs 38 CFR § 1.220 and VHA Handbook 1108.10 (“Drug and Drug-Related Supply Promotion by Pharmaceutical Company Sales Representatives at VA Facilities”). As a result, promotional activities that are permissible when conducted with HCPs who do not work for the federal government may be prohibited when these same activities are conducted with HCPs who work for the federal government.

**Department of Veterans Affairs (VA):** Federal agency that provides patient care, services, and benefits to U.S. veterans.

**Department of Defense (DoD):** Federal agency that oversees the four branches of the U.S. military (Army, Navy, Marine Corps, and Air Force).

**Indian Health Service (IHS):** Federal agency that is responsible for providing federal health services to American Indians and Alaska Natives.
**Key Points to Ensure Compliance**

- Always check local IHS, VA, or DoD site rules, which may be more restrictive than the guidelines set forth in this Chapter.

- For non-VA Facilities, if local site rules permit providing meals, then the following conditions must also be met:

  **On-site at IHS and DoD Facilities:**
  - Meals may not be offered on a regular, repeated, or routine basis to an HCP or group of HCPs;
  - The total value of a single meal cannot exceed $20 per HCP;
  - The total value of all meals, gifts, and educational items from any one source during a calendar year cannot exceed $50 per HCP – note that Pfizer, not each individual colleague, is considered the source; and
  - IHS and DoD employees must confirm in advance that they are permitted to accept an in-office or in-hospital meal under the Standards of Ethical Conduct and the local site rules.

  **On-site at VA Facilities:**
  - You may not provide meals of any type or value to VA staff (including volunteers) or bring food into VA facilities for use by non-VA staff even if given approval by staff.

  **Speaker program meals:**
  - Speaker program meals may only be provided to an HCP employed by a federal institution in connection with a “widely attended gathering” as described in this Chapter.

  **Modest refreshments:**
  - Modest refreshments can be offered to federally-employed HCPs (except for VA employees and volunteers on VA sites) when incidental to a scheduled meeting or legitimate educational interchange not otherwise prohibited by the facility or local rules. Modest refreshments are not considered “gifts” and do not count toward the $50 annual cap for each government HCP. However, if you offer them as part of a meal, then they will count towards the $50 annual cap and will be considered a “gift.” Also, modest refreshments offered on a regular, repeated, or routine basis will be seen as a violation of the ethics rules.

  **Gifts:**
  - Note that whether considered a gift or not, any item of value, including refreshments, provided to a U.S.-licensed physician may be reportable under relevant state laws and/or the Sunshine Act. Additionally, always check the State Laws: HCP and State Employee Restrictions chapter for additional guidance on what is allowed and what will be reported.
Key Points to Ensure Compliance

- Only Review Committee approved (RC-approved) nominally priced educational materials may be provided to a government HCP. It is your responsibility to ensure that the annual aggregate value of all meals and educational items to a government HCP from Pfizer does not exceed $50 annually.

- At VA facilities, you must also submit the RC-approved educational materials to the Chief of Pharmacy Services at least 60 days prior to your educational program or meeting. Additionally, absent permission from VA Pharmacy Benefits Management Service, patient education materials may not contain the name or logo of the manufacturer or promote a specific medication.

- You must learn the sample policies of any institution that you call on and follow those rules, unless they conflict with Pfizer policy or the Prescription Drug Marketing Act (PDMA).

- Federally-employed HCPs may be hired to speak on Pfizer’s behalf only if they receive prior approval by their agency before accepting such an outside engagement and if the HCP:
  - Determines that the speaking engagement does not conflict with his or her official duties;
  - Is speaking in his or her individual capacity and not as an employee of the government;
  - Is not using his or her government position or title to identify himself or herself at the speaker program;
  - Is speaking because he or she is a subject matter expert on a topic;
  - Is not speaking on a matter pending before his/her government agency or institution, or any matter which the employee was assigned during the previous one year period;
  - Is taking personal time to speak rather than speaking during government time; and
  - Is not disclosing any non-public or government confidential information.
Promotional Activities

Impact of Formulary Status on Ability to Promote

Sales Colleagues must comply with any federal institution’s local requirement that only products on formulary or those that comply with VA’s criteria-for-use be discussed with its HCPs. Products that are not on the VA National Formulary must be specifically approved by the Veterans Integrated Services Network, the Chief of Pharmacy, or a designee before engaging VA employees in discussions on the product. In some cases, local regulations will prohibit any discussion of products that are either not on the institution’s formulary or that are on the formulary with restrictions. In all cases, you must accurately and clearly represent the formulary status of the product being discussed.

Promotional Materials

You must make an appointment with individual HCPs prior to calling on VA facilities. Promotional materials to be referenced on a VA site must be approved by the VA medical facility’s Chief of Pharmacy Services or designee. Do not leave promotional materials in patient areas. In addition, be aware of rules pertaining to how you are expected to conduct yourself when leaving promotional materials for HCPs at federal institutions. For example, VA facilities do not permit marketing to students (including residents), and do not permit paging employees via a public address/paging system unless specifically asked by the employee, or waiting in patient-care areas.

Starters

Many government institutions, such as VA clinics and hospitals, may prohibit pharmaceutical companies from leaving starters. As noted above, you must always learn the sample policies of any institution that you call on and follow those rules, unless those rules conflict with Pfizer policy or the PDMA. If a Sales Colleague has questions about whether a customer’s sample policies are consistent with Pfizer policies on starter distribution, contact Starter Administration or your team attorney before leaving starters with that customer.

Even if intended for use in private practice, starters shall not be left for VA DoD HCPs at the government institution in which they work. “Free goods” may only be provided to the VA as a donation.
as long as they are delivered through the VA’s normal channel of distribution (i.e., not from Sales Colleagues directly to HCPs).

**VA Appointment Requirement**

Q. Do Sales Colleagues have to make an appointment before calling on HCPs who work at VA facilities?

A. Yes. Under the new VA rules, VA institutions have incorporated this requirement into their local site rules. Additionally, once on-site you may only detail HCPs with whom you have made an appointment.

**Providing Starters to the VA**

Q. I've been told by an HCP at a VA facility that pharmaceutical companies can not leave starters with the Chief of Pharmacy at the VA. Why does Pfizer’s policy prohibit this?

A. VA policy permits “free goods” to be donated to the VA, but to do this, the free goods must be delivered through the VA’s normal channel of distribution – not from Sales Colleagues. In addition, in most cases, the donation must be pre-approved by the Chief of Pharmacy and the local P&T Committee and the starters cannot be labeled as professional samples. The distribution of starters to VA facilities by Sales Colleagues does not comply with this policy and is prohibited.

**Gifts to Federal Employees (HCPs at IHS, DOD, and VA Facilities)**

Under federal gift rules, a federal government employee may not accept any single gift that has a retail value of more than $20, nor can a federal government employee accept an aggregate value of more than $50 in gifts (retail value) from a single “source” given over a consecutive 12 month period. Pfizer, not each individual colleague, is considered the “source” of the gift when determining whether the $50 limit has been reached. To ensure that Pfizer maintains compliance with the federal rules at all times, the only “gifts” that colleagues can provide to federal employees, including HCPs are Pfizer approved educational items and modest meals under the circumstances outlined in this Chapter.

**Meals in Connection with Promotional Presentations**

Sales Colleagues must review the local site rules of any IHS, DoD, or other federal healthcare facility (excluding the VA) to determine whether in-office or in-hospital meals are permissible. When meals are
permitted by local rule, in addition to following any site rules, you must also ensure the following conditions are met:

- Meals are not offered on a regular, repeated, or routine basis to an HCP or group of HCPs;
- Each meal has a total value of $20 or less;
- The aggregate value of all meals, gifts, and educational items given by Pfizer to an HCP during a calendar year does not exceed $50;
- The meal takes place at the HCP’s office or hospital when hosted by a Sales Colleague; and
- The IHS or DoD employee confirms that he or she is permitted to accept the in-office or in-hospital meal under the Standards of Ethical Conduct and local site rules.

**Note:** The VA rule on Drug and Drug-Related Supply Promotion by Pharmaceutical Company Sales Representatives at VA Facilities prohibits colleagues from providing in-office or in-hospital meals to HCPs employed by the VA or their staff (including volunteers).

Sales Colleagues must coordinate with each other to ensure that in total, Pfizer does not provide more than $50 of value per HCP per year for meals, gifts, and educational items.

Remember that any meals and educational items provided to HCPs employed by the VA, DoD, or any federal government institution will be subject to Pfizer’s HCP Payment Disclosure Policy. All HCPs, including those employed by the VA and DoD, may “opt-out” of receiving these items by notifying their Sales Colleague or by contacting PTI@Pfizer.com. For additional information on Pfizer’s HCP Payment Disclosure Policy, see Chapter 18: Meals, Educational Items, and HCP Payment Disclosure.

**Meals in Connection with Speaker Programs**

Meals may also be provided to HCPs employed by the federal government (including VA employees) as part of an off-site educational speaker program that is a “widely attended gathering” as determined by the hosting colleague and with approval of the colleague’s manager. In order to qualify as a “widely attended gathering” under Pfizer guidelines and the rules of the Office of Government Ethics:

- Attendance at the speaker program must be open to non-federal employees;
- A large number of people must be expected to attend;
• Persons with a diversity of views or interests must be expected to attend (e.g., persons from more than just one practice, specialty area, government agency, and/or a mix of government and commercial employees); and

• The government agency or branch the employee works for must determine that his/her attendance will further agency programs and operations.

In addition, the meal must be provided in connection with a legitimate educational speaker program that:

• Satisfies Pfizer’s standards for a speaker program as set forth in Orange Guide Chapter 9: Speaker Programs for HCPs; and

• Is not offered on a regular or repeated basis to a federal government-employed HCP.

If you are ever in doubt as to whether an event satisfies the “widely attended gathering” standard, check with the ethics counselor for the relevant government branch, and/or contact the relevant team attorney. If an HCP you know to be an employee of the federal government indicates (by formal RSVP or otherwise) that he or she is coming to a speaker program you are planning, you must confirm with that HCP that his or her agency or branch has determined that attendance at the program is in the branch’s interest.

**Lunch and Learn**

Q. A Sales Colleague would like to call on an HCP employed by the VA who has a busy schedule. Because of her crowded schedule, the HCP has offered to meet with the representative during her lunch hour every other Tuesday. May the representative have a “lunch and learn” with the HCP in their office on alternating Tuesdays and bring a modest lunch for the HCP, such as a sandwich and soda?

A. No. VA Rules prohibit you from providing a meal to VA employees at a VA facility, even if the office staff gives approval for you to do so. Additionally, if the Sales Colleague and the HCP wanted to meet in a neutral location the OGE gift rules apply even if the meal was provided off-site, because the HCP is still a federal employee. Thus, the value of the meal would count towards the $20/$50 gift cap.
Speaker Program Meals

Q. A Sales Colleague has invited a DoD HCP to a speaker program that qualifies as a “widely attended gathering.” If the DoD HCP attends the speaker program after confirming in writing with her employer that attendance is in the best interest of the agency, is it permissible for the DoD HCP to receive the same meal as the other attendees if it’s more than $20 in value? Or, is Pfizer required to provide a meal of $20 or less in value?

A. If a VA or DoD HCP attends a widely attended gathering with the permission of their employer, the meal is considered exempt from the federal gift limitations.

Part-Time VA Employees

Q. One of my customers works three days a week at his private practice and two days a week at a VA hospital. When I provide him meals at his private office, am I required to follow the VA/DoD limitations set forth in the Orange Guide?

A. It depends. HCPs who work part-time for the VA are still required to follow the policies of the VA as if they are full-time employees. You should verify with your customer if he or she is employed by the VA, or if he or she is an independent contractor, in which case the rules governing interactions with VA employees may not apply. If your customer is an independent contractor or if you are not sure of his status, check with the ethics counselor of the government facility and/or your team attorney to ensure compliance.

Educational Items

Remember that when given to an IHS, VA, or DoD HCP, the value of an RC-approved (or VA-approved, as necessary) educational item may not exceed $20 and the total aggregate of all gifts (meals and educational items) for the calendar year to each HCP cannot exceed $50. Colleagues must coordinate with each other to ensure that, in total, Pfizer does not provide more than $50 of value per HCP per year for meals, gifts and educational items.
Compliance Responsibility

Q. 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 he is in compliance with applicable gift rules? How can Pfizer get in trouble?

A. It depends. Both the HCP and Pfizer have responsibilities under the federal gift rules. If Pfizer provides a gift to a federal HCP, it may trigger certain reporting obligations for Pfizer. In addition, providing the gift may violate the local institution's policies and result in Pfizer being excluded from the facility. Accordingly, at no time should you ever provide an HCP employed by the federal government with any gift or meal, except as described in this Policy, even if the item has been approved for distribution to non-government HCPs or the item is requested by the HCP. If you are ever in doubt, treat the HCP as if he or she was a government employee and follow the applicable rules herein and at the HCP's local facility.

Non-Promotional Activities

Selecting HCPs Employed by the Government as Speakers

HCPs employed by the federal government are generally prohibited from accepting compensation for speaking engagements that relate to the employee's official duties. This includes receiving compensation to speak to other HCP government employees on behalf of Pfizer. In limited circumstances, HCP federal employees may be compensated to speak on Pfizer's behalf if they are permitted by their government agency or institution to accept outside consulting engagements and they:

- Are speaking in their individual capacity and not as part of their official duties;
- Are speaking because they are a subject matter expert on a topic and not because of their official position;
- Are not speaking on a matter pending before their government agency or institution;
- Are speaking on their personal time rather than government working time; and
- Are not conveying information which draws on ideas or official data that is nonpublic information.
Before seeking to engage a speaker who works in any capacity for a federal government agency or institution, Sales Colleagues must first verify that the speaker has received prior approval from their agency or institution.

### Engaging Part-Time Government Employees as Speakers

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

A. Yes, provided the conditions listed above are met. HCPs who work part-time for a federal government agency are still required to follow the policies of that agency as if they are full-time employees. Of course, all of Pfizer policies related to engaging HCPs as speakers and properly conducting speaker programs must be followed.

### Supporting Independent Medical Education

Federal government agencies and institutions often ask Pfizer to support their independent medical education programs. Pfizer may be permitted to support these activities through independent educational grants. Grant requestors must submit all requests for funding through [www.pfizer.com/independentgrants](http://www.pfizer.com/independentgrants). Requests will be reviewed according to Pfizer's standards for supporting independent medical education. For more information on Pfizer's educational grant process, refer to [http://ecf.pfizer.com/sites/eSOPPortal/Lists/Index/MEG.aspx](http://ecf.pfizer.com/sites/eSOPPortal/Lists/Index/MEG.aspx) for MEG01-POL (“U.S. Medical Education Grants Policy”) and MEG01-GSOP (“Processing of U.S. Medical Education Grants SOP”) for further details.

### Lobbying

Federal and state lobbying laws regulate interactions with government officials and public employees that are intended to influence legislation, regulations, or government policies. Pfizer is required by federal law and many state laws to disclose publicly its lobbying expenditures on a regular basis.

#### Federal Lobbying

The Federal Lobbying Disclosure Act (LDA), as amended by the Honest Leadership and Open Government Act (HLOGA), requires Pfizer to report expenses incurred for all its federal lobbying
activities. This includes not only time and expenses spent by those Pfizer colleagues who are registered as federal “lobbyists,” but also time and expenses of those Pfizer colleagues who support Pfizer’s federal lobbying effort.

Pfizer’s grassroots advocacy programs present additional opportunities for colleagues to interact with government officials and public employees about healthcare policy. To help ensure that Pfizer complies with all registration and reporting requirements, all of your interactions with government officials must be coordinated either through the Pfizer Grassroots program, the Washington, D.C. office, or a Pfizer State Government Relations Director (GRD), depending on the nature of the interaction.

Like the rules that govern your interactions with healthcare professionals, lobbying, ethics, gift, and campaign finance laws regulate interactions with government officials and sometimes public employees as well. In addition to becoming familiar with the information in this Chapter, you should check with your GRD, or team attorney about the relevant laws in your region, since the specific state or local laws applicable to you may vary depending upon the state in which you work.
**Key Points to Ensure Compliance**

- Only RC-approved (and, in the case of the VA, approval by the VA medical facility’s Chief of Pharmacy Services or designee) nominally-priced educational materials may be provided to a government HCP.

- Government officials may be given RC-approved educational materials only—gifts of any value, including meals, are prohibited.

- Public employees may be given approved educational materials subject to each institution’s policies and applicable law.

- Every communication with a state government official or his or her staff must be coordinated through the relevant GRD. Communications with federal government officials or staff must be coordinated through the Washington, D.C. Pfizer office.

- Sales Colleagues should spend no more than one hour per week or four hours per month, if at all, on political activities related to Pfizer business.

- Do not suggest, offer or provide campaign contributions in exchange for a promise to perform any official act.

- Pfizer must report certain expenditures made towards lobbying efforts to the federal government as well as many state governments.

- Even if you are not a “lobbyist,” your time spent supporting the lobbying efforts of others within the Company is reportable under federal law.

- Each state’s reporting requirements are different – be sure to check with your GRD or team attorney if you are unsure whether you need to register as a lobbyist and/or which activities must be reported.

- For more information on state specific restrictions on interactions with state-employed HCPs, see the State Laws: HCP and State Employee Restrictions Chapter.
Who Is a “Lobbyist?”

Under the federal law, a “lobbyist” is any individual who is employed by Pfizer and has: (1) made more than one “lobbying contact” within a three-month period; and (2) spends at least 20% of his or her time engaged in lobbying for Pfizer in that three-month period.

This pertains only to Pfizer colleagues and not to independent contractors retained by Pfizer. A “lobbying contact” is any oral or written communication, including e-mail, with certain executive and legislative branch employees made with regard to federal legislation, a rule, regulation, or any other program, policy or position of the U.S. Government. Affected executive and legislative branch employees include Members of Congress and their staff, the White House, Secretary and Deputy Secretary positions within the federal agencies, and some members of the military.

Most Pfizer colleagues do not qualify to be registered as lobbyists because they do not spend 20% of their time “lobbying” during the reporting period (three-month intervals); however, it is important to remember that even if you are not a “lobbyist,” federal law requires Pfizer to report your time spent supporting the lobbying efforts of others within the Company.

Calculating Lobbying Contacts

Q. I am a Public Affairs colleague. I called Congressman A’s office and spoke with a member of his staff to request the congressman call me back. Two days later, the congressman returned my call, and I explained I was calling about access to medication for the elderly, and we set up a time to meet. Does this count as two “lobbying contacts” for purposes of determining whether I am a lobbyist under federal law? I thought requesting meetings did not count as lobbying?

A. This would likely count as one lobbying contact. The purpose of your first call was to contact the congressman, which you were unable to do. On the second call, however, you did speak with the congressman, and you explained the purpose of your call, which was to discuss some aspect of federal law or policy. While you did call to set up a face-to-face meeting, you also discussed policy issues during the telephone call. The two telephone calls would be considered one lobbying contact and the in-person meeting would count as a second lobbying contact.
Determining Time Engaged in Lobbying Activities

Q. I am a Public Affairs colleague. From time to time, I call congressional staff members and ask a series of prepared questions to gauge perceptions of healthcare issues or policy perspectives. Does the amount of time I spend on those calls factor into the 20% threshold for registering as a lobbyist?

A. It depends. If the questions pertain to the status of legislation affecting Pfizer’s interests, the calls may have been made in an effort to influence the congressional members for whom the staff members work, and the calls therefore would be considered lobbying contacts. If the questions constitute routine information-gathering and there is not an attempt to influence a covered official, then the communications will not amount to lobbying contacts. If you are unsure if your call would count towards the 20% threshold, please consult your GRD or team attorney. Remember, even if you do not qualify as a “lobbyist,” you still may need to keep track of your time spent on some of these types of activities for the Company’s federal lobbying disclosure report.

What Is Lobbying?

The LDA defines “lobbying activities” as lobbying contacts, as defined above, and any efforts in support of these contacts, including preparation and planning activities, research, and other background work intended for use in lobbying contacts. Reportable expenses include time spent by Pfizer colleagues in meetings with federal officials for the purpose of influencing federal laws, regulations or policies, and expenses incurred in connection with lobbying, such as expenses for travel, lodging or food. Pfizer is required to file quarterly reports that provide a list of the specific issues that were addressed by “lobbying activities” and an estimate of the total expenses incurred in connection with these lobbying activities.

Although most Pfizer colleagues do not qualify as “lobbyists,” the time Pfizer colleagues spend in supporting the lobbying efforts of others within the Company is reportable, including:

- Developing “talking points” or “white papers” if they are used for lobbying purposes;
- Attending internal meetings or discussions regarding lobbying strategy (e.g., identifying federal officials who should be targeted or developing and testing messages);
• Fees paid to outside consultants for analyses, studies, or reports, if they are used for lobbying;
• Negotiating contracts with government agencies;
• Providing educational information or materials to influence government formulary decisions; and
• Promotional interactions with certain state hospital administrators or HCPs.

The federal definition of lobbying does not include:

• Drafting and developing comments to proposed regulations in a formal agency rulemaking proceeding;
• Representing Pfizer in an agency adjudicatory matter or criminal proceeding;
• Drafting legislation, regulations, or legal analyses (applicable to attorney work-product only);
• Preparing for and providing “on the record” testimony in a congressional or agency hearing;
• Communicating with government officials as part of Pfizer’s Grassroots advocacy program;
• Requesting a meeting with a congressional or agency official or his or her staff, if the request does not include an attempt to influence the official; and
• Responding to a request by an official for reports, information, statistics, subpoenas, or similar documents.

Pfizer’s Grassroots advocacy program works to inform and educate colleagues on public policy issues, and provide colleagues the opportunity to engage in policy debates by making their voices heard in Washington, D.C. and state capitols across the country. There may be other activities developed by other teams that involve interaction with government officials or public employees and would be subject to the Pfizer policies in this Chapter.

To help ensure that Pfizer complies with all registration and reporting requirements, all of your interactions with state government officials must be coordinated through a GRD. Interactions with federal government officials must be coordinated through the Washington, D.C. Pfizer office. If calling
on HCPs who work for a state or federal facility or institution, check with your team attorney to find out whether your promotional activities are considered “lobbying” in your state.

### Lobbying Do's and Don'ts

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<th>Do</th>
<th>Don't</th>
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<tbody>
<tr>
<td>Provide only RC-approved educational materials to government officials.</td>
<td>Discuss Pfizer products or specific Pfizer activities.</td>
</tr>
<tr>
<td>Coordinate all your activities with government officials through your GRD.</td>
<td>Spend more than one hour per week or four hours per month, if at all, on lobbying activities related to Pfizer business.</td>
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<tr>
<td>Report your lobbying activities as required.</td>
<td>Experiment or try something new without checking with your GRD or team attorney.</td>
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### Reporting Lobbying Time and Expense

As discussed in this Chapter, the laws in the state in which you work will determine whether you are engaged in “lobbying” activities which require Pfizer to register the time and expenses related to them.

If you have been engaged in federal “lobbying activities,” you must track and report the following on the form available at [http://ecf.pfizer.com/sites/LobbyingDisclosureReporting](http://ecf.pfizer.com/sites/LobbyingDisclosureReporting).

- A reasonable estimate of the time spent on lobbying activities, rounded to the nearest hour;
- A description of the specific activity;
- The policy topic(s) worked on; and
- Any expenses associated with these efforts.

You can take a quick [training module for the online form](http://ecf.pfizer.com/sites/LobbyingDisclosureReporting) on how to use the form. You should fill it out only when you have engaged in federal lobbying activity. **Do not** fill it out when you have engaged in state lobbying activity (see the section on state-specific Laws below). The information from the online form is collected for the Company’s quarterly federal LDA reports which are filed on April 20th, July 20th, October 20th, and January 20th of each year with both the U.S. House of Representatives and the
U.S. Senate. **If you have engaged in federal lobbying activity during a reporting period, please make sure you complete an online form no later than one week after the close of the reporting period, or by April 7th, July 7th, October 7th, and January 7th.**

**Determining Time Engaged in Lobbying Activities**

**Q.** When I fill out Pfizer’s lobbying form, I have to include the issue that pertained to the lobbying efforts I supported. If the work I did was about a particular Senate bill, can I just write the bill number?

**A.** No, while the bill number must be reported under the law, the number alone is not a sufficient description of the issue for purposes of disclosing Pfizer’s lobbying activity and filing the federal report. You should try and be as specific as possible, and include, in addition to the bill number, the bill’s name, the bill title and/or section heading if one exists, and the specific provisions that were the subject of your work.

If ever in doubt, consult with a GRD, the Washington, D.C. Pfizer office, or your team attorney to verify whether your activities subject you to registration or reporting requirements.

**Gifts to U.S. Government Officials**

Like the PhRMA Code’s guidelines on gifts to HCPs, almost all states and the federal government prohibit or restrict officials and their staff from accepting gifts from outside sources.

Pfizer colleagues are prohibited from giving any gift to a government official, no matter how inexpensive. Prohibited gifts include meals (food and beverage), travel, lodging, and entertainment. The only items that may be provided to government officials are RC-approved educational materials of nominal value.

**Gifts to Public Employees**

HCPs in government institutions, such as VA hospitals or federal or state prisons, are considered to be public employees. Unless otherwise restricted by state law or a particular institution’s policies (such as with the VA), Pfizer policy permits Sales Colleagues to provide public employees with RC-approved and nominally priced PhRMA Code compliant educational items. For more information on state specific laws, see the State Laws: HCP and State Employee Restrictions Chapter. If you have any questions about whether an item can be left with a public employee, consult with a GRD or your team attorney.
Leaving Educational Items with Public Employees

Q. If I leave RC-approved, nominally priced educational (PhRMA Code compliant) items with an HCP at a federal prison, do I have to track it? What about a state prison system?

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

HCPs Who Sit on State Formulary Committees

Q. One of the physicians I call on also happens to sit on a state formulary review committee. If I am calling on this physician to discuss his private practice only, and not his role on the state formulary review committee, must I treat him differently than any other physician who does not sit on a formulary committee?

A. Maybe. The extent to which HCPs who sit on state formulary committees can interact with pharmaceutical representatives varies widely, depending on the specific laws in your state. Check with the relevant team attorney to ensure your interactions are compliant with applicable state law.

State-Specific Laws

There are two types of lobbying disclosure laws enacted by states that may require you to record and report certain information. The first category is similar to the federal LDA and requires Pfizer to report on a regular basis the lobbying activities undertaken in or directed towards a particular state. The second category affects colleagues who meet with certain state officials or state employees.

States’ General Lobbying Disclosure Laws

Pfizer has a State Government Relations program which is active in almost all 50 states. As part of this effort, certain Pfizer colleagues have registered as lobbyists and have reporting requirements similar to those on the federal level. The laws differ in each state. Depending on the particular state law, if you participate in Pfizer’s Grassroots advocacy programs and other interactions with state government officials or public employees, Pfizer may be required to register you as a lobbyist or make certain
disclosures about your activities. If you have questions regarding whether your participation in state lobbying activities triggers disclosure requirements, you should consult with the GRD responsible for the state. If the GRD determines that you are required to disclose your activities, you will receive a compliance form or timesheet to complete.

Reportable lobbying activities and expenses may include:

- Meetings with government officials or staff;
- Time spent reviewing policy issues in preparation for a meeting with government officials;
- Time spent communicating, including by letter or e-mail, with government officials about policy issues; and
- Any food, travel, lodging, or other expenses you may incur while engaged in lobbying activities.

State procurement or contract lobbying laws may also apply to you if you are involved with the sale of Pfizer products to state institutions (such as public hospitals and state prisons) or their reimbursement through state agencies (such as Medicaid). These laws seek to prevent inappropriate influence over state employees responsible for purchasing products with taxpayer money.

While procurement and contract lobbying laws vary from state to state, most involve registering individuals who interact with state officials regarding state purchase contracts and disclosing lobbyist compensation and lobbying expenses incurred, such as meals (food and beverage), travel, and lodging. To ensure appropriate tracking and disclosure, check with a GRD or your team attorney before engaging in these or related activities.

**States’ Lobbying Laws Impacting Marketing**

Several states have enacted laws that require pharmaceutical representatives who interact with state officials or state employees to register with the state and report their “lobbying” expenditures. In particular, numerous states have laws under which marketing activities involving Medicaid Pharmaceutical and Therapeutics Committee members may be considered lobbying. For example, when certain threshold limits are met, Louisiana requires pharmaceutical representatives to register...
with the Board of Ethics and file semi-annual reports detailing expenditures as they relate to marketing activities directed towards members of the Medicaid Pharmaceutical and Therapeutics Committee.

In Colorado, an amendment to the Colorado Constitution prohibits individuals considered lobbyists from giving anything of value, including gifts and meals, to government employees. Various other states, and even counties, also have lobbying registration and disclosure requirements (e.g., New York and Miami-Dade County, Florida). To ensure that expenses and interactions are properly tracked, please consult with the relevant team attorney before engaging in any marketing interactions with state or local government employees.

State Formularies

Attempts to influence state formulary decisions are currently considered lobbying in many states. As a result, registration and/or reporting may be required. If you are interacting with members of a state committee or agency that make decisions with respect to their state’s formulary you should check with the GRD with responsibility for that state prior to those interactions to determine whether any of your activity could be considered lobbying.

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

Campaign Contributions

It is important to understand the difference between lobbying and grassroots advocacy efforts and campaign contributions. Lobbying and grassroots advocacy efforts are intended to influence government policy. Campaign contributions are intended to influence campaigns and elections.

While corporations like Pfizer are permitted to lobby government officials, federal and various state laws prohibit corporations from making financial contributions to support a candidate’s election. This prohibition applies to both monetary and “in kind” donations, such as employee time and the use of corporate resources on behalf of a campaign committee.
In addition, federal and state anti-bribery laws impose criminal penalties for offering gifts or campaign contributions to government officials in exchange for a change in policy, entering into a federal or state contract, or agreeing to engage in any other official act.

For this reason, you are prohibited from discussing past, present, or future campaign contributions with a government official or public employee.

The Pfizer Political Action Committee

Corporations are not allowed to make direct contributions to any candidates running for federal office, and similar restrictions may apply in certain states as well. However, corporations can sponsor Political Action Committees (PACs), which are supported by voluntary contributions from eligible employees. These corporate-sponsored PACs can then contribute directly to candidates running for federal office and for state office where applicable. A PAC is subject to federal laws and regulations, reporting requirements, and monetary limits on campaign contributions.

Pfizer sponsors a PAC. The Pfizer PAC is a non-partisan committee that supports candidates who value biopharmaceutical innovation and are open to real dialogue on issues that affect patient access to medicines. For more information on the Pfizer PAC, please visit http://sharepoint.pfizer.com/sites/USGovernmentRelations/SitePages/Home_New.aspx.

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

FOR MORE INFORMATION

- Lobbying questions may be referred to the relevant GRD, the Washington, D.C. Pfizer office, or team attorney.
- For more information on state specific laws, see the State Laws: HCP and State Employee Restrictions Chapter.
- For more information on Pfizer’s HCP Payment Disclosure Policy, see the Meals, Educational Items, and HCP Payment Disclosure Chapter.
- For more information on Pfizer’s educational grant process, refer to http://ecf.pfizer.com/sites/eSOPPortal/Lists/Index/MEG.aspx for MEG01-POL (“U.S. Medical Education Grants Policy”) and MEG01-GSOP (“Processing of U.S. Medical Education Grants SOP”).

- For more information about the Pfizer PAC, visit https://governmentrelations.pfizer.com.
- Take the online training module (training module for the online form) on how to complete the federal Lobbying Disclosure form.
- Federal Employee Interaction questions may be referred to your lead BU National Account Manager or team attorney.
- For more information regarding on-site activities at VA facilities, see the March 2012 Legally Speaking article found on the Compliance page of PfieldNet.
# Chapter 5: INTERACTIONS WITH HEALTH SYSTEMS and MEDICAL GROUPS

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Chapter 5: INTERACTIONS WITH HEALTH SYSTEMS, AND MEDICAL GROUPS

Introduction

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

This Chapter summarizes key Pfizer policies regarding interactions by Field Commercial Colleagues with Health Systems. The purpose of this Chapter is to provide guidance to those colleagues who interact with key decision makers at these customers at an account level rather than at the prescriber or individual HCP level. In particular, this Chapter focuses on Account Managers, including Key Account Manager (KAMs), Oncology Key Account Managers (OKAMs), Specialty Account Directors (SAS NADs) and Vaccines Account Managers (VAMs), but the policies apply to all Field Commercial Colleagues to the extent they engage a Health System at the account level. Non-compliance with these policies puts Pfizer at risk and can subject colleagues to disciplinary action up to and including termination of employment.

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

If the application of any policy is unclear to you, discuss the issue with your manager or your team attorney.
Key Points to Ensure Compliance

- When interacting with Health Systems, you are required to follow the policies found in the Orange Guide, including the four core compliance principles:
  - Use only approved materials and selling statements;
  - Stay on-label and discuss only approved products and indications;
  - Provide an accurate and balanced presentation; and
  - Never engage in actual or perceived quid pro quo.
- You may use approved materials and offer approved tools and services, as described in this Chapter. It is your responsibility to ensure the material you intend to use has received appropriate approval before use with customers, and that the material remains current and approved for your intended use. If you are at all unsure about whether material is approved for use with a particular customer, you should check with your team attorney. Additionally, ensure that you use the materials in accordance with any guidance or instructions provided relating to the use of such materials.
- It is not appropriate to modify an RC-approved piece and use it with a customer. It also is not appropriate to use a presentation only approved for use for a specific use with another customer.
- Carefully consider messaging and execution risks, even when not discussing products. Discussions with customers about disease state areas can also present a risk of inappropriate promotion, particularly where the disease states discussed are broader than any approved Pfizer product indication or where a Pfizer product is the only treatment option available.
- Do not discuss a product or disease state with a customer unless you have completed the required training for that product or disease state.
- When proposing collaborations, ensure Pfizer is getting appropriate value in the transaction. The value Pfizer is receiving should be obvious, tangible, and measurable. The value received by Pfizer should be commensurate with the value provided by Pfizer under the collaboration. Goodwill, improved relationships, increased prescribing or product utilization, and improved access to customers do not constitute appropriate value to Pfizer in the context of a collaboration. Use the FMV Calculator Tool to assist with determining FMV available on the Customer Marketing SharePoint Site or the Internal Assessment Guide available on the PfieldNet Compliance page, to assist in determining the fair market value of contributions.
**Key Points to Ensure Compliance**

- Do not discuss the formulary status of a Pfizer product or increased product utilization as part of a collaboration.
- When providing approved tools or resources, do so without any expectation of financial return to Pfizer.
- Do not condition the offer or provision of a program on increased prescribing or improved formulary status.
- To avoid implicating pricing and potential kickback concerns, avoid combining different types of transactions. Do not discuss grants, service agreements, Organized Customer and Payer tools and resources, or other items of value in connection with formulary discussions. Do not link or reference the terms of Pfizer’s commercial rebate agreement when negotiating a collaboration or a service agreement. If the customer tries to link these topics inform them that Pfizer has a strict policy against doing so and immediately inform your team attorney.
- Do not attempt to leverage any additional (e.g., non-formulary) arrangements in order to secure preferential formulary status.
- Do not engage or get involved in medical activities that Field Medical colleagues such as Medical Outcomes Specialists (MOS) typically engage in and are responsible for, such as conducting a customer data evaluation (CDE) for a customer.
- Ensure that collaboration proposals and other projects are aligned with public health objectives that are of interest to Pfizer by consulting with the relevant internal stakeholders including Medical, the relevant brand team, the Customer Marketing-Payer and Channel Access group, and Legal.

**Core Compliance Principles**

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

- Use Only RC-Approved Materials;
- Stay On-Label and Discuss Only Approved Products and Indications;
- Provide an Accurate and Balanced Presentation; and
- Never Engage in Actual or even a Perceived Quid Pro Quo.
The importance of using only approved materials and not engaging in actual or perceived quid pro quo in the context of engaging Health Systems is discussed in greater detail below. For further discussion of staying on-label and providing fair balance, please see Orange Guide Chapter 2: Interactions with HCPs.

**Approved Materials**

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

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

<table>
<thead>
<tr>
<th>Material</th>
<th>Approval Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product-specific material, not approved by an RC in part or in whole.</td>
<td>Requires the approval of the relevant product attorney (or specific product RC, as determined by the relevant product attorney).</td>
</tr>
<tr>
<td>Disease area materials, not approved by an RC in part or in whole.</td>
<td>Depends upon the content. Consult with your team attorney to help determine the appropriate approval process and who can facilitate coordination with product attorneys, as necessary.</td>
</tr>
<tr>
<td>Any modification of already approved materials.</td>
<td>Generally must be brought back through the original approval process for review and approval. However, circumstances may warrant exceptions, so you should work with your team attorney.</td>
</tr>
<tr>
<td>Material</td>
<td>Approval Requirements</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Information that is publicly available.</td>
<td>Requires RC approval for external use.</td>
</tr>
<tr>
<td>E-mail or text to a customer concerning logistical issues (such as to schedule or confirm an appointment) consistent with the guidelines in Orange Guide Chapter 2: Interactions with HCPs.</td>
<td>Approval not required.</td>
</tr>
<tr>
<td>Beyond logistical correspondence (consistent with Orange Guide Chapter 2: Interactions with HCPs), e-mail or text messages to a Hospital System customer mentioning a product or therapeutic area.</td>
<td>Requires the approval of the relevant product attorney (or specific product RC, as determined by the relevant product attorney). Approval is not required so long as the correspondence does not mention a product or make substantive statements about the therapeutic area or disease state. If you have questions or would like to request an exception, consult your team attorney.</td>
</tr>
<tr>
<td>Account manager e-mail of a contract containing the product name.</td>
<td>Approval of the e-mail is not required so long as the draft contract is approved for dissemination and there is no commentary that is or can be perceived as a product claim.</td>
</tr>
<tr>
<td>Customizable RC-approved template, with the ability to fill in blank fields with simple “plug in” information specific to the customer (e.g., customer name and address).</td>
<td>No additional legal approvals required to use with customer, as intended by RC. Consult with your team attorney if you are at all unsure.</td>
</tr>
<tr>
<td>Approved, entirely unmodified materials, that are customer-specific.</td>
<td>Generally must be approved for use with a different customer. However, circumstances may warrant exceptions, so you should work with your team attorney.</td>
</tr>
<tr>
<td>Approved, entirely unmodified materials, that are not customer-specific.</td>
<td>Additional approvals are not required, but it is your responsibility to ensure that the materials were approved through the appropriate channels and remain current and approved for your intended use. Consult with your team attorney if you are unsure.</td>
</tr>
</tbody>
</table>
Once a piece or material is approved for one purpose, it is not necessarily approved for all purposes. For example, a proposal or deck approved by an RC for use with one customer may not be approved for use with another customer without further review. These materials and proposals are customized for the particular customer and are reviewed with that customer in mind. These decks sometimes contain customer confidential information and therefore it would not be appropriate to use “as is” with another customer. If you are aware of a piece used with one customer, or collaboration proposed to one customer, and you think that piece or collaboration may possibly work for a different customer, you must follow up with your team attorney for necessary revisions and approval. Similarly, slide decks approved for training or other internal use must receive approval specifically for use externally with customers or other third parties.

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

### E-mailing a Customer about a Collaboration

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

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

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

A. The particular disease state and the Pfizer product in that disease state will dictate how much can be said. In certain cases, where a risk of off-label use exists, or where Pfizer’s product is the only available product for the disease state, Pfizer’s disease state discussion must be consistent with the label for the specific Pfizer product. In other cases, the disease state discussion possibly could be broader, as long as there is no implication that use of the Pfizer product could result in broader benefits than those mentioned in the product’s label.

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

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

Product Messaging Risks

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

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

**Appropriate Product Discussions**

Q. Xalkori is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive, as detected by an FDA-approved test. Does that mean that Oncology Field Commercial Colleagues, when discussing disease state, can only discuss ALK-positive NSCLC?

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

**Collaborations**

A **collaboration** is an activity or project undertaken by Pfizer with one or more organizations to advance public health goals of interest to both Pfizer and the organization(s). It is different from a traditional service arrangement, where Pfizer might pay a customer a fair market value fee to perform a service on behalf of Pfizer. In a collaboration, it is important that both Pfizer and the customer make equal contributions towards the identified, shared public health objective. Pfizer may provide funds, resources, or expertise to the collaboration. Often, Pfizer is involved to some extent in the creation of the materials or other activities (e.g., providing suggestions or feedback) and may receive the right to use the materials or other output created pursuant to the collaboration. The customer or Pfizer, or both, may retain ultimate control of the goals, activities, and messaging, always subject to Pfizer's right to review (via RC, where applicable) any materials for accuracy and compliance with relevant laws and regulations, as well as Pfizer policies and procedures.
For Account Managers, it is important to recognize that some collaboration concepts may be defined by Pfizer policies as studies which require medical oversight. Drawing this distinction may be necessary in the context of a collaboration with an Account that seeks to measure the impact of an intervention, including a non-drug intervention, such as patient counseling or adherence materials. Because the conduct and publication of a study can expose Pfizer to risk, studies must be done in compliance with applicable Pfizer policies, such as CMCD CT24-GSOP Non-Interventional Studies, CMCD CT25-GSOP Pfizer Non-Sponsored Research, CMCD CT44-GSOP Clinical and Research Collaborations and CMCD 45-GSOP Pragmatic Clinical Trials. It is critical that Account Managers involve the appropriate Field Based Medical Colleagues such as MOSs to lead the assessment any time a customer engagement seeks to collect and examine both existing as well as to-be-collected data from a customer. The MOS will seek to determine whether the proposed engagement may be considered a study under Pfizer policies and next steps required to be in compliance with such policies.

Collaborating around Disease States Not linked to a Pfizer Product

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

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

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

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

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

- **Complexity and customization**—Generally speaking, the more an arrangement involves customized solutions rather than off-the-shelf tools, the more likely the project will rise to the level of a collaboration.

- **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 an agreement. Longer projects may be more complex and are more likely to involve the sharing of data and/or the creation of a publication.

- **Data from the customer** – If the joint project is going to generate data that would be of interest to Pfizer, then some kind of contract is necessary. Whether that would be a Collaboration Agreement or, alternatively, a Data Use Agreement, will depend on, among other things, how the data is generated. If the data is generated as a result of the use of tools and services provided by a Pfizer commercial colleague, then a Collaboration Agreement may be appropriate. If, on the other hand, the data is requested by a Medical colleague and is collected by the customer using routine methods, another type of agreement may be more appropriate. Be sure to work with your medical account team colleague to determine whether Pfizer policies governing the conduct of studies apply.
• **Other Deliverables from the Customer** - Sometimes, Pfizer may negotiate to have the customer develop certain materials or undertake certain activities (e.g., mailings to their HCP employees) as part of a project. In order to secure these or other customer obligations, a Collaboration Agreement may be necessary. (Depending on the details, a Service Agreement may be more appropriate. Be sure to discuss with your team attorney.)

• **Protecting Pfizer’s Interests** – A Collaboration Agreement is a contract that will define the rights and responsibilities of each party on a variety of topics related to the joint engagement, including publications, intellectual property, contributions, and involvement in the making of certain decisions. Depending on the nature of Pfizer’s rights and responsibilities, and the rights and responsibilities of the other party, Pfizer may decide that a Collaboration Agreement is necessary to protect its interests. In particular, intellectual property issues, including the creation of new intellectual property as an output of the undertaking with the customer, may add a layer of complexity to the contract. The need for enhanced intellectual property language in the Agreement may require additional time and also may make it more difficult to secure the approval of the customer. Be sure to discuss with your team attorney.

• **Provision of Pfizer Tools** - Provision of individual “off-the-shelf” tools to a customer in accordance with company policies does not rise to the level of a collaboration, requiring a Collaboration Agreement or team attorney consultation. However, use of multiple Pfizer tools or the need to customize existing Pfizer tools may necessitate a Collaboration Agreement. Colleagues should take care to ensure that the use of multiple or customized tools is warranted, as excessive or inappropriate use of these tools could create kickback risk for Pfizer.

Please consult your team attorney regarding your specific scenario as there are multiple factors to weigh before the final determination of whether a customer engagement is a project or collaboration, and whether an agreement is required (i.e., Collaboration Agreement, Service Agreement, or Data Use Agreement).
**Is this a Collaboration?**

**Q.** As part of my work with a Health System, I will facilitate two off-the-shelf, RC-approved workshops and share related patient education materials. Is a collaboration agreement required?

**A.** No. The work you describe is a project not requiring a collaboration agreement. The resources have not been tailored for the Health System, the timeline is defined and short, and the nature of the interaction is transactional rather than complex. However, to the extent there are implementation guidelines and guidance on the use of those materials, you must follow that guidance.

**Q.** I am discussing a project with a Health System that may include Electronic Medical Record and workflow changes, educational staff training, development of an adherence platform, and creation of a joint Steering Committee with Pfizer participation. The Health System is willing to create and share a related dashboard report around specific data points with Pfizer. Is a collaboration agreement required?

**A.** Yes, you have described a collaboration, which would require a collaboration agreement. Pfizer would have an extended involvement in the execution of the project, by participating on the Steering Committee and any assistance with the EMR and workflow changes. The Health System also has committed to provide certain deliverables to Pfizer, which should be memorialized in an agreement to ensure accountability and protect Pfizer’s interests.

**Q.** I would like to work with an integrated delivery network to put together a mailing to a selected group of patients. Do I need a collaboration agreement?

**A.** Not necessarily. Depending on the scope of the undertaking, as well as whether there are other related efforts that may require a contract, you may be able to handle the mailing by using a Service Agreement rather than a Collaboration Agreement. Be sure to discuss with your team attorney before you start drafting, as a number of additional issues may need to be taken into account (e.g., patient privacy, consent, and potential kickback issues).

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**Intake Committee and the Collaboration Evaluation Process**

To help ensure compliance with all relevant policies and mitigate potential risks, an *Organized Customer Collaboration Evaluation Form* and *Intake Committee* process has been designed to review potential collaboration concepts. The Intake Committee consists of representatives from Legal, KAM Enablement, Field Based Medical, and Regional Customer Marketing. The Intake Committee is responsible for review and approval of collaboration agreements as well as service agreements with certain types of third parties or organized customers such as IDNs, ACOs, and large group practices. Seeking input from brand teams, Outcomes & Evidence (O&E), and other functions as needed, the Intake Committee determines steps required to comply with Pfizer policies.
Committee also maintains a repository of agreements and shares best practices on an ongoing basis. Colleagues also are encouraged to bring their proposals before the Intake Committee for a concept review, especially where the content of the proposed collaboration involves novel or unusual terms. Members of the Intake Committee also have access to a Fair Market Value (FMV) assessment tool to assist in determining the value of certain frequently provided activities or activities with like components that Pfizer may contribute to a collaboration. The tool helps provide a consistent and formatted methodology to the calculation of value that Pfizer may provide to a collaboration. Account Management and Field-based Medical Colleagues who contributed to the development of the tool are available to assist with use of the tool.

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

**Appropriate Value**

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

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

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

Receiving Appropriate Value for a Collaboration

Q. I have a Health System customer that is far below state and national averages in cardiac-related patient outcome measures. Non-valvular atrial fibrillation (NVAF) patients are emerging as a high-risk patient base that requires care across multiple settings. Pfizer currently has tools and resources that can be used by HCPs for screening and managing this population, and Pfizer has experts who can train HCPs on how to better discuss NVAF and educate patients. Finally, Pfizer’s MOS Colleagues will be able to work with the customer using approved medical tools to measure the impact of implementing a comprehensive NVAF program using these resources. The customer is interested in implementing this initially in 10 practices and then in a larger scale roll-out to all 75 practices. The customer will be responsible for developing and implementing all training and communications. The customer will pay the costs of the roll-out. Is this proposed collaboration appropriate for Pfizer to engage in?

A. On its face, provided that the total value provided by the Health System is equal or approximately equal in value to the total value provided by Pfizer, it may be appropriate for Pfizer to engage in this collaboration. Providing assistance to the customer that would aid in improving the diagnosis, management, treatment, and outcomes of NVAF patients not only benefits the customer, it benefits public health and the overall healthcare system. The collaboration would educate and help patients better adhere to medicines in a disease state in which Pfizer currently has interest. Additionally, Pfizer could potentially obtain useful data from this collaboration as to the effectiveness of implementing these types of programs to allow Pfizer to evaluate whether the program could be replicated for other customers and to provide insights to management of patients in this high-risk disease area. Consult with your team attorney in the concept state to ensure that the project is appropriate and whether the concept should be brought to Intake Committee for further guidance.
Receiving Appropriate Value for a Collaboration (continued)

Q. Accountable care organizations (ACOs) are looked upon as a way to facilitate a more coordinated, efficient, and higher quality care for patients. Can I help my customer meet the requirements of an ACO?

A. If the primary objective of the proposed collaboration is to help the customer become an ACO, then it is unlikely that Pfizer can engage in such collaboration. Part of the FMV assessment of Pfizer’s contributions is that it must not only be fairly equal to customer’s contributions but Pfizer must get an appropriate value from the collaboration. A collaboration that is aimed at helping a customer become an ACO on its face does not appear to have any tangible, appropriate value to Pfizer and only benefits the customer, even though the project appears to support a public health interest objective.

Q. In a collaboration, if Pfizer's contribution is $25,000 and the customer is not contributing cash but is providing services valued at $25,000, is that okay?

A. First and foremost you must work closely with your team attorney to assess the value of contributions within a Collaboration agreement. In the above scenario, the proposal may be okay so long as Pfizer’s contribution is not considered payment for the services. Your team attorney will be able to help you work through all the nuances to make a determination if there is equal contribution on both sides.

Metrics and Reimbursement

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

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

**Presenting Financial Metrics to a Customer**

Q. My Integrated Delivery Network customer wants to know how a screening/disease identification collaboration on which we are partnering to improve quality of care might help improve their economic performance in either additional care identified (new patients) or costs averted (e.g., reduced unnecessary re-admissions). Can we assist in projecting what potential financial impact this work may have for them?

A. In presenting a proposed collaboration to a customer, the account team may, as a general matter, present general financial metrics from the proposed initiative based upon publicly available, credible information. The collaboration and any associated financial metrics should be focused on the improvement in quality of care and benefit to the overall health care system. Any projections as to economic performance must be consistent with these objectives. You should always use credible sources that have been approved for such use, and never provide any guarantees around achieving such financial goals. You must always include appropriate disclaimers when presenting financial metrics. Remember, presentations must be approved in advance before use with customers. You should work closely with your medical counterpart and consult with your team attorney for necessary approvals, including appropriate use of the data.

**Reimbursement**

Q. During a needs assessment meeting, a representative from a medical group states that the group would like to increase its reimbursement for certain diagnostic tests and would like to know if Pfizer can assist in educating the group’s providers on the best practices for coding and billing for such tests. Is this an appropriate activity for a collaboration with this customer?

A. No, this is not an appropriate activity. Pfizer cannot provide assistance for the purpose of increasing the group’s reimbursement. Although the appropriate use of some diagnostic tests could potentially increase the appropriate diagnosis (and treatment) of certain medical conditions, Pfizer may not commit resources to a collaboration that is focused on reimbursement of items or services for a customer.
Use of Publically Available Information

Q. What qualifies as credible and reliable publicly available information?
A. That depends. In deciding whether something is credible and reliable determine whether the information is generally accepted by experts in the field. Generally, medical journals, governmental (e.g., CMS) websites as well as the particular customer website are examples of credible and reliable sources. You should work with your medical counterpart and team attorney who can assist in making a determination.

Q. If Pfizer does not commit resources to the specific aspects of the collaboration that are focused on coding, billing, and reimbursement, can Pfizer participate in other aspects of this potential collaboration with the medical group that are focused on related quality measures?
A. It depends. The overall goal of any collaboration must be to address a public health goal. Even if the medical group’s contribution to the collaboration is focused on activities that are intended to address a public health goal, the overall results of the collaboration must also be expected to result in the advancement of such goal.

Offering Pfizer Tools & Resources

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

Many of these programs can be found on the Pfizer intranet site: http://crc.pfizer.com. In offering OCP Resources to a customer, colleagues must not engage - or appear to be engaging - in quid pro quo. For more information on the requirements around who can offer OCP Resources, the situations in which Pfizer can offer these tools and resources, and the associated review requirements, please consult Orange Guide Chapter 14: Organized Customer and Payer Tools and Resources.

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

Q. One of my customers is trying to attain NCQA PCMH accreditation. Can I present a menu of six or seven PCA Quality Programs to the customer solely to aid them in meeting the accreditation standards?

A. No. Pfizer’s policy does not permit providing Quality Programs to customers primarily for the customer to meet its NCQA accreditation. The decision to provide each Quality Program must be based on Pfizer’s goals of improving health outcomes, patient awareness, wellness, disease prevention, and high quality health care. If you have any questions, consult with your team attorney.

Q. Can Quality Programs be used to get access or to assist in building relationships with a customer? What about PROMOS and other OCP Resources?

A. 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 customers with the same intent for which they are created: to promote wellness, disease prevention, patient awareness, and high quality health care.

Sunshine Act

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

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

Avoid Combining Types of Transactions

As the lines between customer types (payers, prescribers, purchasers, etc.) have begun to blur, it is important to ensure separation among Field Commercial Colleague roles to avoid the actual or potential perception of impropriety.
perceived commingling of transactions which could raise anti-kickback and pricing concerns. Even if the risks are not apparent, always consult your team attorney before undertaking any activities that are functionally aligned to other roles within the organization. For example, what is appropriate for an Account Manager may not be appropriate for certain sales roles. Further, when engaging with a customer, particular initiatives must be pursued by themselves and must not be predicated on other programs or additional performance of any kind. When different transactions are commingled inappropriately—for example, OCP Resources offered not for their own approved purposes but rather to secure formulary placement—there can be a risk that the value to the customer of that separate, non-rebate related arrangement would need to be considered and included as a discount to the customer for purposes of price reporting under the Medicaid Drug Rebate Statute for a drug. Therefore, avoid combining certain types of transactions to avoid implicating pricing or anti-kickback concerns. For example:

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

Q. One of my customers is a mid-size medical group that manages its own formulary and is owned by or affiliated with a payer. Pfizer’s product does not have favorable access at the medical group customer. I would like to engage in discussions with this customer 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?

A. No. Pfizer colleagues must not discuss rebates received by a customer affiliated with a payer or any other customer with a medical group as that would violate contractual confidentiality obligations Pfizer has with those customers. Even though the medical group is affiliated with the payer customer, Pfizer’s contract is with the payer and discussions related to the terms of those contracts must remain confidential. Additionally, Pfizer colleagues must not provide tools or engage in adherence arrangements in conjunction with or in exchange for formulary access. Commingling other arrangements with formulary discussions elevates risk under the anti-kickback statute and raises the risk that separate, non-rebate arrangements might need to be considered for purposes of price reporting.

Medical Activities

Interacting with Medical Outcomes Colleagues

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

Medical Outcomes roles are non-promotional roles and have been tailored to focus on the medical needs of managed care and other organized customers including IDNs and large medical groups. The objective of these interactions must be non-promotionally focused (e.g., not done with a goal of obtaining prescriptions for a Pfizer product). There are limited instances when both the MOS and FMD may engage in activities governed by promotional standards, such as giving payer value proposition/formulary presentations or certain RC-approved presentations.

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

Internal Interactions between Medical Outcomes and Field Commercial Colleagues

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

Medical Objectives, Account Plans, and Customer Insights

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

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

**Medical Outcomes Customer Accounts**

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

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

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

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

- Conduct product or disease training, using RC-approved materials;
- Provide general information about medical objectives or an overview of Medical Review Committee (MRC) approved topic(s) or materials;
  - Medical Outcomes Colleagues are not permitted to discuss the details of MRC-
approved content or share actual MRC-approved materials with Field Commercial Colleagues. Field Commercial Colleagues must not ask for this information or seek to influence the way in which medical content is developed or delivered to HCPs or other customers.

- Share aggregated customer insights, information about geography or regional level dynamics, or to seek feedback. For example, information can be shared about gaps in HCP understanding about a disease or treatment. Customer information discussed must be in aggregate and not specific to any particular HCP or customer's prescribing/utilization of Pfizer products or medical inquiries.
  
  - Field Commercial Colleagues are not permitted to ask Medical Outcomes Colleagues to share any type of off-label information for a Pfizer product or information about unapproved Pfizer products;
  
  - Field Commercial Colleagues are not permitted to seek assistance from Medical Outcomes Colleagues with overcoming barriers to customer prescribing/utilization of Pfizer products; and
  
  - Field Commercial Colleagues are not permitted to request information from Medical Outcomes Colleagues about the substance of responses provided to customers who have made unsolicited medical requests for information.

Organized Customer Planning and Coordination

Medical Outcomes Colleagues are usually the primary Field Medical Colleagues who serve the medical needs of managed care, IDNs, large medical groups, and other organized customers. For organized customers that have assigned Medical Outcomes Colleagues, those colleagues will make determinations about when FMDs are needed to assist. If an organized customer does not have an assigned Medical Outcomes Colleague, Account Management Colleagues are permitted to work directly with FMDs to discuss field medical support for a particular organized customer. However, it is recommended that MOS Colleagues are engaged first for all medical needs as the Integrated Account team medical lead.
Account Management Colleagues may meet with Medical Outcomes Colleagues (or FMDs if an Outcomes Colleague is not assigned) regarding the following:

- Account prioritization and planning;
- Customer needs assessments;
- Large project or collaboration agreement development and planning;
- Non-product medical activities such as disease presentations, health trend/channel presentations, and quality of care presentations; and
- Account level dynamics such as utilization of products in a specific therapeutic area, quality metric gaps or goals, key events (e.g., placement of new products on formulary), and other information relevant to respective medical and commercial account objectives (e.g., benefit design, adherence rates).

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

**Customer Data Evaluation (CDE) Discussions**

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

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

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

**Unsolicited Medical Requests (UMRs)**

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

Account Management Colleagues who receive a formulary presentation request from an organized customer that has dedicated Medical Outcomes support are permitted to forward the request directly to the Medical Outcomes Colleague assigned to the customer. Account Management Colleagues who receive a product UMR from an organized customer that has dedicated Field Medical support are permitted to provide the Field Medical Colleague’s contact information to the organized customer so that the customer can contact the Field Medical colleague directly with questions. Account Management Colleagues are not permitted to forward the question themselves; the organized customer must initiate contact with the appropriate Field Medical Colleague.

**Organized Customer Requests to Discuss Research**

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

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

External Interactions between Medical Outcomes, Field Commercial Colleagues, and Organized Customers

Introductory Meetings

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

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

Organized Customer Meetings

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

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

**Formulary Committee Presentations**

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

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

Medical Outcomes Colleagues may deliver non-product presentations to organized customers on topics such as disease state/burden of disease, Health Trends, Health Channels, and quality of care topics. Field Commercial Colleagues may be present at these presentations when:

- The non-product presentation is RC-approved; or
- A Medical Review Committee (MRC) has approved the content to be presented in the presence of Field Commercial Colleagues.

The determination as to when it is appropriate for a Field Commercial Colleague to attend non-product presentations given to organized customers must be left to the discretion of the Medical Outcomes Colleague. Field Commercial Colleagues must not attend if the Medical Outcomes Colleague determines it is not permissible or advisable.

Customer Data Evaluation (CDE) Development and Presentations

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

Interacting with Field Medical Director (FMD) Colleagues

For additional information about appropriate interactions with Field Medical Director Colleagues see Orange Guide Chapter 2: Interactions with HCPs.
Orange Guide – Chapter 5: Interactions with Health Systems and Medical Groups

Medical and Commercial Interactions

Q. I am a KAM, and one of my large medical group customers has provided me with spreadsheets that contain data on a particular disease state related to that medical group, which includes an affiliated hospital. The group 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 de-identified list of specific patients, including length of admission, diagnosis, etc. Can I, as a KAM, receive this data from the customer and what analysis can I perform with it?

A. In every situation where the customer wishes to provide patient data for analysis, the Field Commercial Colleague should refer their MOS Colleague directly to the customer to determine what sort of data analysis may be appropriate. While in some situations commercial field-based colleagues may perform high level analysis based on publicly available information, such situations are limited and need the approval of the team attorney. Under no circumstance may any Pfizer colleague receive patient specific information unless appropriate consents are in place and even then only Pfizer Medical Colleagues will be able to receive such information. In the event you find yourself in possession of such information in error, consult your team attorney immediately. Please consult Orange Guide Chapter 8: Privacy – Protecting Personal Information for more information on the appropriate use of patient information.

Q. A Health System customer wants assistance in development of an IDN specific guideline and treatment pathway around a specific disease state. Can Pfizer Field Medical and Field Commercial Colleagues collaborate with the customer on this project?

A. If there are branded or unbranded RC-approved resources of such as an independent third-party developed criteria or recommendations for treatment of a disease state, consistent with product labeling, you may utilize them with the customer. However, if the goal of the collaboration is to support the development of treatment guidelines, consult your team attorney on how best to proceed.

FOR MORE INFORMATION

- For more information on interacting with Field Medical Colleagues including both MOS and FMDs, see The Green Guide: Governance for External Medical Activities.
• For more information about collaborations and collaboration agreements involving Key Account Managers, including how to get them approved and prepared, GIP KAMs may proceed to their respective SharePoint site and see the Organized Customer Collaborations Process Guidelines at http://ecf.pfizer.com/sites/CMI/CMi%20Deliverables/Org%20Cust%20Collaboration%20Process%20Guidelines_071114%20FINAL%20APPROVED.docx. All other Account Managers should proceed to the respective link on the Customer Resource Center.

• Please refer to Orange Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure for more information on our disclosure obligations under the Sunshine Act and certain state laws.

• For information on the appropriate use of patient information, please see Orange Guide Chapter 8: Privacy – Protecting Personal Information.

• For additional guidance on OCP Tools and Resources see Orange Guide Chapter 14: Organized Customer and Payer Tools and Resources or visit http://crc.pfizer.com.

• Refer any questions to your manager or team attorney.
Chapter 6: CLINICAL RESEARCH AND INVESTIGATOR-INITIATED RESEARCH

Supporting Legitimate Medical Research

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

Clinical studies for which Pfizer is the regulatory sponsor are those studies where Pfizer (or a party acting on Pfizer’s behalf) designs, conducts and oversees the study. Actual execution of clinical study protocols is often undertaken by service providers (contract research organizations, or CROs as well as academic groups) who are engaged by Pfizer. As regulatory sponsor of a clinical study, Pfizer is responsible for compliance with the regulatory obligations applicable to such research and development activities.

Pfizer also provides support for studies sponsored and initiated by outside investigators or institutions, referred to as Investigator-Initiated Research (IIR) studies. Pfizer may support IIR studies that advance medical and scientific knowledge by providing funds, a compound or product, pure drug substance, laboratory analyses, or a combination of one or more of these. However, Pfizer is not the legal or regulatory sponsor of IIR studies.

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

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

**Types of Funding or Support**

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

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

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

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

**Investigator-Initiated Research Grants**

Pfizer may not design, conduct, or monitor IIR studies. Rather, they must be conducted independent of any influence or management by Pfizer. The evaluation of an IIR request cannot be influenced by an investigator’s, institution’s or organization’s generation of past, present, or potential future business for Pfizer, nor by any decisions the investigator or institution has made or may make in the future regarding Pfizer or Pfizer products.

All proposals for an IIR grant should be referred to a Field Based Medical or Asset Team Medical colleague who can assist the requestor in submitting the proposal through the INSPIIRE application website at [www.pfizer.com/iir](http://www.pfizer.com/iir) (as required by CT25-GSOP). Alternatively, requestors may submit IIR grant proposals through the INSPIIRE application portal on their own. All submitted proposals are referred to a Grant Review Committee ("GRC"), a multi-disciplinary team, responsible for reviewing the scientific rationale and merit of the proposal and determining whether to support an IIR study. Because IIR support could potentially influence prescribing, purchasing, or recommendation of Pfizer products, the GRC does not include any Commercial (e.g., Sales or Marketing) colleagues. This reduces the risk that an HCP’s past support of Pfizer products or future prescribing habits might be considered in any grant decision.
Investigator-Initiated Research 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 IIR grant?

A. Yes, if an HCP independently expresses interest in applying for research funding, you may suggest submitting a proposal for an IIR grant. However referral to a local Field-Based Medical colleague would be preferable. If you do speak with the HCP about Pfizer’s IIR program, do not make any promise or suggestion that the IIR proposal will be supported, nor assist in any way in drafting the IIR proposal or submitting it through the INSPIIRE web portal. The HCP can access information about the requirements and application process for IIR grants at [www.pfizer.com/iir](http://www.pfizer.com/iir). Note, Commercial colleagues must not proactively solicit the submission of IIR 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.

Requests for Study Medication or Pure Substance

A request for study medication or pure drug substance (for pre-clinical studies) to support legitimate medical research should be referred to your Field Based Medical or Asset Team Medical colleague for consideration as an IIR request (or a Compound Transfer request if it only involves pure drug substance). Starters may never be used for clinical trials or as support for IIR studies, and it would be inappropriate for you to try to obtain or promise samples for any research purposes.
Key Points to Ensure Compliance

- All decisions to engage a physician as a Clinical Investigator or to provide support for an IIR study must be made by colleagues in a medical, clinical, or scientific function.

- Funding or other support for medical research may never be provided to:
  - Establish, maintain, or improve Pfizer's relationship with an HCP or Account;
  - Gain or improve access to an HCP or Account;
  - Reward past or present, or induce future, prescribing or purchasing; or
  - Influence an upcoming formulary decision or reward a past formulary decision.

- Do not attempt to influence a decision by Medical or Clinical colleagues to hire Clinical Investigators or award grants for IIRs based on the potential impact to Pfizer sales.

- Do not provide starters (samples) to HCPs for use in IIR studies or other research.

Clinical and Research Collaborations

Clinical and Research Collaborations (CR-Collaborations) are engagements under which Pfizer collaborates with an external party to perform research and/or clinical activities. Unlike IIRs under CT25-GSOP, CR-Collaborations can be initiated by Pfizer (i.e., Pfizer approaches an external party to propose a collaboration) or initiated by a third party (i.e., a third party approaches Pfizer to propose a collaboration). CR-Collaborations are managed by the External Medical Communications (EMC) CR-Collaborations Group.

CR-Collaborations are subject to the requirements of CT44-GSOP: Clinical and Research Collaborations. Engagements are defined as collaborations when Pfizer provides financial and/or non-financial benefits (e.g., intellectual property rights, data, pure compound, formulated drug, products, etc.) to an external party and one or more of the following applies:

- The conduct of such study requires approval of, and/or consultation with, an IRB or EC and/or a regulatory authority (including approval via an IND or a CTA).
- Pfizer intends to use the data from such study to:
  - Support an application to a regulatory authority;
Fulfill a regulatory commitment; or
Obtain and maintain access to a medicine in a national/local health system or a national/local formulary (e.g., recommendation of the CDC’s Advisory Committee on Immunization Practices, ACIP); or

- Pfizer is involved in designing, conducting, monitoring and/or supervising a Phase I – IV clinical trial, any non-interventional study (e.g., observational or epidemiological study) or any exploratory clinical study.

Please note that CR-Collaborations are not subject to the requirements of CT25-GSOP Pfizer Non-Sponsored Research. CT25-GSOP only applies to investigator initiated research (IIRs). Studies that were previously initiated as “Collaborative IIRs,” as defined within CT25-GSOP several years ago, are now subject to the requirements of CT44-GSOP.

It is important for Account Managers and others to understand that a customer engagement may actually be or become a study to which Pfizer Medical policies apply. This most often occurs in the context of a collaboration with an Account that seeks to measure the impact on patients of an intervention, including a non-drug intervention, such as patient counseling or adherence materials. Because the conduct of a study can expose Pfizer to risk, studies must be done in compliance with applicable Pfizer Medical policies, such as CT44-GSOP and CT25-GSOP. It is critical that Account Managers work closely with Field-Based Medical colleagues, such as MOSs and FMDs, any time a customer engagement project involves examining existing or anticipated customer data. Your Field-Based Medical colleagues will assist you in determining whether the proposed engagement is a clinical study under Pfizer policies and, if so, in complying with those policies.

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

**Pfizer-sponsored trials** are clinical studies that are designed, conducted, supervised and funded by Pfizer and for which Pfizer holds regulatory responsibility. Pfizer compensates investigators who participate in these trials based on the fair market value of their expertise and effort in conducting the research.

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

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

### Clinical Studies and Prescribing Habits

**Q.** A very influential physician is reluctant to prescribe a certain Pfizer product. Can I recommend to my Field Medical Director (FMD) that this physician be selected as an investigator in an upcoming clinical trial for that product, so that she can gain additional first-hand experience regarding the product’s use?

**A.** No. You may not recommend a physician as an investigator if a purpose for choosing the physician is to influence prescribing habits. Investigators must be selected solely on the basis of their research experience and clinical training, not their past, current or potential future prescribing habits.

### “Compassionate Access” Requests

From time to time, you may receive requests from HCPs to provide one of Pfizer’s investigational drugs for a seriously ill patient. Such requests on behalf of patients are called “compassionate access” requests.
If anyone asks you about compassionate use of a Pfizer product, refer the inquiry promptly to Pfizer Medical Information or direct them to PfizerCARes (Pfizer’s Compassionate Access Request system). The Pfizer Medical colleagues assigned to the product are the only individuals at Pfizer authorized to address compassionate use requests. Remember, you must never discuss unapproved products or indications with HCPs.

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

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

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

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

**Referring Physicians as Potential Clinical Investigators for Pfizer-Sponsored Studies**

**Q.** As part of our overall plan to improve Pfizer’s relationship with a key institution, my team wants to alert qualified physicians to (non-IIR) Pfizer-sponsored research opportunities. Is this OK?

**A.** Yes. It is permissible to encourage physicians who would be appropriate investigators, based on their training and experience, to seek out opportunities to participate in Pfizer-sponsored studies. It would not be permissible, however, to encourage Pfizer Medical colleagues to select these physicians to be investigators or show them any special treatment. Decisions regarding who will be engaged as Clinical Investigators must be based on the physicians’ expertise, training, and other relevant factors, such as availability of appropriate facilities and staff and access to the target population of study participants, and not on their past, current, or potential future prescribing of Pfizer products.
**IIR Protocols**

You may not write, suggest, or comment on protocols for independent investigators to submit to Pfizer for IIR support. If you receive a request from a sponsor or Clinical Investigator for assistance with drafting a protocol, you must direct the applicant to the appropriate Pfizer Medical colleague. If a potential Clinical Investigator wishes to receive Pfizer assistance in drafting a protocol, Pfizer Medical may decide to support the engagement as a CR-Collaboration, if appropriate.

**Collaboration with Physicians on Questionnaires and Surveys**

Q. May I provide protocols for surveys, data collection tools, or other materials to HCPs to help them conduct patient research about different interventions?

A. You may provide only those protocols for surveys, data collection tools, and other materials that have been approved for promotional use by a Pfizer Review Committee. You are prohibited, however, from customizing any approved material for particular physicians or institutions, unless such customization is also approved by a Pfizer Review Committee.

**No Assistance with Patient Recruitment**

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

**FOR MORE INFORMATION**

- For more information on SOPs please refer to the [eSOP portal](http://esop.pfizer.com).

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• For any questions about compassionate use of a Pfizer product refer the inquiry promptly to Pfizer Medical Information or direct them to PfizerCARes (Pfizer’s Compassionate Access Request system).

• Questions may be referred to a Pfizer Medical colleague, your manager, or Pfizer Legal counsel.
Chapter 7: P&T COMMITTEE INTERACTIONS

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Chapter 7: P&T COMMITTEE INTERACTIONS

P&T Committees

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

Pharmacy & Therapeutics (P&T) Committee: the committee within an Account such as an institution or managed care organization that decides which pharmaceutical products are included on the formulary.

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

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

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

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

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

**Day-to-Day Interactions**

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

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

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

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

Q. If a physician asks if I know whether he or she is a P&T Committee member, what should I say?
A. Always answer truthfully. While P&T Committee members often do not wish to be identified as such, answering honestly is the best way for you to demonstrate the core value of integrity with the HCP.

Buying Lunch for a P&T Committee Member

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

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

Q. A physician 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?
A. Maybe. Presenting product information to an HCP who is a member of a state Medicaid P&T Committee is appropriate as long as the guidelines in this Chapter are followed. However, you should consult with your manager before adding the HCP to your call cycle.
Calling on a P&T Committee Member During a Formulary Decision

Q. If an HCP who is a P&T Committee member is part of my normal call cycle, can I call on the HCP more frequently when I know that there is a pending formulary decision for one of the products I carry?

A. Maybe. Increasing the number of calls to the HCP in and of itself is not considered "special treatment" and may be appropriate so long as the provisions of this Chapter are followed and the purpose for the increase in call volume is to provide relevant on-label information for the HCP to consider in making a decision. However, you should consult with your manager before deciding to call on an HCP more frequently under these circumstances. Keep in mind you may not increase the number of meals provided in connection with the increase in detailing or calls as this could be considered “special treatment.”

Generating Support for Formulary Placement

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

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

- 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 de minimis logistical matters such as requesting time slots on behalf of HCPs who have agreed to testify; and
- Asking influential HCPs to write letters or otherwise communicate with members of the P&T Committee to show their support for a Pfizer product.
### Generating Support for Formulary Decisions

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

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

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

- Inviting a P&T Committee member to become a speaker, consultant, or member of an advisory board if the invitation is even partially motivated by a desire to influence an upcoming formulary decision;
- Writing letters or creating talking points for use by an HCP or P&T Committee member who would like to advocate for a Pfizer product;
- Taking a P&T Committee member out to a meal that is extravagant or otherwise not in compliance with the PhRMA Code;
- Providing any payment (such as an exhibit/display fee or speaker fee) to a P&T Committee member or their institution if the payment is even partially motivated by a desire to influence an upcoming formulary decision;
- Providing any unapproved item to a P&T Committee member; and
- Linking financial support from Pfizer, either directly or indirectly, with influence over that P&T Committee member’s exercise of judgment in serving on their P&T Committee.
Discussion of Extraneous Financial Transactions

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

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

Responding to Requests for Funding by P&T Committee Members

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

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

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

Who May Present?

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

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

What Information May Colleagues Present?

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

If Pfizer Requested the Opportunity to Present Information

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

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

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

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deck, the slides must be approved by the appropriate Review Committee before use. When proactively providing product information, colleagues must never include information about off-label uses, including efficacy or safety information that conflicts with the approved labeling. Colleagues must never include new clinical data that has not yet been approved for product promotion in the presentation materials. If a P&T Committee makes a specific unsolicited request for off-label information during the presentation, only Medical Colleagues (or a Headquarters-approved physician consultant) may respond to the request in accordance with the guidelines set out for them (i.e., the Medical Colleague must acknowledge that the information is off-label; provide a brief answer that is truthful, not misleading, based on substantial scientific evidence, and non-promotional in tone; and then continue with the original presentation). Field Commercial Colleagues may remain in the meeting during this time, but if a more extensive answer or discussion is needed to respond to the customer’s request, the Medical Colleague should speak to the customer after the meeting out of the presence of Field Commercial Colleagues.

P&T Committee Standing Requests for Off-Label Information

Q. 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?

A. 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 a Pfizer Medical Colleague (or Headquarters-approved consultant) may respond to this standing written request for off-label information, in accordance with the policies set out in the Green Guide: Governance for Field-Based Medical Activities.
If the P&T Committee Requested that Pfizer Provide Information

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

- **If the response will not include off-label or unapproved information**, any colleague, including a Sales Colleague, can respond to the request using RC-approved materials.

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

MOS Colleagues may respond to requests for unapproved but on-label information (e.g., where no RC-approved materials exist to use in a response). Because of their background and training, they may also respond to requests for pharmacoeconomic or outcomes information if they have materials approved for such responses. A FMD may respond to requests for both unapproved and off-label information. In the absence of a specific request for such information about our products, no colleague may present unapproved or off-label information about Pfizer products to a P&T Committee or one of its members.
Joint Sales and Medical P&T Presentations

Q. May Field Commercial Colleagues and Medical Colleagues present together to a P&T Committee?

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

FOR MORE INFORMATION

- Questions may be referred to your manager or team attorney.
- For medical inquiries, contact Pfizer Medical Information at 1-800-438-1985.
Chapter 8: PRIVACY: PROTECTING PERSONAL INFORMATION

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Chapter 8: PRIVACY: PROTECTING PERSONAL INFORMATION

Privacy

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

This Chapter highlights certain key Pfizer policies regarding the protection of Personal Information. Examples of activities involving collection or access to Personal Information of others (both HCPs and patients) include health screenings, surveys, clinical outcomes research, and mentorships as well as managing Personal Information in your possession—such as on your computer.

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

Patients’ Privacy and Personal Information

“Personal Information” includes any information that alone or in combination with other data can be used to identify a person such as name or initials, address, phone number, or e-mail address. “Sensitive Personal Information” is a subset of Personal Information that includes personal information about a person’s physical or mental health (e.g., a person’s medical history, physical or mental condition, diagnosis or treatment, including “protected health information” of “PHI” of a “Covered Entity” under HIPAA, or the identity of the person’s health care provider or health insurer), geolocation data, financial information, national identifiers such as social security number, as well as information about their race, ethnicity, religion, or sex life/sexual orientation.
Governing Laws and Pfizer Policies

There are many federal and state laws applicable to the collection, use, and disclosure of Personal Information and Sensitive Personal Information. Regardless of the circumstances under which Personal Information is disclosed, when an individual chooses to share such information with a person they trust, they generally expect the person to hold that information in confidence and to keep it secure. Pfizer respects this expectation and is committed to appropriately protecting all Personal Information in its care in compliance with applicable privacy laws and regulations and Pfizer’s corporate policies and procedures. Pfizer’s policy is to employ appropriate safeguards to protect all Personal Information it receives and maintains, regardless of the form, format, location, or use. See Corporate Policy 404 - Protecting the Privacy of Personal Information.

Key Points to Ensure Compliance

- Always disclose that you are a Pfizer employee when interacting with patients, such as at a consumer health fair or during a mentorship or preceptorship, by wearing your Pfizer name tag at all times.

- Corporate Policy 404 - Protecting the Privacy of Personal Information requires all Pfizer colleagues to employ appropriate safeguards to protect Personal Information they have access to, including the Personal Information of customers or patients.

- Do not request or collect Sensitive Personal Information for any reason unless there is a clear business need for such Sensitive Personal Information and you have specific approval from your team attorney to do so.

- Avoid situations likely to lead to the inadvertent disclosure of Sensitive Personal Information, such as private conversations between HCPs and patients.

- If you become aware that Pfizer, a business partner or a service provider has received Sensitive Personal Information or more extensive Personal Information than intended, expected, or necessary for the business purpose, immediately notify your team attorney.

- When setting up a mentorship or preceptorship, Pfizer colleagues must remind physicians 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.
Key Points to Ensure Compliance

- Pfizer usually does not perform work on behalf of an HCP, Health Plan, or other “covered entity” under HIPAA. Therefore, it is not appropriate for any field-based colleague to enter into a Business Associate Agreement. If you are asked to sign a Business Associate Agreement, you may offer either the Pfizer Privacy Pledge or Patient Health Information Confidentiality Agreement template found on FieldNet, as appropriate. If this does not satisfy the party making the request, you must consult with your team attorney.

- Doctors are permitted to disclose protected health information about their patients to persons “subject to the jurisdiction of the FDA” for activities related to the quality, safety, or effectiveness of an FDA regulated product or activity for which the person has responsibility. Continue to follow the process established for collecting information about and reporting these events pursuant to Corporate Policy 903 – Your Responsibility to Report Information about Safety, Quality or Performance of Pfizer Products.

- Do not sign any non-Pfizer Confidentiality Agreement without consulting with with your team attorney.

- Do not discuss with an HCP the fact that you may know their prescribing practices based on their prescriber data.

- Do not share an HCP’s prescriber data with anyone outside of Pfizer.

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

- Employ the same safeguards to protect the confidentiality of prescriber data as you would any other Personal Information. As a general rule, prescriber data should be used only for internal business purposes and not in discussions with Pfizer’s customers (including the HCPs themselves) or external third parties.

- Any suspected breach of security of Personal Information or Sensitive Personal Information must be immediately reported pursuant to Corporate Policy 411 – Information Incident Response Policy. Lost or stolen computers or other devices containing Pfizer data must be reported to the user’s local Service Desk / Help Desk - the worldwide list of contact telephone numbers is available online at http://ITSupport.pfizer.com.

- Any other incidents of potential unauthorized access to Pfizer data must be reported as soon as possible to the Global Security Operations Center at 212-733-7900 or GSOCwatchroom@pfizer.com. You may also report incidents to your team attorney.
Laws Protecting Personal Data

One of the most important federal healthcare laws in the area of privacy is called the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH Act) (collectively, HIPAA). HIPAA imposes strict limitations on the use and disclosure of Sensitive Personal Information (called “protected health information” under HIPAA), 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 and Accounts including hospitals, health plans, and the vendors who provide services to them.

The collection and use of Personal Information is also regulated by other laws and regulations, such as state privacy laws, including state HIPAA laws. For example, there are state security breach laws that apply in the event that personal information is lost or improperly accessed and used.

Business Associate Agreements and Confidentiality Agreements

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

A confidentiality agreement will usually meet the needs of the covered entities mistakenly requesting BAAs. To address such requests, Pfizer has developed two Pfizer template forms, either of which you are permitted to offer to the HCP as assurance of your intent to keep Personal Information and Sensitive Personal Information (including protected health information) confidential. The Privacy Pledge can be signed and provided to HCPs or customers who might have general concerns about Pfizer’s position on HIPAA as it relates to its representatives or others who interact with covered
entities. The Patient Health Information Confidentiality Agreement can be signed and provided to an HCP or institution that would like a specific agreement to cover situations where a Pfizer representative inadvertently comes into contact with Sensitive Personal Information. No changes can be made to these templates unless your team attorney has approved the change in advance.

The Privacy Pledge and Patient Health Information Confidentiality Agreement can be downloaded from PfieldNet at [http://PfieldNet.pfizer.com](http://PfieldNet.pfizer.com) under the “Compliance” tab.

### Business Associate Agreements

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

**A.** No. You must not sign a Business Associate Agreement, even if required by an HCP in order to be allowed access to a facility. Colleagues may sign the Pfizer Privacy Pledge or Patient Health Information Confidentiality Agreement template found on PfieldNet. Providing a copy of one of these documents with your signature is usually sufficient to satisfy the HCP’s concerns about patient privacy. If the HCP continues to insist on a Business Associate Agreement, please promptly contact your team attorney who may be able to provide assistance to you.

### Signing Customer Confidentiality Agreements

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

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

### Steps to Protect Patient Privacy

#### Data Minimization

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

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

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

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

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

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

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

Obtain Patient Consent (via Written Authorization) Where Appropriate

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

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

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

**Report Data Incidents**

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

**Mentorships and Preceptorships**

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

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

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

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

**Adverse Event Reporting**

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

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

**Consent Forms and Mentorships**

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

A. Oral permission is not acceptable. As a convenience to your HCP mentor, you can download a template Patient Authorization Form from PfieldNet for the HCP to use. Ultimately, it is the responsibility of the HCP to obtain the appropriate written authorization from the patient.

Remember, you must also wear your Pfizer name tag at all times.

**Handling Patients’ Personal Data**

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

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

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

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

**Chart Reviews**

Q. Is it permissible to conduct chart reviews as part of our collaborative studies/programs with customers? If I sign a Business Associate Agreement, would that make it allowable?

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

**Consumer Health Fairs and Screenings**

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

Q. May a colleague with a medical background counsel consumers on how to interpret their screening results at a Pfizer-sponsored health screening?

A. No. Pfizer colleagues are not permitted to counsel patients about screening results, regardless of their education background or experience. The patient should be referred to his or her HCP.

REMEMBER

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

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

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

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

Securing Consent and Personal Information from Consumers

As a general policy, Pfizer does not use Personal Information to communicate directly with patients unless the patient has consented (or "opted in") to receiving such communications.

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

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

These guidelines apply only when consumers are asked to provide Personal Information, such as name, address, e-mail address, or a phone or fax number. When a Pfizer program requires a consumer to provide Personal Information as a term or condition of use of or access to the program, a simple, timely, cost-free mechanism (toll-free number or prepaid mail-in form) must also be provided that allows the consumer to discontinue or “opt out” of the program at any time.

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

Handling HCP Personal Information

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

As a general policy, Pfizer restricts access to Personal Information to individuals who “need to know” the information as related to their job duties. In general, most Pfizer colleagues, including Sales Colleagues, do not need access to Personal Information about HCPs, their employees, or the employees of Pfizer customers like Health Plans or GPO’s for any reason and should not request, collect, or retain any such information. This type of information includes, but is not limited to:

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

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

You may engage in an on-label discussion directly with the HCP to solicit and learn information about his or her clinical approach and use of specific products in order to tailor your promotional presentation; however, you may not directly convey the data you possess on his or her prescribing. You are also prohibited from sharing an HCP’s prescriber data with other individuals and entities outside of Pfizer. Within Pfizer, access to HCP prescriber data should be limited to colleagues that call on the HCP and their managers. Access to such data by other colleagues should occur on a strictly need-to-know basis. HCP prescriber data should only be used in the development of your team’s promotional strategy. Using prescriber data inappropriately not only compromises your credibility with the HCP, but it is also a violation of Pfizer policy, may subject you to disciplinary action up to and including termination, and may violate state laws limiting the use of such data.

The American Medical Association (AMA) administers a program by which physicians 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 a prescriber’s request. If an HCP has opted-out, Pfizer will respect that preference and will not use his or her prescriber data in connection with promotional activities. If you learn that an HCP on whom you call has asked for his or her prescriber data not to be released, even though you would not have access to the HCP’s prescriber data, you should be especially careful to avoid any discussion of prescribing habits in your promotional presentations to the HCP. The AMA program allows physicians to report specific instances of inappropriate behavior by pharmaceutical sales representatives or companies. Thus, it is important that you familiarize yourself with these rules and conduct your activities accordingly.
Providing Your Personal Information When Required By Vendor Credentialing Processes

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

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

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

- Always tell your manager if a hospital or institution (or institution’s vendor) wants you to provide your Personal Information to gain site access.
- If the hospital, institution, or vendor has a written credentialing policy, be sure to provide a complete and current copy to the Vendor Credentialing team and your team attorney to review in advance.

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• Do not sign any Business Associate Agreement or other legal document without consulting your manager and team attorney.

• Give the hospital or vendor Pfizer’s approved template Confidentiality Letter Agreement (available through a link in the Guidelines, accessible on PfieldNet).

• Do not share your Personal Information before the health care provider or vendor signs an approved Confidentiality Agreement to protect your information.

• Do not modify Pfizer’s approved template Confidentiality Letter Agreement without your team attorney’s approval in advance.

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

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

Corporate Policies on Your Responsibility for Safeguarding Personal Information

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

• Corporate Policy 403 on the Acceptable Use of Pfizer Information Systems;

• Corporate Policy 404 on Protecting the Privacy of Personal Information; and

• Corporate Policy 405 on Enterprise Records and Information.

• Corporate Policy 411 on the Information Incident Response Policy.

• Corporate Policy 903 on 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:

- Not leaving your Pfizer equipment or Personal Information unattended or in an unsecured location, e.g., an unlocked car;
- Encrypting your computer and using encrypted USB flash drives; (i.e. Never using unencrypted e-mail to transfer Personal Information outside of the Pfizer network
- Properly destroying media or paper containing Personal Information;
- Promptly reporting lost or stolen Pfizer equipment and other potential data incidents to Pfizer's Global Security Operations Center (GSOC) (212-733-7900 or GSOCwatchroom@pfizer.com) or to the local IT Service Desk (the worldwide list of contact telephone numbers is available online at [http://ITSupport.pfizer.com](http://ITSupport.pfizer.com)); and
- Never using unencrypted e-mail to transfer Personal Information outside of the Pfizer network.

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

**FOR MORE INFORMATION**

- For more information on information system policies, see [Corporate Policy 403, Acceptable Use of Pfizer Information Systems](#).
- For more information on protecting the privacy of Personal Information, see [Corporate Policy 404, Protecting the Privacy of Personal Information](#).
- For more information on records management, see [Corporate Policy 405, Records and Information Management](#).
- For more information on handling sensitive information, see [Handling Sensitive Information: Safeguarding Our Information](#).
• For more information on information system policies, see Corporate Policy 411, The Information Incident Response Policy.

• For more information on information system policies, see Corporate Policy 903, Your Responsibility to Report Information about Safety, Quality or Performance of Pfizer Products.

• For copies of the Privacy Pledge and Patient Health Information Confidentiality Agreement, see the “Compliance” tab on PfieldNet.

• For access to the Patient Authorization template, see the “Compliance” tab on PfieldNet.

• For more information on health screening and hiring vendors, see Orange Guide Chapter 13: Health Screenings.

• Questions may be referred to your manager or Legal.

• You can also call the Privacy Office Helpline at 212-733-0228 (worldwide) or 877-356-6195 (within the U.S.), or you can e-mail the Privacy Office at Privacy.officer@pfizer.com.
Chapter 9: SPEAKER PROGRAMS FOR HCPs

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Chapter 9:  SPEAKER PROGRAMS FOR HCPs

Introduction

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

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

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

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

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

- Speaker programs must be submitted in Centris with the lead time required depending on the type of program (e.g., live programs must be entered at least 14 calendar days prior to the proposed program date). All speakers must be in CentrisCentris and selected based only on expertise, credentials, and ability to communicate with the target audience.

- You must have a pre-program discussion with each speaker to review policies and the approved slide deck (downloaded from the appropriate system) for each program. Reserve sufficient time to review the deck and applicable Pfizer policies including your duty to correct.

- At the program, you are responsible for projecting the slides using your Pfizer device with a projector (except at roundtable programs, where handouts may be used). This ensures the presentation is the current, unaltered RC-approved version. For a webconference or teleconference program, you are also responsible for ensuring appropriate A/V equipment is used (e.g. it is generally not appropriate to use an iPhone, iPad, or laptop to present the slides or audio content without projecting the slides onto a larger display).

- 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.

- The information provided verbally by the speaker must also be consistent with the RC-approved slides and product labeling and must balance benefits and risks. Pfizer colleagues in attendance should be familiar enough with the deck and Package Insert to identify inappropriate statements or other issues with the speaker's presentation and should correct the speaker.

- Only RC-approved educational information that has been approved for such distribution can be handed out to attendees.

- At the start of all speaker programs, speakers must review the introductory compliance slide, which includes statements that Pfizer is sponsoring the presentation and that they are presenting on Pfizer’s behalf.
Speaker Program Checklist

- For all venue programs, speakers must engage the attendees for a minimum of 45 minutes, inclusive of Q&A. For programs in an in-office setting, a minimum of 30 minutes is required. Set expectations with the attendees ahead of time to ensure they are able to stay for the entire program duration, and if an attendee misses part of a 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.

- The speaker program venue must be appropriate and conducive to a scientific or educational presentation.

- Programs with insufficient appropriate RSVPs 7 calendar days prior to the program (3 calendar days for out-of-office link programs) cannot go forward. The responsible Pfizer colleague must communicate any cancellation as soon as possible to the speaker to avoid an obligation to pay the speaker for the cancelled program.

- If a Pfizer colleague is entering an RSVP on behalf of an attendee, they should only do so when the HCP has clearly indicated their intention to attend the program.

- For in-office programs, three appropriate attendees are required. Two (2) out of the required three (3) minimum attendees must be individuals who have a professional designation that is included on the Approved Attendee List. Additional attendees may only be invited, and permitted to consume any meal provided, if the responsible Pfizer colleague determines that the program contents are appropriate in light of the attendee’s role and responsibility for patient care. For out-of-office programs, there must be a legitimate expectation that at least three (3) appropriate individuals from the Approved Attendees List who are not affiliated with the speaker will attend. Once you have such an expectation, and their RSVPs have been recorded in the system, you may permit attendance by appropriate Medical Assistants (MAs) with an identified role in and responsibility for patient care. Office staff, guests, spouses, and any other individuals who do not have an Approved Attendee designation may not attend out-of-office programs.

- Individuals from the Approved Attendees List and Medical Assistants are prohibited from attending a program on the same topic more than two (2) times and for the same product more than three (3) times during a calendar year.

- 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.
Speaker Program Checklist

- Sales Representatives are not permitted to host a program using a speaker who is on their Territory Credit List ("TCL") more than three (3) times during a calendar year. Sales Representatives within a District must not host a program utilizing a speaker on the TCL of any other district member more than six (6) times in a calendar year in aggregate. Colleagues who do not have a TCL but still host speaker programs (e.g., Vaccines reps, Oncology KAMs) must not host a program utilizing a speaker called on by any member of their district more than six (6) times in a calendar year in aggregate. Unless further restricted by state or other laws, food and beverages must be modest by local standards and, for out-of-office programs, must not exceed $135 per attendee, including tax, tip, and delivery charges. For in-office programs, food and beverages must not exceed $40 per attendee, including tax, tip, and delivery charges.

- While Centris will assist in ensuring that only appropriate attendees come to your program, you must still make a good faith effort to ensure that all attendees: (1) practice in an appropriate specialty that is not excluded for the promoted product; (2) do not hold active licenses from states that impose restrictions on meals (if you plan to provide one at the program); and (3) are appropriate based on Pfizer’s attendee rules.

- The transparency provisions of the Sunshine Act apply to speaker fees and travel expenses, educational items provided during the program, and the value of meals provided to U.S.-licensed physician speakers and attendees. Certain states and federal institutions have additional disclosure obligations for U.S. HCPs, including physicians, nurse practitioners, and physician assistants, as described in Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions.

- To ensure appropriate accounting of the per-person value of a meal, all attendees should be tracked, regardless of whether they have opted out of receiving meals or other disclosable value, but only those who actually consume a meal are subject to disclosure, if relevant.

- If a speaker commits a violation of Pfizer policy, you must correct the violation during the program, coach the speaker after the program, and report the violation in the Centris closeout process. Potential violations that do not involve the speaker may be recorded in your closeout as an “Other Reportable Event.”
Your Role in Setting Up a Speaker Program

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

Timing

All speaker programs must be submitted in Centris within the required minimum lead time. All live and webconference/teleconference sponsor programs must be entered into the Centris system at least 14 calendar days prior to the proposed program date. Centris will prevent the creation of any new live or webconference/teleconference sponsor program less than 14 calendar days prior to the scheduled date of the program. All out-of-office webconference/teleconference link programs must be entered into the Centris system at least five (5) calendar days prior to the proposed program date. Centris will prevent the creation of any out-of-office webconference/teleconference link program less than five (5) calendar days prior to the scheduled date of the link program. All in-office webconference/teleconference link programs must be entered into the Centris at least three (3) calendar days prior to the proposed program date. Centris will prevent the creation of any in-office webconference/teleconference link programs less than three (3) calendar days prior to the scheduled date of the program.

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

This is a critical requirement for ensuring compliance with policies governing interactions with speakers, including accurately determining when a speaker has reached his or her annual speaking fee cap.
Choose the Relevant Topic and Select an Appropriate Speaker

The topic of each speaker program must be RC-approved and included in Centris. After choosing a topic, select a speaker from Centris. Speaker selection must be solely based on the speaker’s expertise, credentials, and ability to communicate effectively to the targeted audience. You cannot engage a speaker in order to establish a relationship, gain or improve access to the speaker, reward past prescribing, or induce future prescribing. A Sales colleague must not host more than three (3) programs in a calendar year utilizing a speaker on his or her Territory Credit List (TCL). Sales colleagues within a District must not host programs utilizing a speaker on the TCL of any member of their District more than six (6) times in a calendar year in aggregate. For example, if a speaker is on a representative’s TCL, that representative may host, at most, three programs in a calendar year utilizing that speaker, and the other members of his or her District may only host an additional three programs utilizing that speaker during the same calendar year for a total of six programs. Colleagues who do not have a TCL but still host speaker programs (e.g., Vaccines territory managers, Oncology KAMs) must not host programs utilizing a speaker called on by any member of their District more than six (6) times in a calendar year in aggregate. Centris Speakers will appear “active” in Centris and available for selection only when they have completed the relevant brand’s Core Product or Topic Training (as applicable) and Pfizer’s compliance training and have signed a Pfizer Speaker Agreement.

Violations of these policies, including holding a program not entered in Centris without prior Legal approval or entering a fictitious program date in Centris, could subject you to disciplinary action. For more information on how to activate a speaker in Centris, consult your manager, Meeting Planner, or the Customer Events & Engagement (CE&E) team.
Speaker Selection

Q. Can experts other than physicians speak at promotional speaker programs?
A. Yes. Any person with the requisite expertise and credentials may speak on Pfizer’s behalf. It may be appropriate in some cases to use nurses, pharmacists, patient ambassadors, or patient advocates to speak on certain topics or to targeted audiences.

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

Scheduling Issues

Q. An out-of-town speaker has asked a colleague to schedule a speaker program to coincide with the speaker’s personal travel schedule, so that Pfizer can reimburse his personal travel expenses. Is this permissible?
A. No. You cannot conduct a speaker program for the benefit of the speaker. Out-of-town speakers may only be used when there is a legitimate business reason to do so, and your scheduling decisions should only be motivated by the availability of the appropriate audience.

Speaker Program Content

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

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

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Remember, any information provided by a speaker must be:

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

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

Speakers may not engage in a consultation during a speaker program and may not review charts or otherwise provide medical advice for individual patients.
Use of Pfizer Approved Speaker Slide Kits

Q. Is a speaker required to use all slides contained in a Pfizer approved slide kit?
A. Speakers must present all required slides in the RC-approved slide deck. In particular, a speaker must appropriately emphasize all slides that relate to safety and risk (e.g., warnings, contraindications, adverse events) to ensure fair balance, even if they appear duplicative. If the presentations listed in Centris allow the speaker to select certain slides from the approved deck, he or she must be certain to include all slides identified as mandatory in the final deck and present them at the program. (Note that for speaker slide decks intended for use with consumers, all slides must be presented.)

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

Review Policies with Speakers

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

- A reminder that the speaker is speaking on Pfizer’s behalf and that all proactive statements must be consistent with the label and approved slide deck;
- A reminder that the speaker must present a current RC-approved slide deck, without any unapproved materials or modifications, and that you will be prepared to project the slides from your Pfizer device with a projector (except at roundtable programs, where handouts may be used);
- A reminder of the appropriate duration of the program, inclusive of Q&A time (minimum of 45 minutes for out-of-office programs, or a minimum of 30 minutes for programs with attendees in an in-office setting);

- A reminder that the speaker must start the program by reviewing the introductory compliance slide(s), which includes statements that Pfizer is sponsoring the presentation and that he or she is presenting on Pfizer’s behalf;

- A reminder that if an attendee asks the speaker a specific unsolicited off-label question, the speaker may answer briefly and limited to the specific question asked, after stating that the information to be discussed is unapproved and is based on the speaker’s personal experience, knowledge, or opinion;
  
  o If the attendee asking the question requires additional information or the question cannot be adequately answered briefly, the speaker (or Pfizer colleague) must refer the attendee to the Pfizer Medical Information department; and

- A reminder of your obligation to make a clarifying or corrective statement if the speaker presents off-label or other unapproved information that was not in response to a specific unsolicited question.

### Use of Unapproved On-Label Clinical Reprints

Q. 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?

A. No. All information presented proactively must be RC-approved.

### Roundtables and Use of Approved Materials

Q. When a speaker program involves a small group of attendees in a “roundtable” format, does the speaker have to use Pfizer approved slides?

A. Yes, a speaker must always use only RC-approved slides.

Q. Can attendees take a copy of the printed materials with them?

A. Maybe. You should consult with the team attorney to determine whether there are any restrictions on providing copies of the printed deck or materials to attendees. Certain teams prohibit the distribution of printed copies of the speaker slide decks as handouts. In any case, the relevant product package insert must be made available to attendees at all speaker programs.
Arrange Meeting and Speaker Logistics with Meeting Planner

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

**Venue Requirements**

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

- Is conducive to the exchange of scientific information. The purpose of the program is to convey information. The venue’s environment should not detract from that purpose.
- Is considered modest by local standards. No more than $135 per attendee may be spent on food, beverage, tax, tip, and delivery charges for an out-of-office speaker program and no more than $40 per attendee may be spent on food, beverage, tax, tip, and delivery charges for an in-office speaker program. What is considered a modest cost for a meal in one part of the country may not be appropriate in another part of the country.
- DOES NOT involve recreation or any other entertainment component. The PhRMA Code expressly prohibits any kind of entertainment at industry-sponsored programs.
Speaker Program Venue Examples (Dos and Don’ts)

<table>
<thead>
<tr>
<th>Permitted</th>
<th>Prohibited</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private room at a restaurant (subject to price restrictions).</td>
<td>Private Box at a theatre performance or sporting event.</td>
</tr>
<tr>
<td>Conference room at a hotel or convention center.</td>
<td>Conference room at a museum or location of a celebrity event.</td>
</tr>
<tr>
<td>Program held at a moderately priced local restaurant.</td>
<td>Program held on a dinner boat cruise or a restaurant that offers or is associated with any form of entertainment.</td>
</tr>
</tbody>
</table>

Speaker CVs

Q. 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?

A. No. Although Pfizer maintains copies of speaker CVs in Centris, they are for internal use only and have not been RC-approved for external distribution.

Programs at Private Clubs

Q. May I hold a speaker program in a private room at a restaurant located within a country club or golf club?

A. Generally, no. Holding a program at a country club or golf club, where recreation is often provided, may have the appearance of impropriety and is therefore discouraged. Programs should never involve any recreational activities and the cost of using any venue as well as payment for the meal must be billed directly to Pfizer.

Preparing and Distributing Invitations

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

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

Invitations that have been approved for use should normally be distributed in person or by regular mail with no additional written statements beyond the content of the invitation itself. Colleagues may also deliver approved speaker program invitations via e-mail, but only if the e-mail accompanying the invitation is limited to the following language:

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**Pfizer Speaker Program Invitation Template**

Subject: “Pfizer Speaker Program Invitation – Event Date [XX/XX/YYYY]”

“Dear [insert name],

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

- Per Pfizer policy, this invitation is only intended for the healthcare professional addressed above and should not be forwarded to others.
- Please review important notifications provided at the bottom of the invitation.
- If you know of another healthcare professional who might also be interested in attending, please let me know.

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

Sincerely,

[Colleague name]

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

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

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

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

**Determine the Appropriate Audience**

You, not the speaker, are responsible for selecting the audience for your speaker program. The audience should consist of attendees with a legitimate interest in the scheduled topic, and the invitees must not be chosen for the purpose of encouraging referrals for the speaker. It is impermissible for a speaker to promote his or her own practice in connection with a Pfizer speaker program. (Likewise, speakers may not distribute business cards for the purpose of promoting their practices during programs.)

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

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

The audience of a speaker program must include at least three (3) appropriate attendees – as defined below for in-office and out-of-office programs – who are not affiliated with the speaker (i.e., not part of the speaker's medical practice, practice group, or institution). If attendees receive compensation as employees from the same business entity, even if they work in different locations, they are considered members of the same practice or institution. The speaker does not count toward the three attendee minimum.

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

Out-of-Office Speaker Programs

For Pfizer-hosted out-of-office branded and unbranded programs, both live and webconference/teleconference, you must have a legitimate expectation that at least three (3) individuals from the Approved Attendees List below who are not affiliated with the speaker will attend, unless an exception has been given by Legal and Compliance for a unique program type. It is your responsibility to determine that the individual has an Approved Attendee designation, utilizing the HCP Look-Up Tool or Centris functionality. Centris Additionally, you must confirm that: (1) each Approved Attendee has appropriate responsibility for patient care; and (2) the program content is relevant to the Approved Attendee’s role. Except as stated below, office staff, guests, spouses, and any other individuals who do not have an Approved Attendee designation may not attend out-of-office programs.
## Approved Attendees List

<table>
<thead>
<tr>
<th>Occupation</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced Nurse</td>
<td>AN</td>
</tr>
<tr>
<td>Certified Nurse Anesthetist</td>
<td>CNA</td>
</tr>
<tr>
<td>Clinical Nurse Specialist/Certified Nurse Specialist</td>
<td>CNS</td>
</tr>
<tr>
<td>Chiropractor</td>
<td>CRP</td>
</tr>
<tr>
<td>Doctor of Dental Surgery</td>
<td>DDS</td>
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<tr>
<td>Doctor of Osteopathy</td>
<td>DO</td>
</tr>
<tr>
<td>Doctor of Podiatric Medicine</td>
<td>DPM</td>
</tr>
<tr>
<td>Lab Director (Xalkori only)</td>
<td>---</td>
</tr>
<tr>
<td>Licensed Practical Nurse</td>
<td>LPN</td>
</tr>
<tr>
<td>Medical Doctor</td>
<td>MD</td>
</tr>
<tr>
<td>Medical Student</td>
<td>MS</td>
</tr>
<tr>
<td>Naturopathic Physician</td>
<td>ND</td>
</tr>
<tr>
<td>Nurse-Midwife</td>
<td>NM</td>
</tr>
<tr>
<td>Nurse Practitioner</td>
<td>NP</td>
</tr>
<tr>
<td>Doctor of Optometry</td>
<td>OD</td>
</tr>
<tr>
<td>Physician Assistant</td>
<td>PA</td>
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Once you have a legitimate expectation that at least three (3) Approved Attendees who meet criteria 1 and 2 above will attend a program, and their RSVPs have been recorded in the system, you may permit attendance by appropriate Medical Assistants (MAs) with an identified role in and responsibility for patient care. It is your responsibility to determine whether an MA has an identified role in and responsibility for patient care before allowing the MA to attend. MAs need not be from the same office as any attendee with an approved designation. Please note that this policy applies only to Medical Assistants. Other office staff, spouses, guests, and individuals with designations that are not listed in the Approved Attendees chart remain prohibited from attending out-of-office programs. Please manage your invitees and attendee rosters carefully to ensure your program is compliant.

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

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

Webconference/Teleconference Speaker Programs

Webconference and teleconference programs use technology that allows attendees to participate in speaker programs from remote locations ("link sites") when physical attendance at the speaker’s location ("sponsor site") is not possible. For webconference or teleconference programs conducted in-office, individuals from the Approved Attendee List, Medical Assistants, and other appropriate office staff attending the program from link sites (as well as any attending at the sponsor site) are counted toward the aggregate number of attendees required by Pfizer’s minimum attendance policy, including for determining a program’s minimum anticipated attendance seven (7) calendar days prior to the program as discussed in more detail below. However, for any sponsor or link program site located at an out-of-office venue (e.g., a restaurant), there must be a legitimate expectation that at least three (3) individuals from the Approved Attendees List will attend at that out-of-office site. Once you have a legitimate expectation that at least three (3) Approved Attendees will attend a webconference or teleconference program at an out-of-office venue, you may permit attendance at that site by appropriate MAs with an identified role in and responsibility for patient care. This site attendance requirement applies to both sponsor and link out-of-office venues.

The Pfizer colleague must ensure that A/V will be appropriate for each webconference or teleconference program site and that the attendees can clearly hear the speaker’s presentation and see the slides (e.g., it is generally not appropriate to use an iPhone, iPad, or laptop to present the slides or audio content without projecting the slides onto a larger display). An appropriately trained colleague must monitor the webconference or teleconference program to ensure compliance with all of the policies set forth in this Chapter.
Providing In-Office Meals to Office Staff

Q. When conducting an in-office speaker program at a medical office, is it ok to provide a meal to office staff in addition to individuals on the Approved Attendees List and Medical Assistants at the program?

A. Yes, it is generally permissible to provide office staff with a meal so long as they are appropriate attendees for the speaker program, meaning they have a defined role and responsibility for patient care, and they attend the program to receive relevant scientific or educational information. If they are not appropriate attendees for the speaker program or are unable to attend the program to receive the information presented, they should not consume the meal provided for speaker program attendees or be included in the attendee roster.

Specialty Exclusions

Q. May I invite HCPs to a speaker program if they belong to a specialty that is excluded for the product being discussed?

A. No. If you are unsure whether a prospective attendee is subject to an applicable exclusion, consult the HCP profiles in Veeva CRM to verify his or her status before extending an invitation. Remember, if you cannot detail an HCP on a particular product, you are not permitted to invite the HCP to a speaker program on that product.

Speaker Suggesting or Inviting Attendees

Q. May a program speaker or invitee personally invite other prospective attendees? May a speaker suggest attendees?

A. A speaker or invitee may suggest other attendees to you in advance of the program, but it is your responsibility both to determine that each of the prospective attendees is appropriate and then to extend the official invitation. RSVPs for the program should not be collected by the speaker or other attendees.

You cannot conduct a speaker program for the benefit of the speaker, and therefore, it would be improper to invite attendees at the request of a speaker without a justifiable business rationale for including them. Your sole purpose in holding the speaker program must be to educate attendees about Pfizer products (or other topics in an approved presentation). Therefore, it would be improper to invite attendees at the request of a speaker without an appropriate business rationale for including them.
Speakers to One Medical Office or Practice

Q. May a Pfizer colleague invite a speaker to speak in-office to attendees at a single medical office or practice?

A. Yes, if overall at least three (3) appropriate attendees who are not affiliated with the speaker are expected to attend and two (2) out of those three (3) minimum attendees are individuals who are included on the Approved Attendee List set forth above. Please note that Pfizer cannot pay members of the same business organization to educate each other.

Spouses or Domestic Partners as Guests

Guests of attendees, including their spouses or domestic partners, are not permitted to attend Pfizer promotional speaker programs unless they independently qualify as appropriate attendees. For out-of-office programs, this means the spouse/domestic partner must be on the Approved Attendees List (or a Medical Assistant, when appropriate). For in-office programs, there must also be a legitimate reason for a spouse/domestic partner to attend and the colleague must determine, on a case-by-case basis, that the program content is appropriate in light of the individual’s role and responsibility for patient care.
How to Handle Uninvited Guests

Q. What should I do if someone who was not invited to the program shows up?

A. Appropriate attendees may attend programs, even if they are not directly invited, if there is room for them at the program. However, you must determine whether the attendees are appropriate based on Pfizer’s in-office and out-of-office attendee policies. You must also ensure that the attendees are not part of an excluded specialty or currently licensed in a restricted state. You must accurately record the attendees’ details in Centris. If an attendee is deemed not to be appropriate, based on notifications in Centris or the attendee’s responses to screening questions, you must respectfully ask him or her to leave the program.

Q. What should I do if a receptionist at an office I call on indicates that he or she will be attending a speaker program to which he or she was not invited?

A. Because a receptionist’s responsibilities are generally administrative, he or she would not be an appropriate attendee. It is your responsibility to inform him or her that he or she should not attend the program. You must ensure that all speaker program attendees are appropriate, given their role and responsibilities in patient care and the program content.

Q. 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 his or her meal?

A. No. You must remind the attendee that Pfizer guidelines and the PhRMA Code prohibit guests, spouses, or domestic partners from attending Pfizer speaker programs. This is clearly stated on the approved speaker program invitation. If the guest does not independently qualify as an appropriate attendee, you must respectfully ask that they leave the program.

RSVPs and Cancellation of Programs

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

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

If you have at least three (3) RSVPs recorded in the system from appropriate attendees for the particular program type, and you had a legitimate expectation that they would attend, but you receive unexpected cancellations after the RSVP requirement has been met (e.g., less than seven (7) calendar days prior to a scheduled out-of-office program), and fewer than three appropriate attendees will attend the program, you are not required to cancel that program. However, if there are no appropriate attendees, a speaker program must be cancelled.

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

Q. For an upcoming out-of-office program, I have three (3) RSVPs from appropriate Approved Attendees (and have a legitimate expectation that they will all attend). Two (2) MAs have also RSVP’d that they will attend. On the day of the program, one of the individuals who is an Approved Attendee informs me that she will be unable to make it. Do I have to cancel the program? If I don’t cancel, are the MAs still permitted to attend although I don’t have three (3) attendees with Approved Attendee designations?

A. You are not required to cancel the program. If you have three (3) RSVPs from appropriate Approved Attendees recorded in the system, and you had a legitimate expectation that you would have three (3) such individuals attend but had a cancellation close to the program date (for out-of-office, within seven calendar days), you may hold the speaker program. In addition, the MAs may attend even though you may only have two (2) Approved Attendees in attendance. However, if there are no appropriate attendees, a speaker program must be cancelled.

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

U.S. HCP Payment Disclosure Policy

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

If an HCP does not want to have items reported, he or she must not accept or receive meals, speaker fees, or other value from Pfizer. Pfizer maintains a record of HCPs who have “opted out” of receiving disclosable items from Pfizer, which you can view on the PfizerNet Compliance page or OpSource. Colleagues should review the list prior to choosing a speaker, inviting attendees, and conducting a speaker program. If an attendee has opted out, but nevertheless consumes a meal, the value of the meal will be reported.
For additional information on Pfizer’s HCP payment disclosure Policy, see Chapter 18: Meals, Educational Items, and HCP Payment Disclosure.

**Your Role During a Speaker Program**

**Electronic Sign-Ins at Speaker Programs**

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

**Screening Walk-In Attendees**

Appropriate attendees may attend programs, even if they are not directly invited, if there is room for them at the program. However, colleagues are expected to screen all walk-in attendees to the extent possible in order to ascertain whether each is an appropriate attendee based on Pfizer’s in-office and out-of-office attendee policies, including brand-specific specialty exclusions, state license restrictions, etc. To assist with this screening, colleagues can match attendees in Centris with data in the Pfizer Universe to flag any walk-ins who may not be appropriate attendees. If there is no match, colleagues must ask appropriate screening questions.

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

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

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

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

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

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

Q. What should I do if a speaker presents off-label information during his or her presentation that was not in response to a specific unsolicited question?

A. You must:

- Promptly and courteously clarify to the audience that the off-label information provided is not within product labeling and is not a part of the approved Pfizer presentation. This should be done as soon as possible after the speaker has presented the off-label information, even if the speaker proactively informs the audience that the information is off-label.

- Remind the speaker after the presentation that Pfizer’s guidelines require that off-label information be provided only in response to a specific, unsolicited question.

- When you close out the program in Centris, indicate, as prompted in the system, that a violation was committed by the speaker. Once submitted, you will be contacted for additional information. Speakers who proactively speak off-label may be subject to further action, up to and including deactivation.

- Keep in mind that the mandatory Pfizer Speaker Program Policy slide at the beginning of each speaker program notifies attendees that a Pfizer colleague must make a corrective statement if the speaker presents information that is inconsistent with an FDA-approved label or Pfizer policy.

Note: If the speaker answers an unsolicited off-label question briefly and as permitted by policy as stated earlier in this Chapter, no “corrective” statement is required and no policy violation should be indicated when you close out the program.

Handouts and Give-aways

Copies of the approved package insert for each Pfizer product being discussed must be made available at each presentation. Only RC-approved educational materials that are approved for such distribution may be provided to attendees. If permitted by the Review Committee, you may disseminate paper copies of Centris presentation slides at a program. Colleagues should consult with their brand teams to determine whether they are permitted to provide copies of the printed deck or materials to attendees. You may not distribute electronic copies of Centris presentation slides without first consulting your team attorney. You, not the speaker, are responsible for copying and disseminating any approved
materials to attendees. Copies of slides created by the speaker cannot be handed out (even if they have been RC-approved through the Speaker Slide Exceptions Process).

**Gifts to Attendees of Speaker Programs**

**Q.** Can I purchase token gifts for attendees at my speaker program? Can I purchase a token thank you gift to give to the speaker?

**A.** No. Attendees may only be given RC-approved educational promotional items that have been approved for distribution, that comply with Pfizer guidelines and the PhRMA Code, and that are permissible under state law. Further, you are not permitted to provide speakers with any additional items of value for speaking on Pfizer’s behalf.

**Payment and Reimbursement**

**Speaker Fees**

You are not responsible for negotiating the amount of a speaker’s speaking fee. Fees are determined based on pre-set criteria.

Each speaker has a limit on the total speaking fees (not including travel expenses) that he or she can earn from Pfizer in a calendar year. An individual speaker’s annual limit will be set through Pfizer Headquarters and any increases must be approved in advance by Headquarters.

**Speaker Fees**

**Q.** May a speaker waive his or her fees, or request that Pfizer donate the honoraria to charity or to his or her institution?

**A.** A speaker may agree to waive the fees and speak for free (or for less than the contracted rate). However, Pfizer cannot donate speaker fees on a speaker’s behalf.

**Closeouts**

After a program, Pfizer colleagues must enter program information in Centris to close out the program, including flagging any policy violations that may have occurred. If there is not an appropriate check box for a violation, please select “Other Reportable Incident,” and you will be contacted for further details.
Cancellation and Payment Issues

Q. What should I do if I hold a program with fewer than 3 attendees due to last minute cancellations, but the unexpected no-shows cause me to spend more than the applicable meal cap on the meal (including food, beverage, tax, tip, and any delivery charges)?

A. You must always accurately record expenditures on meals, even if they exceed the applicable meal cap. You will be asked to document the circumstances around the potential policy deviation after you close out the program in Centris. You can reduce your risk of violating this important policy by selecting inexpensive menu items and for out-of-office programs, by selecting venues that do not require large minimum guarantees.

Q. In the event that Pfizer has to cancel a speaker program, does Pfizer still pay the speaker?

A. If Pfizer cancels a speaker program within five business days of the scheduled engagement, and the speaker requests payment, Pfizer is contractually obligated to pay the speaker his or her speaking fee, with very limited exceptions. However, you must attempt to re-schedule a cancelled program within 90 days of such cancellation and the speaker will be obligated to conduct the program for no additional speaking fee. Please note that the program may occur more than 90 days after the date of cancellation as long as the program is rescheduled on the same topic within 90 days. You must make every reasonable effort to reschedule the cancelled speaker program within this timeframe. If a program is cancelled more than five business days in advance or if the speaker requests the cancellation, Pfizer is not required to pay the speaker's fee.

Attending the Speaker Program

Q. Do I have to be present during a speaker program that I host?

A. You always must be present with the speaker during the entire speaker program to ensure that Pfizer guidelines are followed throughout, as this is the host's most important role at a speaker program. You must also monitor any program conducted remotely by webconference or teleconference. If you cannot attend, you may ask your manager or other appropriately trained colleague to attend on your behalf. However, you must notify the Meeting Planner and receive approval if there is a change in the program host listed in Centris. If no appropriate colleagues are available to attend, the program must be cancelled.
Speaker Programs at Third Party Meetings

Third party meetings held by groups such as local medical associations, residents at institutions, or local disease advocacy organizations may provide you with an opportunity to promote Pfizer products to individuals who are gathering together for another purpose. Holding a promotional program in this circumstance must be based on a legitimate business purpose to present information about Pfizer products and cannot be based on a desire to support or otherwise fund an independent meeting.

Follow these key principles to ensure that speaker programs conducted in conjunction with third-party meetings are appropriate:

- You must submit programs in Centris prior to the program date with the minimum required lead time described above, as with other speaker programs.
- You must have a legitimate promotional speaker program in connection with the meeting.
- All Pfizer policies and processes regarding speaker programs must be adhered to—for example, programs at third party meetings must meet the duration and content requirements of other speaker programs. Further, if the customer permits spouses or guests to attend its meeting or there will be excluded specialties in attendance, holding a Pfizer speaker program in connection with the meeting would not be appropriate.
- You must make it clear to the customer or organization that Pfizer is not a “sponsor” of its business meeting. Explain that Pfizer is engaging in a separate promotional activity with attendees of the meeting. Identify to the audience a clear start and end to the Pfizer promotional program to avoid the misperception that Pfizer is supporting any part of the meeting itself.
- If you provide a meal, it must be offered only as part of the Pfizer program, and must be incidental to and not otherwise the focus of the program. It would not be permissible to provide the meal more than 30 minutes in advance of the Pfizer program, nor after the program is completed.
- Pfizer cannot split the cost of a meal with the host of a third party meeting. However, you may conduct a Pfizer speaker program during a meal that is provided and paid for entirely by a third party, as long as you make clear that Pfizer is not responsible for providing the meal.
meal. Meals provided by third parties will not be reported as part of Pfizer’s payment disclosure policy.

- Before or after the Pfizer program, you should avoid being present during any discussion of a Pfizer product that you anticipate will be inconsistent with that product’s labeling.

- As with other speaker programs, you must capture all attendee information in Centris. Before confirming the program, you should coordinate with the third party to ensure that you will receive all necessary information about the attendees.

If a colleague were to participate in any way in the content of the non-Pfizer meeting, the entire meeting might be considered a promotional event and could then be governed by the same promotional rules that apply to all Pfizer speaker programs and other promotional activities. For information on detailing at third-party meetings, see Orange Guide Ch. 2: Interactions with HCPs.

If an Account Manager intends to host a speaker Centris program at a third party meeting and the topic of the program does not address products or disease states, the Account Manager may work with the host of the third party meeting to publicize the program. Specifically, the Account Manager may ask the host to include the Pfizer program on the agenda for the third party meeting. The Account Manager also may provide the host with an approved invitation for the third party to distribute to attendees.

In all instances, it must be clear that Pfizer is not the “sponsor” of the third party meeting and that Pfizer is engaging in a separate promotional activity with attendees of the meeting. Also, as noted above, all Pfizer policies and processes regarding speaker programs must otherwise be adhered to, and the Account manager must capture all appropriate attendee information in Centris.

**Speaker Programs at Third-Party Continuing Education Events**

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

- The Pfizer program must be conducted in a room physically separated from the space where Continuing Education (CE) activity is conducted.
• At the start of the program, you must clearly communicate to attendees that it is a separate Pfizer promotional presentation not accredited for Continuing Medical Education (CME) credit.

• Pfizer cannot provide meals or beverages in connection with the Pfizer program. Any meals provided by a CME provider must be made available to all CE event attendees, including those not attending the Pfizer presentation. This policy applies to all programs at CE events, including programs hosted by Account Managers with topics that do not address products or disease states.

• No advice or input may be provided regarding the content of the medical education activity.

• No financial or other support, including payment for event expenses or meals, assistance with setting up logistics, or handling non-Pfizer speaker arrangements, may be provided in connection with the Pfizer program (subject to very narrow exception for logistical expenses discussed below). Financial support for a CE event may only be funded by an independent medical education grant requested through Pfizer’s Independent Grants for Learning & Change website. For more information, see Orange Guide Chapter 3: Support of External Organizations.

Third-Party Meeting Venues

Q. I have been offered an opportunity to conduct a promotional speaker program as part of a local medical group’s two-day annual meeting. However, the meeting venue is a country club and I understand that the group is providing various entertainment activities in connection with the meeting (e.g., rounds of golf). May I still conduct the program?

A. Possibly. If Pfizer has no control over the venue and we are reasonably comfortable that Pfizer can provide an educational presentation segregated from any entertainment component, this might be acceptable. Please remember that Pfizer cannot support, nor may you participate in, any of the entertainment activities. Consult with your team attorney for guidance in these situations.
Meals Provided by Medical Education Organizers During a Pfizer Speaker Program

Q. 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?

A. Yes. As long as Pfizer is not paying for the meal and it will be made available to all event attendees (including those not attending the Pfizer presentation), it is acceptable for the meal to be provided during the Pfizer program. Be sure to make clear that Pfizer is not providing the meal or sponsoring the medical education event.

Physical Separation of Speaker Programs at Medical Education Events

Q. The organizers of a medical education event require that Pfizer pay a fee to cover expenses that are directly associated with a promotional speaker program, such as the cost to rent a separate presentation room. Must this fee be paid through a medical education grant from the office of Independent Grants for Learning & Change?

A. No. Standard fees required to cover the fair market value of logistical expenses associated only with the Pfizer speaker program may be paid by the appropriate Pfizer Colleagues.

Q. 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?

A. Generally no. However, if it is possible to physically separate your presentation space within the event room, you may consult with your team attorney about an exception to determine if and how the program may be conducted appropriately under the circumstances.

FOR MORE INFORMATION

- For more information about Pfizer’s policies and procedures for conducting speaker programs, please refer to Centris or the “Speaker Programs” tab at [http://OpSource.Pfizer.Com](http://OpSource.Pfizer.Com).
- For more information about Pfizer’s policies for conducting compliant speaker programs for consumers, see Orange Guide Chapter 16: Consumer and Employee Interactions.
• To determine whether an HCP is licensed in Minnesota or Vermont, consult Veeva CRM or the HCP License List on the PfieldNet Compliance page.

• For more information about state laws that limit the provision of gifts (including meals) to HCPs, see Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions.

• For more information about the HCP payment disclosure policy, see Orange Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure.

• Refer any additional questions to the Customer Events & Engagement team, your manager, or your team attorney.
Chapter 10: STARTERS

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Chapter 14: STARTERS

Introduction

Pfizer provides healthcare professionals (HCPs) with free pharmaceutical drug product samples (referred to as "starters") to give to patients so that they can evaluate the efficacy and tolerability of our products for the patient before filling a prescription. Starters also provide HCPs an opportunity to become familiar with a drug and its properties, thereby enhancing their ability to make appropriate prescribing decisions. The distribution of starters is highly regulated under federal and state law, and the misuse of drug samples can have severe implications for both individual colleagues and Pfizer.

The Prescription Drug Marketing Act of 1987 (PDMA) is the key federal law governing the distribution of drug samples. Pfizer policies for complying with the PDMA are described in the Starter Compliance Manual, and the key points are summarized in this Chapter. The distribution of starters is also impacted by other healthcare laws such as those dealing with fraud and abuse and off-label promotion.

In addition, several states have laws that affect whether and to whom starters may be distributed. For example, some states have particular limitations on distributing starters for controlled substances like Lyrica. Likewise, some states impose requirements (that differ from federal law) on when lost or stolen starters must be reported, as well as which mid-level practitioners (e.g., nurse practitioners, physician assistants) may prescribe drugs and are authorized to accept starters.

This Chapter summarizes certain key Pfizer policies regarding distribution of human biopharmaceutical starters. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination of employment.
Key Points to Ensure Compliance

- It is illegal to sell, purchase, or trade, or offer to sell, purchase, or trade, starters. Starters may be provided only to licensed healthcare professionals eligible to receive starters and only if they are expected to distribute them for free, on-label use by their patients.

- The amount of starters allocated by each brand team must be based on the expected on-label use of the product. Starters must not be provided to HCPs in quantities that may appear to be intended as an inducement to use Pfizer products (i.e., a kickback). Providing starters in quantities or dosages based on off-label use is not permitted.

- Starters may be packaged separately or in kits that may include PhRMA Code compliant educational items. All of the patient and provider materials packaged with starters must be reviewed and approved by the applicable Review Committee (RC) prior to distribution.

- Individual starter units cannot be altered in any way either before or after they are delivered to an HCP.

- Only licensed HCPs authorized by their states’ laws to receive and prescribe medications may sign a request for starters. Pfizer policy requires Sales Colleagues to witness the signature personally on every starter request.

- Sales Colleagues using Veeva are required to use the electronic Starter Activity Form (eSAF) within Veeva for starter transactions – a paper Starter Activity Form (SAF) may only be used in the very limited circumstances described in this Chapter.

- All starter transactions must be documented completely and accurately at the time of the transaction. (Those limited transactions that use paper SAFs must be entered into Veeva as soon as possible after the call is made.)

- Starters may not be provided to HCPs for use in clinical trials, other research activities, or for distribution to patients in order to mitigate the cost of their treatment. HCPs seeking to assist patients who cannot afford their medications should be referred to Pfizer RxPathways. Starters may not be provided for charitable activities or an HCP’s other philanthropic endeavors, nor may they be provided to missions or nonprofit organizations under any circumstances.
Key Points to Ensure Compliance

- Starters are not to be provided to HCPs for their personal use or taken by colleagues for their personal use ("personal use" includes use by family or friends).
- Any loss or theft of starters must be reported immediately to North American (NA) Sample Operations and the responsible District Manager. Significant losses and thefts must be reported by NA Sample Operations to the FDA within five days of a Pfizer colleague becoming aware of the loss or theft and, if required, to the regulatory agency in the state in which the incident occurred.

Starter Allocation

A prescription drug starter sample is defined under the PDMA as a **product unit that is packaged for distribution to healthcare providers free of charge**. Such items must be clearly labeled to reflect their intended use and are provided to promote the sale of the drug. Off-label uses of a product should not be considered for starter allocations. Although HCPs may prescribe our products for off-label uses, our products cannot be promoted outside the approved labeling and therefore Pfizer may not knowingly provide starters for such uses.

When Sales Colleagues distribute starters, they are engaging in product promotion. Leaving a starter with an HCP implicitly delivers a message that the product is appropriate for its labeled use. When an HCP states or implies that he or she is using a Pfizer product for an off-label use, providing starters to that HCP for such off-label use may be considered off-label promotion and could subject Pfizer to prosecution.

Teams determining starter allocations should also consider the potential demand for a product on the black/grey market and/or the potential risk of diversion. If the product has a greater diversion potential, teams should consider limiting the number of starters distributed to the minimum amount necessary.
On-Label Use Starter Allocation and Distribution

Q. I am on a product team reviewing starter allocations for a product that physicians often prescribe for off-label uses. I would like to take the market for these uses into consideration when planning starter allocations, even though Sales Colleagues will not detail these uses. Is this permissible?

A. No. Off-label uses should not be considered when determining starter allocations. When Pfizer distributes starters, it is engaging in product promotion. Providing starters to HCPs in quantities or at dosages that might be deemed to support off-label uses could be seen as off-label promotion. Off-label use can also be implied if Pfizer provides starters to a specialist who does not treat the condition for which the product is indicated (e.g., Detrol LA to pediatric urologists, Viagra to OB/GYNs).

Starter Packaging

Separate starter packaging, including the sample identification on the label (i.e., “Sample – Not for Sale”), is required by the FDA. Also, the OIG Compliance Program Guidance for Pharmaceutical Manufacturers notes that companies should clearly and conspicuously label individual samples as units that may not be sold (thus minimizing the ability of recipients to intentionally or inadvertently commingle samples with purchased product).

Starter “packaging” includes all product containers (e.g., blister cards and bottles), individual unit boxes (e.g., the box containing a single sample bottle) and starter packs. Starter packages must remain intact and, as the labeling on starters is FDA-approved, Pfizer Sales Colleagues may not alter starter labeling or packaging. Applying stickers or writing on starter packaging is not permitted. Any alteration or removal of starter packaging can render the product “misbranded” under the law.

However, the outer shelf display packaging that holds together product containers with individual unit boxes or starter packs typically does not contain the FDA-approved labeling. Its removal does not, therefore, result in the misbranding of the product. If asked to do so by the recipient HCP, a Sales Colleague may remove the product containers or starter packs from the outer display packaging if it will allow the starters to more easily fit in the space available. Sales Colleagues must ensure that at least one package insert is left with each type of product starter left behind.
Stickers

Q. Can a Sales Colleague place Pfizer Review Committee-approved (i.e., RC-approved) product stickers on starters?

A. No. Stickers or labels may not be affixed to any starter packaging. Starter packaging has been approved by the FDA, and altering it by affixing stickers or labels could “misbrand” the package, rendering it a “homemade” and in violation of the law. If an HCP requests adhesive tracking labels for use in recording his or her practice’s receipt of starters or distribution to individual patients, Sales Colleagues may follow the instructions found in the “Starter Policies and Process” section of the “Starter Information” folder on PfieldNet at http://pfieldnet.pfizer.com/workspace/Pages/Welcome.aspx and use the accompanying template to create them. Please note, however, that while these can be left with the starters they are not, under any circumstances, to be affixed to them by a Pfizer colleague.

Appropriate Use of Formulary Stickers

Q. Can a Sales Colleague put “Now on Formulary” or other approved stickers in the sample closet?

A. Yes. With the approval of the HCP’s office staff, a Sales Colleague can place RC-approved stickers in the sample closet to identify Pfizer’s starters, but the stickers cannot be placed on starter packaging itself and may never be placed on a competitor’s product or product packaging.

If a colleague has any questions about what may be done with respect to a particular product’s starter packaging, he or she should consult his or her manager, North American (NA) Sample Operations, or the relevant team attorney.
Key Points: Basic Rules Regarding Handling of Starter Packaging

- DO NOT alter or remove product packaging as it contains information required by law and approved by the FDA;
- DO NOT remove starter bottles from the individual unit boxes in which they were provided (if applicable); and
- DO NOT apply stickers or labels to any starter packaging, including the individual unit boxes, product containers, sample packs, and outer display packaging.

Inclusion of Materials with Starters

Provided that starter product packaging remains intact, starters may be offered in kits that include PhRMA Code compliant educational items, such as patient journals or other disease state educational booklets. Starter kits may also include co-pay coupons, co-pay cards, savings cards, and other similar offerings to consumers for the specific starter product.

Before such materials may be distributed in a starter kit, they must be reviewed and approved for such use by the applicable brand RC. When presenting such items for review, the RC team must be advised that the items will accompany starters as part of a starter kit or other promotional program. These additional materials must be submitted to the FDA at the time of first use. As with any promotional materials, Sales Colleagues may not alter these additional materials in any way or add their own promotional materials to them.

Adding Materials to Starter Packages

Q. Can a Sales Colleague insert RC-approved promotional items such as a packet of co-pay cards or vouchers into a starter package for the relevant product?

A. No. Promotional materials must be specifically approved by RC for distribution as part of a starter package. If a Sales Colleague independently adds materials to a starter package – even if those materials are themselves RC-approved – it could constitute an impermissible alteration of the starter packaging.
Distribution of Starters to Approved Recipients

Detailed procedures for starter accountability and compliance are set forth in the U.S. Starter Compliance Manual. Sales Colleagues and other colleagues involved directly in starter distribution should be familiar with the policies and procedures set forth in this manual.

By law, pharmaceutical companies may provide starters only to licensed HCPs with authority to prescribe medication or, at the prescriber’s direction, to the pharmacy of the institution in which the licensed HCP works. Only a licensed HCP may sign a request for starters. The authority to prescribe and/or accept starters varies by state. Certain restrictions may apply to mid-level HCPs (e.g., NPs and PAs) and their ability to prescribe and/or receive starters within their state.

In addition, some states have particular limitations on distributing starters for controlled substances like Lyrica. Sales Colleagues should check with their manager, NA Sample Operations, or their team attorney if they have questions about who can receive particular Pfizer starters in their state.

Starters cannot, under any circumstances, be provided to an HCP:

- If the HCP intends to seek reimbursement from the government for the starter;
- If the HCP is within an excluded medical specialty;
- If the HCP intends to use the starter for his or her personal use;
- To reward the HCP for past prescribing or as a financial inducement for future prescribing;
- If it is reasonably certain that the HCP intends to provide the starters for an off-label use; or
- If the prescriber’s license number has not been verified in Veeva.

In the past, other pharmaceutical companies and individuals have been charged under the Federal False Claims Act and the Anti-Kickback Statute and fined hundreds of millions of dollars for encouraging HCPs to bill government programs for starters. For this reason, HCPs must confirm their understanding and acceptance of the fact that starters “cannot be sold, traded, bartered, returned for credit, or utilized to seek reimbursement” by signing the eSAF (or paper SAF, in those limited circumstances where paper SAFs are permitted).

Pfizer policy further provides that Sales Colleagues must personally witness the signature on all starter requests.

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If a Sales Colleague suspects that an HCP is charging the government or patients for starters, the colleague must immediately stop providing starters to that HCP and discuss the situation with his or her manager, NA Sample Operations, or relevant team attorney.

Pharmaceutical companies are required to maintain records tracking the movement of all starters from the time they leave the distribution facility to the time they are delivered to a healthcare provider. Significant losses, including inventories with unacceptably large negative variances and all thefts of starters, must be reported by NA Sample Operations to the FDA within five business days. Some states also have reporting obligations that are more stringent than federal law. It is essential, therefore, that Sales Colleagues notify NA Sample Operations of all thefts and starter losses immediately upon becoming aware of them. Record falsification and diversion of starters must also be reported to the FDA.

Pfizer NA 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 in order to ensure compliance with all applicable tracking and reporting laws.

Additionally, Pfizer routinely conducts reviews and audits of Sales Colleagues’ starter activities. Failure to comply with applicable laws and Pfizer’s policies may result in disciplinary action, up to and including termination of employment, and may cause both a Sales Colleague and Pfizer to be liable for substantial penalties.
On-label Use of Starter

Q. If a starter package containing a particular dosage of a product is not used on-label by a particular specialty because they would never see the appropriate type of patient, but there is another starter dosage that would typically be used on-label by the same specialty, is there any limitation on what Sales Colleagues can distribute to that specialty?

A. Yes. Sales Colleagues may only distribute starter packages which are consistent with the on-label use of the product for each particular specialty. Thus, if a Pfizer product has different approved dosages for individual indications, Sales Colleagues may only distribute those starter dosages that are indicated for the treatment of conditions that the prescribers they call on are likely to see among their patient population.

Distribution of Starters to Physicians for Personal Use

Q. If one of a Sales Colleague’s physicians asks her for additional Lyrica starters because the physician’s spouse suffers from fibromyalgia, can the colleague give them to the physician?

A. No. Federal and state laws, as well as industry guidelines (the PhRMA Code on Interactions with Healthcare Professionals and the American Medical Association’s Code of Ethics) prohibit the distribution of starters to HCPs for their own or their family’s personal use.

Distribution of Starters to Colleagues for Personal Use

Q. If a colleague is suffering from an infection and he or she asks a Sales Colleague for one or two doses of an antibiotic that the colleague promoted while on a field ride, is it ok to provide it?

A. No. It is not permissible to give any person, even a colleague, any starter for his or her personal use. This could be considered practicing medicine without a license under various state laws. If a colleague makes such a request of a Sales Colleague, he or she must decline and report the request to his or her (or another) manager, team attorney, or the Compliance Helpline.

Hospitals, VA, and DoD Institutions

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

Some hospitals and healthcare institutions have policies that require starters to be left in the pharmacy and not with the individual physicians who have requested them. Sales Colleagues may do this only after completing a paper dual-signature "In House Pharmacy" Starter Activity Form. This form is used to document the physician’s request for starters and the pharmacist’s receipt of the starters in the institution pharmacy. The "In House Pharmacy" Starter Activity Form can be ordered from NA Sample Operations by logging on to PROMOS Prime and choosing that item under the order category “Starter Ops Forms.” As further described in this Chapter, for Sales Colleagues using Veeva, this is one of only two very limited exceptions under which a paper SAF may be used.

Meanwhile, many government institutions, such as Department of Veterans Affairs (VA) clinics and hospitals, prohibit pharmaceutical companies from leaving starters. Other government institutions that do accept starters generally require them to be provided to the Chief of Pharmacy and not to individual physicians. Even if intended for use in private practice, starters should not be left for VA or Department of Defense (DoD) physicians at the government institution in which they work. For more information on the distribution of starters in these government institutions, see the Federal Employee Interactions and Lobbying Chapter in this Guide.

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

**Starters May Not Be Distributed for Research, Charitable Activities, or To Defray Patients’ Pharmacy Expenses**

Starters may not be used for clinical trials or other research activities; nor may they be provided to non-profit organizations for missions or other charitable activities or to HCPs for distribution to patients as a means of mitigating their medication costs. A request for medication or other clinical supplies to support legitimate scientific investigations must be referred to the relevant Medical team for consideration as an Investigator-Initiated Research (IIR) grant. (For more information on scientific
research, see the Pfizer-Sponsored and Non-Sponsored Clinical Research Including Investigator-Initiated Research Chapter in this Guide.) HCPs seeking to assist their patients in mitigating their medication costs should be referred to Pfizer RxPathways. (For more information, see the Patient Assistance Programs Chapter in this Guide.)

Requests for medication from charities or from healthcare providers for charitable missions should be directed to the Pfizer Corporate Responsibility department.

**Managing Starters**

As required by law and Pfizer policy, Sales Colleagues must adhere to strict requirements regarding documentation of their receipt and delivery of starters and management of their starter inventory.

**Starter Storage Requirements**

Starters must be stored securely and under thermostatically-maintained temperature-controlled conditions in accordance with the product’s labeling to maintain their integrity, stability, and efficacy. They are to be stored away from hazardous materials and any other substances that could cause contamination or otherwise degrade them.

Starters may be transported in an automobile trunk during the business day, but should never be left there overnight. For this reason, only the number of starters that are expected to be distributed on a particular day should be carried in a Sales Colleague’s trunk, with any excess quantities removed and returned to storage at the end of the day.

If starters are stored in a commercial warehouse unit, the lease contract for that space should contain language confirming that it is artificially temperature-controlled and be in Pfizer's name with access made available to both the Sales Colleague and his/her manager during normal hours of operation. In addition, Sales Colleagues should confirm that the facilities in which they lease space either use an onsite generator to maintain their unit’s ambient temperature in the event of a power outage or will call them if such an outage lasts 24 hours or longer. Sales Colleagues whose storage facilities sustain an unmitigated power outage lasting more than 24 hours should suspend sampling and contact Starter Compliance via e-mail (StarterCompliance@pfizer.com) for further instructions.
**Accurately Document Receipt and Delivery of Starters**

To accurately document receipt and delivery of starters, Sales Colleagues must strictly adhere to the policies and procedures in the [Starter Compliance Manual](#), including:

- Guidelines for acknowledging the receipt of starter shipments immediately upon acceptance;
- Documentation of the starters delivered to licensed HCPs;
- Procedures for transferring starters between Sales Colleagues; and
- Entry of starter transactions into Veeva at the time of their occurrence.

Failure to adhere to these policies and procedures can place Sales Colleagues and Pfizer at risk under the PDMA and other applicable laws, distort their on-hand reported inventory balance, and undermine the reconciliation of their annual starter inventory.

**Key Points: Documenting the Receipt and Delivery of Starters**

- Document all starter transactions completely and accurately at the time they occur.
- Use Veeva to document all starter transactions (unless one of the limited exceptions permitting paper SAFs apply).
- Provide complete, accurate, and truthful information on all eSAFs (and paper SAFs, when permitted).
- Witness the receiving HCP sign the Veeva screen (or paper SAF) at the time of delivery.
- Immediately report any and all shipment shortages or overages, starter losses, and thefts to NA Sample Operations for further evaluation and reporting to the FDA, as needed.

**Completion of eSAFs and SAFs**

Sales Colleagues using Veeva must use their approved device (i.e., tablet or iPad) for every starter transaction – subject to two very limited exceptions outlined below. A paper [Starter Activity Form (SAF)](#) may only be used:
• When a Sales Colleague is delivering starters at an institution that requires starters to be left with its pharmacy and not with the individual HCPs requesting them (in this case, the dual-signature “In House Pharmacy” SAF described in this Chapter must be used); or

• With prior written approval from NA Sample Operations in very limited circumstances while the Veeva system is inoperable due to significant hardware or software malfunctions for an extended period of time, until such time as the malfunction is resolved. (Sales Colleagues should ensure that their approved devices (i.e., tablets or iPads) are charged; drained batteries do not qualify as a device malfunction.) Written requests may only be submitted by Sales Colleagues by e-mailing a description of the issue, including information provided as part of the CSC Help Center assigned ticket, to StarterCompliance@pfizer.com.

If a paper SAF is used as permitted above, Sales Colleagues must enter the relevant information into Veeva as soon as possible after completing the paper SAF transaction.

The Veeva and paper SAF starter call records are designed to document requests for starters and confirm receipt of provided starters. The Veeva (and paper SAF) starter transactions are Pfizer’s legal record of each starter transaction and must accurately reflect the date on which the request and delivery occurred, the name, address, license number, and professional designation of the prescriber, and the products and quantities that they are given.

The Veeva eSAF (or paper SAF) must be completed in its entirety before it is presented to the prescriber for signature. If a prescriber does not provide his/her signature to confirm request/receipt of starters, the Sales Colleague must not provide him/her with starters. A receipt form may be provided to a physician when using the Sales Colleague’s approved device (i.e., tablet or iPad) by checking the receipt requested by mailbox option on the screen. (If using a paper SAF in the limited circumstances described above, the yellow copy of the form must be left with the recipient to retain for their records.)
Witnessing Signatures for Starters

Q. When a Sales Colleague delivers starters to a physician’s office, can the receptionist take the approved device (i.e., tablet or iPad) to the HCP for signature?

A. No. The Sales Colleague’s device should never be given to anyone to take away and should always remain in the Sales Colleague’s immediate proximity. Pfizer policy requires that the Sales Colleague always personally witness the HCP signing the form. (In the limited circumstances where a paper SAF is permitted, a receptionist may take the SAF to the HCP for signature as long as the Sales Colleague can clearly see the HCP signing the form.)

Reconciling Starter Inventory

The PDMA requires that every Sales Colleague have at least one physical inventory count of their starters taken within each 12-month period. Successful reconciliation requires accurate starter recording in Veeva, timely call reporting, routine synchronization with the Veeva server, and the correction of any errors or discrepancies found in the course of recording starter information.

Sales Colleagues should regularly review their weekly Veeva Starter Activity Reports (SARs) and periodically conduct their own physical inventory count. This count should be reconciled against the Ending Balance Report that is sent to each Sales Colleague with their SAR. If a Sales Colleague finds an error or discrepancy when reconciling starters, he or she should immediately contact NA Sample Operations for further guidance.

In addition, all starter losses and thefts should be reported to NA Sample Operations immediately so that the required notification can be submitted to the FDA within five days.

Reminder on Expired Starters

Expired starters cannot be given to a healthcare provider under any circumstances and should, instead, be returned promptly to Pfizer’s authorized destruction facility. Sales Colleagues should rotate their starters upon receiving each delivery, placing those closest to their date of expiration in front to ensure that they distribute them first.
HCPs seeking to return expired or damaged starters should be directed to call Pfizer’s Starter Customer Service Team (1-800-533-4535) to schedule an appointment for the pickup of those items.

### Paying for Bins in Starter Closets

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<tr>
<th>Q.</th>
<th>Can a Sales Colleague pay for bins or space in starter closets in physicians’ offices?</th>
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<tr>
<td>A.</td>
<td>No. Paying for space in starter closets could violate anti-kickback laws.</td>
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### Free Trial Vouchers: An Alternative to Starter Distribution

Some product teams use **free trial voucher programs** as a substitute for, or alternative to, the physical distribution of starters.

In a voucher program, instead of providing HCPs with starters for patient use, Pfizer (via Sales Colleagues and/or through Pfizer’s patient websites, for example) provides HCPs or patients with certificates (vouchers) that patients can redeem at a pharmacy for a free “trial prescription” of a medicine. The HCP must give the patient a prescription for the amount of product covered by the voucher. The patient takes the prescription and voucher to the pharmacy, where he/she receives the product free of charge. A third party administrator that contracts with pharmacy networks then reimburses the pharmacy. Pfizer teams implementing voucher programs must follow the **Policy on Free Trial Vouchers, Co-Pay Relief, and Similar Consumer Programs (Co-Pay Relief Policy)**, **New Limitations Regarding Free Trial Voucher Programs Advisory (Restrictions on Free Trial Vouchers - July 2011)**, and related documents that can be found on the **Co-Pay Relief Programs page** on OpSource.

Improper use of vouchers can implicate the state and federal false claims acts and anti-kickback laws and could also be deemed to impact the “best price” of a product (i.e., the discount the Company is required to give the Medicaid program on every unit of product it reimburses). For more information, see **White Guide Chapter 6: Government Healthcare Programs**.

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Key Points for Developing a Voucher Program and Distributing Vouchers

- Voucher disbursements must be recorded completely and accurately in Veeva to ensure compliance with all applicable federal and state reporting requirements;
- Vouchers must never be offered or provided to HCPs contingent upon the HCP’s past, current, or future prescribing practices;
- Vouchers may not be provided to HCPs to substitute for a discount (i.e., contingent upon sale of the product to that customer);
- Vouchers may not be offered to HCPs for personal use; and
- Vouchers are a form of product promotion. They may not be offered to HCPs for off-label uses; nor may they be offered to an HCP that practices in a specialty that is excluded for that specific product.

FOR MORE INFORMATION

- Questions may be referred to NA Sample Operations, the relevant Sales Manager, or team attorney.
- For Pfizer’s policies for complying with the PDMA, see the Starter Compliance Manual.
- Sales Colleagues who need to order “In House Pharmacy” Starter Activity Forms can obtain them by calling Standard Register at 1-800-313-8263.
- For more information on the use of product in scientific investigations, see the Pfizer-Sponsored and Non-Sponsored Clinical Research Including Investigator-Initiated Research Chapter.
- For more information on distributing starters in government institutions, see the Federal Employee Interactions and Lobbying Chapter.
Chapter 11: PATIENT ASSISTANCE PROGRAMS

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Chapter 11: PATIENT ASSISTANCE PROGRAMS

Introduction

For decades, Pfizer RxPathways has been responsive to the evolving needs of patients. Based on the growing complexity of today’s healthcare reimbursement environment, Pfizer has enhanced Pfizer RxPathways (PRxP) from a program to a service that connects patients, regardless of their insurance status, to any of the assistance programs and resources that are offered by Pfizer that can best meet their needs.

With this change, offerings that were previously provided by PRxP, such as patient assistance, reimbursement support services and savings have been decoupled and established as their own programs.

Pfizer and the Pfizer Patient Assistance Foundation™ offer prescription assistance to patients through The Pfizer Patient Assistance Program and the Pfizer Savings Program. Both programs help eligible patients get access to their Pfizer medicines for free or at a savings. A Patient Assistant Program (PAP) is a program that can help eligible patients obtain medications at a lower cost or, in some circumstances, at no cost.

This Chapter summarizes certain key Pfizer policies regarding the Pfizer Patient Assistance Program and Pfizer Savings Programs. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination of employment.
**Key Points to Ensure Compliance**

- Marketing teams must follow the requirements described in this Chapter when creating marketing materials that reference Pfizer Patient Assistance Programs (PAPs).
- Field and Commercial Colleagues must follow the requirements described in this Chapter when discussing PAPs with customers.
- Internal questions about PAPs should be e-mailed to the Pfizer RxPathways team at PfizerRxPathways@pfizer.com.
- Patients and healthcare professionals should visit PfizerRxPathways.com to learn more, or contact a customer service representative for Pfizer RxPathways at 1-866-706-2400.

A PAP:

- May not make assistance determinations with regard to any provider, practitioner, supplier, or insurance plan used by the applicant;
- Should assess applicants on a first-come, first-served basis;
- Should not exhibit any characteristics of a marketing program or in any way promote Pfizer products; and
- Should have written formal guidelines establishing the criteria for assistance eligibility and the policies and procedures for administration of the programs.

**Patient Assistance Program Compliance Requirements**

A PAP:

- May not make assistance determinations based on any provider, practitioner, supplier, or insurance plan used by the applicant;
- Should assess applicants on a first-come, first-serve basis;
- Should not exhibit any characteristics of a marketing program or in any way promote Pfizer products; and
• Should have written formal guidelines establishing the criteria for assistance eligibility and the policies and procedures for administration of the programs.

Pfizer and the Pfizer Patient Assistance Foundation have carefully implemented Pfizer PAPs to ensure compliance with the above and relevant laws.

**Pfizer RxPathways General Overview**

Access to medicines is a cornerstone of Pfizer’s commitment to health care. For decades, Pfizer has partnered with healthcare providers, community health centers, free clinics and pharmacies to support their work in helping patients access medicines they need through patient assistance programs and financial support tools.

Based on the growing complexity of today’s healthcare reimbursement environment, Pfizer has recently enhanced Pfizer RxPathways from a program to a service that connects patients, regardless of their insurance status, to any of the assistance programs and resources that are offered by Pfizer that can best meet their needs. It is important to note that with this change, offerings that were previously provided by PRxP, such as patient assistance, reimbursement support services and savings have been decoupled and established as their own programs.

**Now patients can** call Pfizer RxPathways and consult with a Pfizer Medicine Access Counselor who will connect them with the Pfizer-wide financial assistance programs and resources that best meet their needs including:

**Pfizer Savings Program**\(^1\) – Helps uninsured patients, regardless of income, access their Pfizer medicines at a savings through participating pharmacies.

**Pfizer Insurance Support** – Helps patients understand their insurance coverage and reimbursement options for certain medicines, including cost-sharing requirements and prior authorization information.

**Pfizer Patient Assistance Program**\(^2\) – Provides free Pfizer medicines to eligible patients through their doctor’s office, to their home, or – in some cases – via a co-pay card that will cover the entire cost of their co-pay at the pharmacy.\(^3\)

\(^1\) Rev.01/17

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Free Medicine through Health Centers and Hospitals – Eligible uninsured patients may be able to receive free medicine through select health centers and hospitals across the country that partner with Pfizer.\textsuperscript{iv}

Treatment-Specific Patient Medicine Support Hubs – Provides comprehensive support services for specific oncology and specialty medicines.

Brand Co-Pay Card – Assists eligible patients with their co-pay costs.\textsuperscript{v}

Medicine Access Counselors will also connect patients to industry programs and resources, such as:

- Partnership for Prescription Assistance – Offers a gateway for patients to more than 475 private and public assistance programs.
- Rx Outreach – A non-profit charitable organization that provides eligible patients with access to more than 500 medications at an affordable cost.
- NeedyMeds – A non-profit information resource dedicated to helping people locate assistance programs to help them afford their medications and other healthcare costs.

**Pfizer Patient Assistance Program & Pfizer Savings Program General Overview**

Patients who need help accessing their Pfizer medicines may be eligible to receive their Pfizer medicine for free through the Pfizer Patient Assistance Program. Qualified patients may receive their medicine at no cost through the doctors office, at home or, in some cases, via a co-pay card that will cover the entire cost of their co-pay at the pharmacy. To be eligible, patients must live in the United States, U.S. Virgin Islands or Puerto Rico and have no prescription coverage or not enough coverage to pay for their medicine. Patients seeking Pfizer medicines for free must meet income guidelines and receive treatment from a licensed HCP on an outpatient basis.

The Pfizer Savings Program helps patients without prescription coverage get savings on Pfizer medicines through participating pharmacies. Savings can vary from 36 to 75 percent, depending on the product and patient’s income level. This program is an option for patients who are uninsured and whose household income exceeds the eligibility requirements for receiving free medicines through
Pfizer Patient Assistance Program or for patients who need assistance with Pfizer branded medicines no longer offered through the program.

**Free Medicines Through Health Centers & Hospitals**

Pfizer RxPathways also partners with nearly 350 federally-qualified community health centers, approximately 50 Disproportionate Share Hospitals, select free clinics, and state pharmacy programs.

Through this initiative, Pfizer donates select medicines to participating institutions who in turn provide the medicines for free to patients treated at the facilities, based on eligibility requirements determined by Pfizer. Participating institutions report back to Pfizer on a regular basis (monthly or weekly) which medicines have been dispensed to patients, and Pfizer replenishes the stock. Participating institutions are audited on a regular basis to ensure compliance with program rules and may be subject to suspension or termination from the program if any infractions are found. To learn more about the program, contact the Pfizer RxPathways team at PfizerRxPathways@Pfizer.com.

**Other Assistance Programs**

Pfizer RxPathways will connect patients to other Treatment-Specific Patient Medicine Support Hubs described below:

**Treatment-Specific Patient Medicine Support Hubs**

Some Pfizer brands offer brand-specific “Patient Hub” programs that offer a variety of services for patients, including reimbursement support, and additional “wrap around” services like nursing support lines, etc. Examples of “hub” programs include the Pfizer Bridge Program for endocrine care products, the Gaucher Personal Support program, and the Pfizer XelSource Program. Hub programs have separate 1-1-800 numbers and websites. If patients prescribed one of these products contact Pfizer RxPathways, they will be transferred to the appropriate hub program.

**Co-Promoted Products**

Some of the medicines sold by Pfizer are manufactured by partner organizations. Patient assistance programs for these medicines are often run by the product manufacturer, not Pfizer. Patients who call
Pfizer looking for assistance with medicines in this category will be referred to the appropriate partner PAP. Information on these programs can also be found on the Pfizer RxPathways website.

**Industry-Sponsored Service**

Pfizer also participates in the Partnership for Prescription Assistance (or “PPA”) which offers a single point of access to more than 475 patient assistance programs, including Pfizer RxPathways. Patients who contact Pfizer for help but who have been prescribed medicines not manufactured by Pfizer will be referred to the PPA. More information is available at www.PPARx.org.

**Pfizer Patient Assistance Program & Pfizer Savings Program - Eligibility and Enrollment**

**Eligibility Requirements – Savings on Medicines through the Pfizer Savings Program**

Savings on Pfizer medicines are available to uninsured patients only. To enroll, patients can call Pfizer RxPathways toll-free number at 844-989-PATH (7284) to be connected to the Pfizer Savings Program. Patients will be asked to provide basic information about themselves, including name, address, medicine prescribed, household income, and attestation that they are uninsured. (Note: The information requested may include Sensitive Personal Information (SPI) and may not be used or disclosed unless certain conditions are met. For more information on SPI, see Orange Guide Chapter 8: Privacy: Protecting Personal Information. Patients will be sent a Pfizer card that they can present to the pharmacist when filling their prescription at their pharmacy. Savings will be applied to the cash price of the medicine. Savings vary based on the medicine prescribed and the patient’s income, and can range from approximately 36% to 75% off of the retail price of the medicine.

**Eligibility Requirements – Free Medicines through the Pfizer Patient Assistance Program**

Patients who do not have prescription coverage (uninsured) or those who do have prescription coverage (either private/commercial insurance, or public insurance like Medicare Part D or Medicaid) but still need help paying for their medicine due to high cost-sharing requirements (underinsured) may be eligible for free medicines through the Pfizer Patient Assistance Program. In general, to qualify for free medicines, patients need to:
• Complete an application form that asks for basic information, household income, address, insurance information (if they have insurance). Note: The information requested in the Application form may include Sensitive Personal Information (SPI) and may not be used or disclosed unless certain conditions are met. For more information on SPI, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.
• Have their HCP complete a section of the application that asks for basic information about the HCP, including name, address, DEA number;
• Provide proof of income, such as a W2 form or prior year’s tax return;
• Meet income eligibility requirements for the Pfizer medicine they have been prescribed (income limits vary by medicine but start at 400% FPL);
• Have a valid prescription for the desired Pfizer product;
• Live in the U.S., Puerto Rico or the U.S. Virgin Islands; and
• Be treated by a HCP licensed to practice in the U.S. or Puerto Rico.

Patients prescribed certain Pfizer medicines may first be required to seek alternate forms of assistance through third party co-pay foundations, Medicaid, or Medicare Low Income Subsidies before they can be considered for free medicines through PRxP.

Uninsured patients or patients with public insurance who meet eligibility requirements will receive their medicine for free and be enrolled in the program for 12 months and can re-apply if they still need assistance at the end of their enrollment period. Their medicine will be shipped to their doctor’s office in most cases, or for some products, directly to their home address.

Patients with commercial/private insurance and who meet eligibility requirements will receive a card that will cover the entire amount of their co-pay, so that they can obtain their medicine through the retail or specialty pharmacy at no charge by presenting the card to the pharmacist. They will be enrolled in the program through the end of a calendar year, and can re-apply if they still need assistance at the end of their enrollment period. This co-pay card is separate from brand-specific co-pay cards.

Pfizer has checks in place to ensure patients and HCPs do not abuse a PAP. Forms of such abuse include falsifying income information, ignoring refill limits, and supplying or requesting a supply of a product beyond its covered amounts under a PAP.
Referring Patients to Pfizer RxPathways

Q. You are a Sales representative and one of your HCP customers tells you that he has Lyrica patients who are uninsured. He asks you how Pfizer can provide some assistance to cover the costs of their Lyrica. The Pfizer Patient Assistance Program lists Lyrica as being covered. Should you tell him to have his patients apply to the Pfizer Patient Assistance Program?

A. Patients should be referred to the Pfizer RxPathways website or its toll-free number (1-866-706-2400) for information to complete screening and determine eligibility for available assistance programs. Sales representatives must not imply or guarantee specific assistance. All first-time callers to the PRxP call center will be asked to complete a phone screening and will be provided with the medicines and services for which they may be eligible.

A Special Note about Medicare Part D Patients

As described above, patients with prescription coverage through commercial plans or public plans like Medicare Part D can apply for assistance through the Pfizer Patient Assistance Program if they are having difficulty paying for their medicines. The assistance available to eligible patients complies with the specific guidelines that have been published about PAPs and Medicare Part D.

Under the Medicare Prescription Drug Improvement and Modernization Act, Medicare beneficiaries may enroll in Part D and thereby have all or part of their prescription drug costs covered by the government. Since its enactment, the Office of Inspector General (OIG) has cautioned that manufacturer PAPs that donate their drugs that are payable under Medicare Part D are likely to implicate kickback issues.

Cost-sharing subsidies provided by manufacturer PAPs present the typical risks of fraud and abuse associated with kickbacks, such as steering beneficiaries to particular drugs, increasing costs to the federal government, providing a financial advantage over competing drugs, and reducing beneficiary incentives to use less expensive and equally as effective drugs. The OIG’s Special Advisory Bulletin entitled Patient Assistance Programs for Medicare Part D Enrollees explains, for example, that subsidies provided by manufacturer PAPs may lock beneficiaries into the manufacturer’s product, even if there are other equally effective, less costly options.

PAPs that operate entirely outside Medicare Part D, however, minimize kickback risks. In these circumstances, a Part D enrollee chooses to obtain medication without using the Part D insurance.
enrolled Part D beneficiary will receive assistance through a PAP but will not file any claims for payment with the Part D plan. The PAP assistance will not count toward the beneficiary’s true out-of-pocket costs (TrOOP) or overall Part D spending.

Thus, in connection with providing patient assistance outside of Part D, Pfizer must ensure the following:

- That the applicable PAP includes safeguards that ensure that Part D plans are notified that the drug is being provided outside the Part D benefit;
- That the PAP provides assistance for the whole Part D coverage year or the portion of the year remaining after the beneficiary received PAP assistance;
- That the PAP assistance remains available even if the beneficiary’s use of the drug is periodic;
- That the PAP maintains accurate and timely records to verify the provision of the drugs outside the Part D benefit;
- That the assistance is awarded based on reasonable, uniform, and consistent measures of financial need and without regard to providers, practitioners or suppliers; and
- That the arrangement complies with any applicable guidance issued by the Centers for Medicare and Medicaid Services.

**Patient Assistance Programs and Medicare Part D**

**Q.** A patient with Medicare Part D prescription coverage is having difficulty paying for her Pfizer primary care medicine. Can she apply for help through the Pfizer Patient Assistance Program?

**A.** Yes. Patients with prescription coverage – such as Medicare Part D, Medicaid, or commercial insurance – who are having difficulty paying for their Pfizer prescription medicines can apply for assistance through the Pfizer Patient Assistance Program. Patients should call Pfizer RxPathways at 1--844-989-PATH or visit [http://www.PfizerRxPath.com](http://www.PfizerRxPath.com) to learn more. If eligible, this patient will receive her Pfizer medicine for free through the end of the calendar year, and the assistance will be provided entirely outside of the Part D plan.
Guidance for Marketing: Including PRxP and the Pfizer Patient Assistance Program/Pfizer Savings Program References in Marketing Materials

Marketing materials that reference PRxP or any of its programs, including implementation guides, must be created in line with the below requirements:

- The PRxP team will make available to Marketing teams and through PROMO Prime a set of unbranded PRxP materials that can be used by Field Force Colleagues for purposes of discussing the PRxP. The team will also make limited materials available on the Pfizer Patient Assistance Program/Pfizer Savings Program.

- Marketing teams may include in their marketing materials the PRxP logo and PRxP pre-approved taglines and logo lock-ups without requiring the approval of the PRxP RC. The placement of the logo and tagline should be either at the bottom of the piece or in an area where it can be separated from the brand, therapeutic area or other messaging in the materials. Marketing teams should send samples of these materials to PRxP to keep on file.

- If a Marketing team wishes to include PRxP and/or The Pfizer Patient Assistance Program/Pfizer Savings Program information beyond the standard PRxP logo and tagline, those materials should be reviewed by the PRxP team and require the approval of both the PRxP Review Committee and the brand, therapeutic area, or other relevant Review Committee that normally approves these materials.

Guidance for Field and Commercial Colleagues – Talking About Pfizer RxPathways and the Pfizer Patient Assistance Program/Pfizer Savings Program

Pfizer Field Commercial Colleagues may engage in proactive discussions regarding PRxP and limited proactive discussion regarding the Pfizer Patient Assistance Program/Pfizer Savings Program subject to the following requirements:

- Messaging must be consistent with PRxP Review Committee approved materials, including any applicable implementation guides or PRxP trainings.

- While Field Commercial Colleagues can proactively discuss the Pfizer Patient Assistance Program/Pfizer Savings Program with healthcare professionals, messaging must remain...
broad, consisting of basic information about the programs, application processes, and eligibility criteria.

- The call-to-action should still remain, “visit [http://www.PfizerRxPath.com](http://www.PfizerRxPath.com) for more information since each patient’s case is unique.”

In addition, the following Do’s and Don’ts apply:

<table>
<thead>
<tr>
<th>DO</th>
<th>DON’T</th>
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<tbody>
<tr>
<td>Remind HCPs that there are many Pfizer medicines available through Pfizer’s PAPs.</td>
<td>Do not promote Pfizer’s PAP as a tool to influence prescribing habits and do not overpromise what the program can deliver.</td>
</tr>
<tr>
<td>Explain that the Pfizer Patient Assistance Program and the Pfizer Savings Program helps eligible patients in need get their Pfizer Medicines for free or at a savings to a range of Pfizer assistance programs and resources.</td>
<td>Do not promote Pfizer RxPathways as a discounting program.</td>
</tr>
<tr>
<td>Remind HCPs that patients with insurance (such as Medicaid, Medicare Part D, or private/commercial insurance) may still qualify for assistance if they meet eligibility guidelines.</td>
<td>Do not describe assistance through the Pfizer Patient Assistance Program as a way to fill gaps in coverage (e.g., donut hole).</td>
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**Donation of Pfizer Products to Support PAPs**

Drug products donated by Pfizer to a PAP, whether or not Pfizer-sponsored, may be considered a charitable contribution and may generate tax deductions. Pfizer colleagues may never provide free product with the intent to motivate the prescribing of a Pfizer product, nor may their actions imply that the purpose of a contribution is intended to motivate prescribing of a Pfizer product. For more information on donating Pfizer products for charitable use, consult your team attorney.
FOR MORE INFORMATION

- The Pfizer RxPathways Team at PfizerRxPathways@pfizer.com.
- RC-approved FAQs and Talking Points can be found on http://Pfieldnet.pfizer.com, the Corporate Affairs Resource Center or in the Colleague Resource Center on http://world.pfizer.com.
- Refer any questions to your team attorney.

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i The Pfizer Savings Program is not health insurance. For a complete list of participating pharmacies, click here or call the toll-free number 1-866-989-PATH (7284). There are no membership fees to participate in this program. Estimated savings range from 36% to 75% and depend on such factors as the particular drug purchased, amount purchased, and the pharmacy where purchased.

ii The Pfizer Patient Assistance Program is a joint program of Pfizer Inc. and the Pfizer Patient Assistance Foundation™. The Pfizer Patient Assistance Foundation is a separate legal entity from Pfizer Inc. with distinct legal restrictions.

iii Co-Pay Assistance provided through the Pfizer Patient Assistance Program is not health insurance. For a complete list of participating pharmacies, call 1-844-989-PATH (7284). No membership fees apply. Patients who participate in any federal or state programs, such as Medicaid or Medicare, are not eligible for co-pay assistance. However, these patients may be eligible to receive their medicine for free through the Pfizer Patient Assistance Program. Terms and conditions apply.

iv Product availability varies by institution and eligibility.

v Terms and Conditions apply.
Chapter 12: DISCOUNT AND REBATE CONTRACTING

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Chapter 12: DISCOUNT & REBATE CONTRACTING

Introduction

Pfizer and Greenstone enter into a variety of contractual arrangements with customers, for purposes of this Chapter, when “Pfizer” is used, it refers to both Pfizer and Greenstone. A very common type of contractual arrangement between Pfizer and its customers is a discount arrangement under which Pfizer provides a discount on its products (hereinafter “Discount Arrangements”). A second type of contractual arrangement into which Pfizer may enter with customers is for the purchase by Pfizer of an item of tangible value (such as data) or services (such as consulting or the administration of an adherence program). These purchase and service agreements are covered in Orange Guide Chapter 15: Non-Discount Customer Arrangements.

Pfizer enters into Discount Arrangements in order to meet competition and to make Pfizer products available on formularies or source programs, where applicable. Generally, these discounts are made in the form of rebates, which are typically paid based on the units of product dispensed. Pfizer may provide discounts to customers such as Distributors, Specialty Pharmacies, Health Maintenance Organizations (HMOs), Pharmacy Benefits Managers (PBMs), Integrated Delivery Networks (IDNs), Long Term Care Pharmacy Providers, Large Physician Practices, Group Purchasing Organizations (GPOs), and the government. For purposes of this Chapter, the term Account refers to those Pfizer customers to whom Pfizer may provide a discount on its products to meet competition and to make Pfizer products available on formularies or source programs, where applicable. This Chapter provides guidance on the process of negotiating and entering into Discount Arrangements with Accounts, which is referred to in this Chapter as "contracting."

Not all Field Commercial Colleagues, and only certain Account Managers, are responsible for contracting with their Accounts. Generally, Field Sales Colleagues are not responsible for contracting with Accounts, in part because the individual HCPs on whom they call prescribe, but generally do not purchase, Pfizer products. While certain Account Managers are most often responsible for contracting, all colleagues are responsible for adhering to Pfizer's policies regarding contracting. Non-compliance with these policies by any colleague, even those who are not responsible for
contracting, can put the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination of employment.

**Contracts** are legally enforceable agreements between two or more parties. Because a contract may be oral or written, your actions, including oral statements, may bind the company even in the absence of a written agreement. For this reason, colleagues must never make an oral promise or sign an agreement before receiving all necessary approvals. This applies to any sort of contract and is not limited to Discount Arrangements.

**Discount Arrangements**

Pfizer seeks to memorialize each Discount Arrangement with an Account in a written contract through the contracting process. Written contracts clearly spell out the terms and conditions under which the Account may be eligible for a discount on Pfizer’s products. In addition, written agreements help ensure that Pfizer’s Discount Arrangements meet the applicable safe harbors in the Anti-Kickback Statute. As explained in Chapter 1, the Department of Health and Human Services Office of Inspector General (OIG) has defined certain “safe harbors” to permit legitimate activities that might otherwise be seen as violating the Anti-Kickback Statute. Activities that fall entirely within a safe harbor do not violate the Anti-Kickback Statute. The **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. In addition, the **Managed Care safe harbor** permits Pfizer to provide a wide array of discounted items or services to certain eligible managed care organizations under specified circumstances. Having the terms of the discount clearly spelled out in a written contract helps ensure that the arrangement meets the requirements of applicable safe harbors. For these reasons, all discounts must be specified in a written agreement between Pfizer and the Account.

**Discounting and Price Reporting**

Generally, Pfizer must provide the federal government, under various programs, with either the largest discount that they provide to certain eligible Accounts, or a minimum percentage discount as noted below.
For example, as part of the Medicaid Drug Rebate Program, Pfizer must enter into a national rebate agreement with the Secretary of the U.S. Department of Health and Human Services (HHS) for states to receive federal funding for outpatient drugs dispensed to Medicaid patients. This rebate agreement requires manufacturers to provide the federal government with a rebate equal to the greater of 23.1% of **Average Manufacturer Price (AMP)**\(^1\) or the difference between a manufacturer’s **Best Price (BP)** and the AMP for each unit of product paid for by State Medicaid agencies. Notably, any discount Pfizer offers to eligible Accounts must be included in Pfizer’s price calculations and reporting for covered products.

**Average Manufacturer’s Price (AMP)** means the average price paid to a manufacturer by retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies. This definition was created by the Patient Protection and Affordable Care Act.

**Best Price (BP)**: the lowest price available to any entity unless the sale, discount, or other price concession is specifically excluded by law or is provided to an entity specifically excluded by statute or regulation. It takes into account cash discounts, free goods contingent upon purchase, volume discounts, and rebates.

In determining the relevant price points and corresponding rebate amounts under the Medicaid Drug Rebate Program, Pfizer follows the guidance promulgated by the federal government, including the Deficit Reduction Act of 2005 (DRA), the final rule promulgated by the Centers for Medicare & Medicaid Services (CMS) implementing sections of the DRA (Final Rule), the Average Manufacturer Price Final Rule and, The Patient Protection and Affordable Care Act, as well as other applicable formal rulemaking.

\(^1\) The Patient Protection and Affordable Care Act (“PPACA”) additionally revised the statutory minimum rebates for pediatric, clotting, and generic drug products.
Commercial discounts may also affect a number of other government programs in which Pfizer participates, including Medicare, 340B Public Health Services Outpatient Drug Discount Program, and its Federal Supply Schedule agreement with the Department of Veterans Affairs. Pfizer participates in and remains vigilant to compliance with all of these programs and any related requirements.

**Off-Invoice Discounting**

Because the above-referenced metrics involve the prices made available to eligible Account entities, Pfizer must make sure to factor into price reporting all concessions made as part of the sale of products to such eligible Accounts. Failure to do this may be perceived as false reporting. With respect to Medicaid, for example, when reporting BP, 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.

For these reasons, all colleagues are prohibited from discussing grants, sponsorships, additional service contracts, collaborations, OCP Tools and Resources, and other “off-invoice” items of value in connection with discount or rebate negotiations. Additionally, providing grants, additional service contracts, or other items of value in order to gain formulary status or source program acceptance may also be considered an improper inducement under the Anti-Kickback Statue and is prohibited by Pfizer policy.

Where possible, meetings on formulary or source program negotiations should be kept separate, and discussions of these topics should be independent of discussions about other potential business opportunities, including any pull through activities. In addition, our internal contracting analyses should be separate and independent from the analysis of other business activities with the relevant Account.

Where it is not possible or practical to have separate meetings on contracting issues, the following guiding principles will help mitigate risk. These guidelines can also be used and adapted, as appropriate, when separate meetings on commercial and Medicare Part D arrangements are not possible or practical.
Prior to the meeting:

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

During the meeting:

- Stick to the agenda.
- Firewall discussions into appropriate segments. One possibility is to separate all discussions where Pfizer is purchasing goods or services from the account (i.e., where Pfizer is the “customer”) from those where Pfizer is providing discounts, goods, or services to the account (i.e., where Pfizer is the “seller”).
- Choreograph the attendance of individuals who are not part of the contracting process by having individuals step out of or arrive later during a joint meeting so that individuals who should not be privy to contracting discussion are not in attendance.
- Manage the other side’s attempts to link discussions of multiple projects by deferring the issue for future conversation or delegating the issue to colleagues not in attendance.
- Approach discussions of non-contracting business opportunities carefully during the negotiation period prior to and around the time of rebate contract expiration.

After the meeting:

- Evaluate the contracting offer and other business proposals independently and on their own merits; separate business teams within Pfizer should do the respective evaluations.
- Be mindful of how financial and other notes regarding the contracting offer and other business opportunities may appear in hindsight. For example, the valuations for each business opportunity on the same worksheet may imply that the opportunities are connected and interdependent when the intent was otherwise.
• In some instances Legal may advise the business unit to have a cooling off period between contract negotiations and other arrangements or other discounting discussions.

“Swapping” Discounts between Commercial and Part D Plans

Many managed care organizations, including HMOs, 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 commercial business. The government has expressed concern that entities will utilize Medicare Part D leverage to obtain preferential discounts for their commercial books of business.

Medicare Part D: the part of the Medicare program that subsidizes the costs of outpatient prescription drugs for Medicare beneficiaries in the United States. It was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and went into effect on January 1, 2006.

"Swapping" describes a situation whereby a managed care organization 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. Many HMOs 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 their Part D plan costs, while they often remain entirely at risk for their commercial plan costs. Pfizer must never engage in swapping and must avoid situations that could create a perception that swapping has occurred.

The Following are Examples of "Swapping":

• A pharmaceutical manufacturer and an HMO have a commercial agreement that provides the HMO with an average 10% rebate on all products. The parties enter into negotiations to reach agreement on new commercial and Medicare Part D agreements. In exchange for the HMO placing its products on the new Part D formulary, the pharmaceutical manufacturer offers to increase its rebate on the commercial agreement to an average 12.5% rebate. The additional 2.5% rebate could be considered an improper reward to the HMO for providing the pharmaceutical company with access to the HMO's Part D plan.


- A pharmaceutical manufacturer and an HMO have no existing contractual relationship and seek to negotiate new commercial and Part D rebate agreements. During the negotiations, the parties reference and compare the terms of both agreements. Since the agreements were negotiated at the same time, any concessions made by the HMO to accept lower rebates on the Part D agreement could be construed to have occurred in order to improperly compensate the pharmaceutical company for providing the HMO with greater rebates on its commercial plans.

**Meetings on Commercial and Part D. Contracts**

Q. May I discuss a commercial contract and a Part D contract in the same meeting with an Account?

A. Yes. You may do this if the two are not linked or discussed contemporaneously. For example, it is acceptable to discuss the commercial contract during the first half of your meeting, and then indicate to the Account that you are moving on to the Part D contract discussion for the remainder of your meeting.

**Additional Tips when Negotiating Contracts with Accounts**

- Do not discuss previously undisclosed information that may be material under SEC regulations, including, for example, potential changes in Pfizer's pricing policy.
- Do not disclose confidential or proprietary information.
- Do not disclose pricing information, terms, or even the existence of contracts with competitors.
- Any purchase of goods or services from a company must be at fair market value; necessary to fulfill a bona fide business need; and outlined in a signed writing, executed in advance of such purchase. See also, Orange Guide Chapter 15: Non-Discount Customer Arrangements.
- When discussing a Pfizer product, follow the Food Drug and Cosmetic Act's guidance and Pfizer's policies on product promotion.
Key Points to Ensure Compliance

- Do not discuss grants, service agreements, other items of value, or OCP Tools and Resources in connection with discounting negotiations.
- Do not offer lump sum payments in exchange for formulary placement or other types of Account access.
- Do not discuss or negotiate commercial and Medicare Part D rebate agreements at the same time.
- Do not link or reference the terms of Pfizer's commercial rebate agreement when negotiating a Medicare Part D rebate agreement, or vice versa.
- Do not attempt to leverage a commercial rebate agreement in order to secure access to a Medicare Part D rebate agreement, or vice versa.
- Do not attempt to leverage any additional (e.g., non-formulary) arrangements in order to secure preferential formulary status.
- Do not discuss Pfizer pricing policies or practices with competitors or Accounts.
- Only offer approved pricing and discounts to Accounts.

Antitrust and Competition Laws

Antitrust and competition laws protect free enterprise. While their complexity makes them difficult to summarize fully, at a minimum these laws prohibit agreements between Pfizer and our competitors to set prices, terms, or conditions of sale. The term “Prices” includes discounts. To ensure full compliance with U.S. antitrust laws, you should never discuss the following topics with any competitor or with multiple Accounts at any time:

- Pfizer's pricing policies;
- Pfizer's current or future prices, discounts, rebates, or other terms and conditions of sale generally or as they relate to other Accounts;
- Pfizer's current or projected profits or profit margins;

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• An Account’s current or projected profit or profit margins;
• Pfizer’s current or projected costs;
• Pfizer’s business, marketing, and promotional plans;
• Pfizer’s bidding policy or its intent to bid or not to bid for particular business;
• Pfizer’s plan to do business or not do business with particular Accounts; and
• Pfizer’s intention to engage or not engage in particular research activities.

Antitrust laws also prohibit discriminatory pricing and promotional practices. More specifically, U.S. antitrust laws prohibit selling goods of like grade and quality to competing purchasers (who are resellers of those goods) at different prices where competition will be damaged. In essence, this requires Pfizer to offer similarly situated Accounts the same prices and discounts absent an exception or defense. Pfizer therefore carefully assesses prices and discount offers prior to them being offered. In order to ensure compliance, no Pfizer colleague should make a price or discount offer to an Account unless such offer has been approved.

**Discount Arrangements and Confidentiality**

Pfizer colleagues should use caution in discussing discounts and rebates with anyone other than the Account eligible for the price concession. The contracts under which Pfizer provides discounts to its Accounts often contain confidentiality provisions that limit both parties’ ability to share with third parties the discounts and other terms of the agreement. Some contracts even limit Pfizer’s ability to share, internally with other Pfizer colleagues, information that is confidential under the agreement. To ensure compliance with our contractual obligations to our Accounts, Pfizer colleagues should not share with third parties any information that may be confidential under our Discount Arrangements with our Accounts, absent review of the governing contract by your legal counsel. This includes instances where you seek to share information with a customer of a Pfizer Account (for example, a plan under a pharmacy benefit manager). Remember, our contractual obligations of confidentiality are with the Account and not the customer of the Account.
Contracting in the Generic Market

Generally, the legal risks in the generics market are substantially similar to the legal risks in the branded market. Increasingly, Congress, CMS, the Federal Trade Commission, and other federal and state agencies are scrutinizing branded manufacturers’ relationship with generics. As such, be sure to adhere to the practices and principles laid out in this Chapter when engaging in contracting for both branded and generic products.

FOR MORE INFORMATION

- Questions may be referred to your manager, Organized Customer Legal, Global Established Products (GEP) Legal, Contracting Development, or Compliance Manager.
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Chapter 13: HEALTH SCREENINGS

Introduction

Colleagues working with Organized Customers or certain Specialty Markets may wish to support or hold health screenings. These screenings often take place as part of larger health fairs. Pfizer sponsors screenings to benefit the quality of patient health care. Screenings can promote the early detection of diseases and may offer patients a meaningful opportunity to manage a disease or condition.

This Chapter is relevant to all colleagues who have a budget that supports health screenings, and are colleagues who are permitted to offer or implement health screenings sponsored by Pfizer.

Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination of employment.
Key Points to Ensure Compliance

- Only provide health screenings in accordance with the guidelines in this Chapter.
  
  o Do not design your own program for a customer.
  
  o Do not modify approved health screening tools.
  
  o Do not alter or customize materials in any way for a customer.

- Offer approved health screenings without any expectation of return to Pfizer.
  
  o Do not condition the offer of a health screening on increased prescribing or formulary status.
  
  o Do not offer health screenings as an inducement to place Pfizer products on formulary.

- Make health screenings widely available.
  
  o Do not choose customers to receive screenings based on their likelihood to prescribe Pfizer products or in return for previous prescribing.

- Health screenings cannot be tied to the use of Pfizer products in any way.
  
  o You may under some circumstances, after consultation with and approval by your team attorney, seek information about products or programs used by those participating in the screenings, but you may not use such information to promote the use of Pfizer products. For further information on appropriate consumer interactions, see Chapter 16: Consumer and Employee Interactions.

Screenings Offered to an Employer for its Employees

Screenings must be funded out of your promotional budget and approved by your Payer and Channel Access (PCA) Regional Director or Sales Director. You must not offer health screenings to employers who are HCPs or payers of healthcare items and services, such as hospitals, clinics, medical practice groups, and Managed Care Customers (MCCs) who seek reimbursement from the federal government, except for employers who may receive a government retiree drug subsidy for retirees. Unless
otherwise approved by your team attorney or PCA Legal, the screening must be limited to current employees and their beneficiaries and must expressly exclude retirees who are beneficiaries under the employer's retiree health plan.

These screenings are promotional in that they "promote" Pfizer generally (Pfizer is the "product"). Colleagues can promote Pfizer products at the screenings as long as the exhibit and display booth is physically separate and apart from the screening area. However, no financial Return on Investment (ROI) analysis can be performed that ties a product's sales or market share to this event. Additionally:

- The screening must be conducted by an approved third-party vendor that routinely conducts such screenings, and the vendor must sign Pfizer's Screening Services Agreement.
- The screening cannot be organized or designed in any way to generate referrals for any particular customer.

**Privacy Issues**

Consumer health fairs and screenings implicate privacy issues when they involve obtaining individually identifiable health information. Pfizer's ability to use any personal data 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. Such authorization is contained in Pfizer's release form. For more information on the topic of patient consent, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.

Data may be shared with an employer or employer health plan if: (1) the data is aggregated and de-identified; and (2) all participants whose data is being shared have signed the Pfizer Patient Authorization and Release form. It is never appropriate to share personal health information that has not been aggregated and de-identified.

- Aggregated de-identified data from screening participants can ONLY be provided to an employer or the employer's health plan IF the screening participants have signed Pfizer Patient Authorization and Release forms, which must specifically provide that the data can be provided to the employer or the managed care plan managing the Rx drug benefit.
• The Pfizer Patient Authorization and Release form is available on PfieldNet within the “Compliance” tab under the “Forms” tab.

Providing Health Screening Data to a Customer

Q. One of my customers wants Pfizer to conduct a disease screening for employees of an employer to whom the customer provides pharmacy benefits. The customer also wants Pfizer to provide them with the aggregated, de-identified data from the screening. Can I organize the screening and provide the data?

A. Maybe. The only reason you can conduct a disease screening is to improve patient care. You cannot subsidize the operating expenses of the customer or the employer by conducting a screening that they would do on their own. If there is an independent valid reason for Pfizer to fund the screening, Pfizer can organize it. Aggregated, de-identified data from the screening can only be provided to the customer if each employee screened signs Pfizer’s Patient Authorization and Release and the release specifically provides that the data can be provided to both the employer and the managed care plan administering the drug benefit. MCCs are not appropriate entities to whom Pfizer should offer screenings. In the scenario above, the MCC should not appear as a co-sponsor of the event unless the MCC independently provides funding or services.

Screenings Offered to the Public at Large

*If organized by a Hospital, Non-Profit Organization, Managed Care Organization, or Other Third Party:*

• Pfizer’s office of Independent Grants for Learning & Change (“IGLC”) can support a screening organized by a third party through an unrestricted educational grant, provided that the event meets Pfizer’s requirements for unrestricted educational grants. You must NEVER promise that a grant will be provided for a health screening or for any other reason. The requestor must apply directly to IGLC for funding and will receive notice from IGLC regarding whether the request has been approved.

• The requesting organization is solely responsible for logistics and content of the event.

• The screening event must be advertised and open to the community at large (e.g., advertised in the newspaper or on TV or radio).
The screening must not be organized or designed in any way to generate referrals for any particular customer.

Pfizer exhibits and displays are not permitted at any event funded by an IGLC grant.

**If organized by Pfizer:**

- The screening may be funded out of your promotional budget and must be approved by your PCA Regional Director or Sales Director.

- These types of screenings are promotional in that they "promote" Pfizer generally (Pfizer is the "product"). Colleagues can promote Pfizer products at these screenings with an exhibit and display as long as the exhibit and display booth is physically separate and apart from the screening area and adheres to other Pfizer policies and procedures governing advertising and promotion. No financial ROI analysis can be performed, tying a product's sales or market share to this event.

- The screening must be conducted by a third-party vendor that is not a HCP or payer and that routinely conducts such screenings. The vendor must sign Pfizer's Screening Services Agreement, which can be downloaded from PfieldNet under the “Compliance” tab at [http://pfieldnet pfizer.com/Compliance/Pages/Home.aspx](http://pfieldnet.pfizer.com/Compliance/Pages/Home.aspx).

- The screening cannot be organized or designed in any way to generate referrals for any particular customer.

- The screening must be advertised and open to the community at large, and any materials advertising or promoting the event must be approved by the relevant Review Committee (“RC-approved”). If you are unsure which Review Committee is appropriate, consult your team attorney.
On Site Health Screenings “Open to the Community”

Q. Is a disease screening held on site at a Managed Care Customer's facility but open to the community appropriate for an educational grant request?

A. No. Even though the event is "open to the community," the benefit to the MCC and its members outweighs the community benefit of the screening. An event held at the MCC location could be seen as an attempt to generate new members for the MCC, something that Pfizer cannot fund. Health screenings that are organized by local not-for-profit organizations or hospitals and conducted in venues that are likely to attract the broader community are more appropriate for an independent educational grant request. In any event, all requests for educational grants to support health screenings must be submitted by the requestor online to Pfizer’s office of Independent Grants for Learning & Change. For more information, see Orange Guide Chapter 3: Support of External Organizations.

REMEMBER:

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

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

Other Key Points for Health Screenings

Field Commercial Colleague Participation

Colleagues may hand out materials approved by RC for use with consumers in spaces separate from the area where the screening is occurring. You must wear your Pfizer name tag throughout the screening, which will help identify you to consumers as a Pfizer employee. For more information on appropriate Field Commercial Colleague interaction with consumers at health fairs and screenings, see Orange Guide Chapter 8: Privacy: Protecting Personal Information and Orange Guide Chapter 16: Consumer and Employee Interactions.
Important Points to Remember

- Do not use a screening to drive or attempt to generate patient referrals to any HCP.
- Contract with an approved third-party vendor that routinely conducts such screenings to perform the disease screening customer program.
- Data may be shared with an employer or employer health plan if: (1) the data is aggregated and de-identified; and (2) all participants whose data is being shared have signed the Pfizer Patient Authorization and Release form. Clearly identify yourself as a Pfizer employee to all screening participants.
- Use only approved documents and obtain necessary documentation:
  - Pfizer Vendor Agreement;
  - Pfizer Patient Privacy Release; and
  - An invoice from the vendor for the services.

Health Screenings and Exhibit Booths at Health Fairs

Q. Pfizer is participating in a local health fair where we will be organizing and conducting lipid screenings. Can Pfizer also have a separate promotional exhibit and display booth where we hand out approved consumer materials on Pfizer products?

A. Yes. So long as the exhibit booths are separate and not joined with the screening, you can provide RC-approved consumer materials at a health fair where Pfizer is also conducting a health screening. For example, the exhibit booths and health screenings can be at the venue as long as the two events are held in separate rooms or there is a partition. It should never be the case or appear to be the case that Pfizer is conducting the screening in order to encourage people to ask their doctor about Pfizer products.

FOR MORE INFORMATION

- For more information on requests for educational grants to support health screenings, see Orange Guide Chapter 3: Support of External Organizations.
• For more information on interactions with consumers at health fairs and screenings, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.

• Questions may be referred to your manager, team attorney, or PCA Legal Team.
Chapter 14: ORGANIZED CUSTOMER AND PAYER TOOLS AND RESOURCES

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Chapter 14: ORGANIZED CUSTOMER AND PAYER TOOLS AND RESOURCES

Introduction

Organized Customer and Payer Tools and Resources (hereinafter, “OCP Resources”) are programs provided by Pfizer that are designed to educate customers, benefit patients, and improve patient outcomes. The purpose of the OCP Resources is generally to promote wellness, disease prevention, patient awareness, and high quality health care. OCP Resources can be categorized as:

- Product Support; or
- Unbranded.

Please be aware that some tools and resources may require tracking and disclosure under the Sunshine Act. The Sunshine Act requires us to report payments or transfers-of-value to U.S.-licensed physicians or teaching hospitals. The payments or transfers-of-value that we report may be direct (e.g., a U.S.-licensed physician receives something from Pfizer) or indirect (e.g., a U.S.-licensed physician receives something from an organization paid by Pfizer). We may have to report the payment or transfer-of-value even if Pfizer did not influence or direct who should receive the payment or transfer-of-value.

This Chapter is relevant to all colleagues who are authorized to offer or provide OCP Resources to Accounts, such as medical groups, long term care, HMOs, VA and DoD accounts, certain hospitals, employers, and pharmacy benefit managers. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination of employment.

Field Commercial Colleagues should consult Orange Guide Chapter 5: Interactions with Health Systems and Medical Groups for additional guidance before offering or providing OCP Resources to customers.
Key Points to Ensure Compliance

- Do not offer or provide OCP Resources, including Quality Programs, that are not RC-approved.
  - Do not design your own OCP Resource for a customer.
  - Do not modify approved OCP Resources.
- When offering or providing approved OCP Resources, do so without any contingencies or conditions.
  - Do not condition the offer or provision of OCP Resources on increased prescribing or improved formulary status.
  - Do not offer or provide OCP Resources as an inducement to place Pfizer products on formulary.
- OCP Resources may not underwrite operational or other services for which the customer would otherwise have to engage or pay on its own.
- Make all OCP Resources and tools widely available.
- Unless otherwise approved by RC, OCP Resources should not be discussed in conjunction with branded materials as such execution may convert the OCP materials to a branded resource.
- Only Product Support Programs can be used to further the use of a particular Pfizer product. Unbranded Programs may impact use of a Pfizer product but only because of their overall impact on a relevant patient type, disease state, or product class.
- OCP Resources and the manner in which they are used should clearly disclose the role Pfizer played in their creation and dissemination.

Product Support Programs

Product Support Programs are OCP Resources that aim to promote our products through education on their appropriate use or to show how well our products may work. These OCP Resources are developed by the relevant brand team for use by certain groups and with certain customers. Generally speaking...
Product Support Programs are intended for use by Account Managers rather than by Sales Colleagues. Furthermore, Product Support Programs are intended for Accounts such as IDNs and health plans, and are not intended for individual HCP audiences.

Product Support Programs, similar to the materials Pfizer presents to HCPs must be approved by a Pfizer Review Committee and, if they discuss Pfizer products, must be consistent with product labeling. Product Support Programs cannot be modified or changed in any way. If different materials are needed for a certain activity, those materials must be approved by a Pfizer Review Committee prior to use.

The information obtained from a Product Support Program can be provided back to the customer to demonstrate the efficacy of the initiative. However, you cannot provide data derived from a Product Support Program with one customer to a different customer because the data has not been approved by a Pfizer Review Committee and may not be appropriate for sharing. Be sure to work with Field Medical Colleagues on projects measuring the efficacy of an intervention to ensure compliance with Pfizer policies governing non-interventional and pragmatic studies.

**Unbranded Customer Programs**

Unbranded Customer Programs support Pfizer’s overall mission of improving the quality of patient care. They are used to educate colleagues or customers on health-related issues in order to enable improved patient-physician engagement as well as to identify best practices and improve health outcomes. While these unbranded resources may be specific to a disease state where Pfizer has an interest, they do not name or imply a specific Pfizer product. Unbranded Customer Programs focus on improving patient care by providing customers with information about, for example, quality accreditation standards, HCPs’ patient interaction skills, and management of medical conditions.

Unbranded Customer Programs must be approved by a Pfizer Review Committee and cannot be modified or changed in any way. If different materials are needed for a certain activity, those materials must be approved by a Pfizer Review Committee prior to use. Unbranded Customer Programs may not underwrite operational or other services in which the customer would otherwise have to engage or for which the customer would be obligated to pay on its own. Furthermore, these programs may not be used to aid a customer’s accreditation or achievement of measures that would positively impact their reimbursement. All current Unbranded Customer Programs are identified at [http://crc.pfizer.com](http://crc.pfizer.com).
Quality Programs

Quality Programs are unbranded assets for use by all health care stakeholders, including both Accounts and individual HCPs. These unbranded resources support improved health outcomes, patient awareness, wellness, disease prevention, and high quality health care, and they focus on addressing the overall quality of healthcare rather than promoting Pfizer products. Quality programs include programs such as: (1) Older Adult Sensitivity Training; and (2) The Art of Active Listening. Quality Programs must never be provided to customers with the expectation that their use will increase the use of Pfizer products and should not be subject to a return on investment (ROI) calculation.

The Value of Quality Programs in Meeting Objectives

Q. Can I conduct a financial ROI analysis on implementation of an OCP Resource?
A. It depends on the OCP Resource. You may not conduct a ROI analysis on a Quality Program. For other OCP Resources, an ROI may be appropriate so long as it measures the impact to a Pfizer product as a part of the overall market. You may not calculate nor may you use Unbranded OCP Resources to achieve a gain in market share.

Q. I know I cannot conduct a financial ROI analysis on Quality Programs since they are not to be tied to prescribing. Can I conduct any analysis to determine whether the Quality Program was beneficial to the customer?
A. Non-financial analyses, like measuring whether a program has improved patient or physician understanding of a disease or enhanced the ability of physicians to discuss sensitive issues with patients effectively, are appropriate to conduct in order to determine whether the Quality Program met its objective of improving patient outcomes or increasing physician understanding.

OCP Resources Recipients

OCP Resources must be made widely available to those Account customers who meet certain capability criteria as part of Pfizer’s overall mission to enhance the quality of healthcare. Offering the OCP Resources only to select customers could be perceived as providing items of value in order to increase prescribing or improve formulary status with those customers in violation of the anti-kickback laws or
other healthcare laws. However, you may consider availability of internal Pfizer resources as well as the customers for whom the tools will most positively impact patients in prioritizing accounts.

To ensure that the offering of these OCP Resources does not violate applicable law, you must never provide OCP Resources in exchange for increased prescribing or improved formulary status. Even though a customer may decide to change prescribing habits or formulary status based on the information it receives from an OCP Resource, you must never make these changes a condition or expectation of receiving OCP Resources.

OCP Resources and the manner in which they are implemented with customers and patients should clearly disclose Pfizer's role in their creation and dissemination.

**Discussing Pfizer Products While Meeting about Unbranded Customer Programs**

Q. If I am meeting with a customer to discuss Unbranded Customer Programs, am I prohibited from discussing Pfizer products during that meeting?

A. You are permitted to discuss Pfizer products during the meeting only if you ensure that the customer understands that the program is not related to the promotion of Pfizer products and that Pfizer does not expect or intend that the customer use our products as a condition of Pfizer providing the program. The program must be provided with no strings attached. Your discussions about Pfizer products should be clearly separate from your discussions about the Unbranded Customer Program.

The decision to provide an OCP Resource must be based on the customer’s capabilities (as determined by Pfizer), not because providing the OCP Resources will improve your relationship with the customer or subsidize costs the customer would otherwise have had to pay. Even though an improved customer relationship might be an unintended result of providing OCP Resources, you may never offer or provide such a program with that intent.

Pfizer’s reason to offer or provide OCP Resources must **never** be to:

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

Referencing OCP Resources During Formulary Discussions

Q. If an Account’s formulary decision maker asks me for additional reasons why a Pfizer product should be included on its formulary, may I discuss the quality and variety of our OCP Resources?

A. No. OCP Resources may never be offered as a reason for including a Pfizer product on formulary. The OCP Resource may be perceived as an item of value offered to increase prescribing in violation of the anti-kickback laws. Consequently, you must never affirmatively discuss OCP Resources in relation to a formulary decision. If a customer makes an unsolicited inquiry about the availability of OCP Resources, you may address it by:

• Stating that at the conclusion of your product discussion you can provide information about the OCP Resources that Pfizer makes available to its customers; and

• Stating that an offer or provision of OCP Resources to the customer is in no way influenced by or tied to the customer’s pending formulary decision.

FOR MORE INFORMATION

• Consult the PCA intranet site for information and guidance on OCP Resources, as well as a listing of available Quality Programs.

• Field Commercial Colleagues should consult Orange Guide Chapter 5: Interactions with Health Systems and Medical Groups before offering or providing OCP Resources to customers.

• Please refer to Orange Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure for more information on our disclosure obligations under the Sunshine Act.

• Questions may be referred to your manager, PCA Customer Marketing, your team attorney or Organized Customer Legal Team.

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Chapter 15: ARRANGEMENTS WITH SPECIALTY PHARMACIES AND OTHER NON-DISCOUNT ARRANGEMENTS WITH ACCOUNTS

Introduction

Pfizer enters into a variety of contractual arrangements with its customers. As discussed in Orange Guide Chapter 12, Pfizer provides discounts to certain organized customers, often in the form of rebates. In addition, Pfizer enters into non-discount arrangements with customers to procure goods or services on behalf of Pfizer. Hiring an HCP to be a speaker at a Pfizer speaker program is one example of a non-discount arrangement. Similarly, purchasing data from a specialty pharmacy or hiring a specialty pharmacy to conduct patient outreach on behalf of Pfizer are other examples of non-discount arrangements. This Chapter discusses those non-discount arrangements between Pfizer and its organized customers, or Accounts, including managed care organizations, retail pharmacies, specialty pharmacies, group purchasing organizations, and integrated delivery networks. Where relevant, the chapter divides non-discount arrangements into those where Pfizer is purchasing some item of value (a “Purchase Agreement”) and those where Pfizer is procuring a service (a “Service Agreement”).

Anti-Kickback Analysis

The Anti-Kickback Statute prohibits payments intended to induce someone to purchase, prescribe, endorse, or recommend a product that is reimbursed under federal or state healthcare programs. Under Pfizer policy, all customers are treated as if they are subject to the Anti-Kickback Statute, even though they may not participate in a federal healthcare program. Recognizing that the federal Anti-Kickback Statute, if read literally, could restrict many otherwise legitimate marketing activities and even some non-promotional activities, the U.S. Department of Health and Human Services (“HHS”), Office of Inspector General (“OIG”) has defined certain “safe harbors.” Activities that fall entirely within a safe harbor, such as legitimate service arrangements, do not violate the Anti-Kickback Statute.
The Anti-Kickback Statute and safe harbors are critical to consider when entering into non-discount arrangements with any customer, and particularly Accounts who are eligible to receive discounts on Pfizer products under a separate discount arrangement.

When Pfizer is making a payment, directly or indirectly, to an Account that may purchase, prescribe, endorse, or recommend Pfizer products, every non-discount arrangement between Pfizer and that Account must undergo an anti-kickback analysis. This will help ensure that the proposed non-discount arrangement has a legitimate business purpose and that Pfizer is procuring a needed good or service at fair market value (FMV). Arrangements to influence the purchase, prescription, or recommendation of a Pfizer product, or to improve the price or discount at which a customer can purchase Pfizer’s products, are not permitted and may subject Pfizer to liability.

In order to ensure compliance, when entering into non-discount arrangements with Accounts, remember the following principles:

- **Ensure the non-discount arrangement serves a legitimate business purpose.** 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 seen as an illegal kickback.

- **Always ensure you are paying FMV for the good or service.** Paying too much for a good, service, or data increases the risk that the arrangement may be seen as a kickback. The company has recently undertaken the development of a tool to assist colleagues in determining FMV for certain activities that Pfizer may provide to a customer as part of a collaboration agreement. The tool is a Excel based worksheet that can assist both commercial and medical colleagues with quantifying the value of certain activities provided as part of a collaboration. Individuals preparing to engage in a formal collaboration should contact their team’s point of contact for assistance with use of the tool.

- **When procuring Services or data from a Specialty Pharmacy, engage the Specialty Access Solutions Center of Excellence for assistance.**

- **Do not leverage Pfizer's ability to purchase goods or services from an Account in order to induce or influence the purchase, prescription, or recommendation of Pfizer products.** For example, do not condition the purchase of data from an Account on formulary access for a Pfizer product.
To avoid pricing concerns, do not combine discount arrangements with other types of transactions. Do not discuss discount arrangements under which a customer may be eligible for a discount on Pfizer products in conjunction with non-discount arrangements under which Pfizer seeks to procure an item of value or service from the Account.

- Memorialize non-discount arrangements between Pfizer and its Accounts in a written contract. Remember, because contracts can be oral or written, you can unwittingly bind Pfizer. Do not make oral promises to customers.
- Work with your legal counsel. Legal counsel will assist with contract development as well as mitigate compliance risks. Legal counsel may also seek to structure the non-discount arrangement so that it meets an applicable anti-kickback safe harbor, such as the Personal Services safe harbor.

**Personal Services Safe Harbor:** This safe harbor protects legitimate service arrangements recorded in a written agreement, of at least one year in duration, where the compensation is determined in advance and on a fair market value basis. Where appropriate, Pfizer endeavors to make Service Agreements meet the Personal Services safe-harbor.

**Fair Market Value:** Price at which an asset or service passes from a willing seller to a willing buyer based on market demand and supply. Pfizer is required to pay any person or entity in a position to purchase, prescribe, endorse, or recommend our products fair market value for the good or service Pfizer receives in return.

**Purchase Agreements**

The term “Purchase Agreement” refers to a non-discount arrangement between Pfizer and an Account where Pfizer is procuring an item of tangible value to Pfizer. As with any non-discount arrangement, Purchase Agreements must serve a legitimate business purpose where Pfizer is purchasing an item for which it has a bona fide need at fair market value and must be memorialized in a written agreement. Frequently, Pfizer seeks to purchase data to which an Account has access by virtue of its providing services to its patients, members, or affiliated physicians. Purchase of data from an Account and Pfizer’s subsequent use of the data may implicate federal and state privacy laws. Work with your legal
counsel to ensure the Purchase Agreement contains the necessary protections for Pfizer and Pfizer’s proposed use of the data is consistent with our contractual obligations and applicable privacy laws.

All Purchase Agreements with Accounts must be reviewed and approved by an attorney on the Organized Customer Legal team or by your team attorney.

**Service Agreements**

The term “Service Agreement” refers to a non-discount arrangement between Pfizer and an Account where the Account is hired to perform services for Pfizer. Customers are in the unique position of having access to patients taking Pfizer products, to members to whom they provide health benefits, and to providers who are affiliated with the Account. For this reason, Pfizer may from time to time want to retain the Account to engage with such individuals or to disseminate certain information on Pfizer’s behalf. As with any non-discount arrangement, Service Agreements must serve a legitimate business purpose where Pfizer is purchasing a service for which it has a bona fide need at fair market value and must be memorialized in a written agreement reviewed by the appropriate legal counsel.

Common types of Service Agreements include those for dissemination of Patient Educational materials, Medication Compliance, and Co-Promote (also referred to as “now on formulary”) Programs. Other types of service agreements include agreements with organized customers (IDNs) to provide clinical and technical input into the development and testing of prototype Pfizer resource such as a Health IT tool, a specific type of resource intended for use with HCPs, health systems, etc.

All Service Agreements with Accounts must be reviewed and approved by an attorney on the Organized Customer Legal team in conjunction with the relevant product attorney, and may require review and approval by Intake Committee per guidance from legal.

Privacy laws limit the scope of permissible activities Accounts may engage in when interacting with patients on Pfizer’s behalf. The Health Information Technology for Economic and Clinical Health (HITECH) Act and the HIPAA Omnibus Final Rule (Omnibus Rule) restrict certain sales and marketing related activities in which our Accounts are paid or otherwise provided remuneration, directly or indirectly, in exchange for communicating with targeted patients or clinicians on our behalf. As a result of these restrictions, certain communication programs that previously could operate without patient authorization now require prior written patient authorization. In limited circumstances, Pfizer and its
Accounts may implement programs without securing patient authorizations; however, Pfizer and its Accounts must ensure that the arrangements comply with the terms of the limited exceptions to the authorization requirement under the HIPAA marketing rules. State privacy laws may also be implicated by certain arrangements. For more information about HIPAA, see Orange Guide Chapter 8: Privacy: Protecting Personal Information. Please consult an Organized Customer Legal team attorney or your team attorney if you have questions on the permitted scope of Accounts’ interactions or communications involving members or clinicians.

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

### Key Points to Ensure Compliance

- Do not discuss Purchase Agreements, Service Agreements, or other arrangements in connection with rebate negotiations.
- Neither Purchase Agreements nor Service Agreements may reference existing discount arrangements.
- Do not enter into Purchase Agreements or Service Agreements for the purpose of inducing the placement or maintenance of Pfizer products on a formulary.
- Only enter into Purchase Agreements and Service Agreements that support an identified Pfizer business need.
- All Purchase Agreements, Service Agreements, and other arrangements must be approved by the Organized Customer Legal team.
- Only use Pfizer approved templates unless otherwise instructed by Organized Customer Legal.
- Consult the Organized Customer Legal team or the Privacy Office to ensure each arrangement complies with federal and state privacy laws.
Interactions with Specialty Pharmacies

Recently there has been an increase in the development of “specialty” medications, i.e., medications that may have specialized administration, storage, or distribution requirements, FDA mandated REMS requirements and that generally have a higher cost of therapy. Specialty drugs are generally dispensed from “Specialty Pharmacy Providers” which are distinct from traditional pharmacies in their coordination of many aspects of patient care and disease management. They are designed to efficiently deliver medications with specialized handling, storage, or with payer access hurdles using standardized processes that permit economies of scale or the development of expertise in overcoming access challenges. Specialty pharmacies are also designed to help improve clinical and economic outcomes for patients with complex, often chronic and rare conditions, with close contact and management by clinicians. Health care professionals, including both pharmacists and nurses employed by specialty pharmacies, provide patient education, help ensure appropriate medication use, promote adherence, and attempt to avoid unnecessary costs. Other support systems coordinate sharing of information among clinicians treating patients, support payer mandated prior authorizations and help patients locate resources to provide financial assistance with out of pocket expenditures.

Pfizer may enter into non-discount arrangements with specialty pharmacies, such as purchase agreements, service agreements, patient education programs, and medication compliance programs. For example, Pfizer may enter into a service agreement with a specialty pharmacy to disseminate patient education materials. Because of the nature of the relationship and influence health care professionals often develop with patients, it is important to ensure that Pfizer’s interactions with specialty pharmacies are handled appropriately so that: (i) Pfizer does not inappropriately interfere with the pharmacist-patient relationship, (ii) the clinical independence of these professionals is maintained, and (iii) all activities support the clinical benefit of the patient and are not a vehicle for promotion of Pfizer products directly to patients.

Given recent heightened scrutiny related to Specialty Pharmacy arrangements, a new formalized process has been developed to ensure compliance with our contracting policies. All brand teams (across all business units) interested in engaging or contracting with specialty pharmacies to initiate new programming, data purchases, distribution, or defined distribution arrangements are required to engage the Specialty Access Solutions Center Of Excellence (SAS COE) team within Payer and Channel Access. Specifically, the COE Strategy and Innovation Directors are the first point of contact.
for the brand team to discuss new programs and how to proceed with the review, approval, engagement, contracting and implementation of new programs. Specialty Pharmacy Medical Outcomes Specialist must also be notified. Questions may be referred to your manager, Organized Customer Legal Team, or your respective BU Compliance Lead.

Medical Outcomes Specialists may engage with specialty pharmacies for product related training and other above brand medical education or collaborative initiatives; however, they are required to engage the Specialty Access Solutions National Account Directors, and the specialty pharmacy Medical Outcomes Specialist when discussing initiatives or collaboration projects with specialty pharmacies.

Principles Governing Specialty Pharmacy Employee Field Engagement and Activity

Pfizer Commercial Colleagues may interact with Specialty Pharmacy Employees when engaging in non-discount arrangements with the specialty pharmacy. To ensure that such interactions are handled appropriately, Pfizer colleagues must be mindful of the Specialty Pharmacy Employee roles and limitations. For example, Specialty Pharmacy Employees may: (1) interact and discuss business intelligence about physician offices where they can support and enhance one another’s access and/or office relationships; and (2) discuss their ability to provide support for Pfizer products as part of business to business discussion with a physician’s office. However, they are not trained or certified by Pfizer on any of our products and are, therefore, prohibited from promoting any of our products on behalf of Pfizer. Specialty Pharmacy Employees may advise physicians that they can alert a Pfizer Sales Representative that a physician has a product-related question and have the Pfizer Sales Representative contact the office for follow-up. They may also provide physicians with the Pfizer Medical Information toll free phone number. However, the Specialty Pharmacy Employee may not relay the specific product related question to the Pfizer Sales Representative.

Use of Pfizer Materials

Specialty Pharmacy employees, including their Representatives and Clinical Pharmacists, are not permitted to use any Pfizer product promotional materials when such Specialty Pharmacy employees are promoting the specialty pharmacy’s services to their customers. A minor exception is permitted for certain Pfizer brands that have a ‘Welcome Kit/Brochure’ when such Welcome Kits/brochures are
provided to patients. As a general rule, no additional materials that have a Pfizer product brand name on them will be permitted to be distributed through/by Specialty Pharmacy employees following the shipment of the initial Welcome materials. Furthermore, only educational materials will be considered for distribution by Specialty Pharmacy employees to their patients, and Pfizer colleagues must continue to engage SAS Legal and brand GPC Legal to review materials under consideration. Pfizer colleagues may not share any Pfizer IMS Exponent prescription data or other proprietary information such as Fingertip Formulary with Specialty Pharmacy personnel. Use of unbranded disease state educational materials as part of a collaboration or service agreement with a specialty pharmacy may be considered on a case by case basis, but only as part of a formal agreement with the customer approved by your team attorney or the Intake Committee. See Chapter 5 for further information concerning the Intake Committee process.
Key Points to Ensure Compliance

- All brand teams interested in engaging or contracting with specialty pharmacies to initiate new programming, data purchases, distribution, or limited distribution arrangements are required to engage the SAS COE team. Specifically, the COE Strategy and Innovation Directors are the first point of contact for the brand team to discuss new programs and how to proceed with the review, approval, engagement, contracting and implementation of new programs.

- Once Organized Customer Legal Team approvals are obtained, the SAS COE Team will review the new program with the assigned National Account Director and provide the draft agreement (typically a statement of work (SOW)) with the specialty pharmacy. The National Account Director, with support from the SAS COE, will present the new program and the draft agreement to their Specialty Pharmacy account. The Specialty Pharmacy reviews the agreement and works with the SAS COE towards a final agreement.

- Once a SOW is signed, the program can be implemented at the SPP. Before implementation, it is necessary that the SPP complete the appropriate training and implementation steps before the program goes “live.” This may involve SAS COE colleagues opening a new Customer Engagement Program (CEP) and a purchase order for services to be rendered. This on-boarding process is initiated by the NAD and SPP COE Operations Director following the guidance provided in the Specialty Pharmacy On-boarding Guide.

- Pfizer does not pay for any service offering that is considered a “core service” for the SPP, but may pay for services that are considered “enhanced services” at that SPP.

- Remember: Do not discuss or offer any ‘pay for performance’ arrangements such as providing bonus payments or rebates to specialty pharmacies in accordance with their ability to generate new scripts, switches or refills.

- Do not discuss or offer any payments that involve patient referrals. For example, allocating patients to a particular specialty pharmacy in a defined distribution network in accordance with the pharmacy’s ability to generate new scripts, switches or refills.

- Specialty pharmacies can provide valuable, business-related data as part of their agreements with Pfizer. In no instance can this data be utilized externally without notifying the SAS COE Team prior to such use. The SAS COE will seek necessary guidance and approvals for contemplated uses. The SAS COE should consult Medical if unsure whether the requested data may be considered clinical versus business-related.
Patient Education Programs

Patient Education Programs allow Pfizer to provide RC-approved health information to an Account’s patients or members, subject to certain reimbursement and authorization requirements under HIPAA (as amended by the HITECH Act and Omnibus Rule). Unless prior authorizations are obtained from the patients or members, if protected health information will be used by the Account in making the communication, Pfizer may only provide unbranded health information to the Account’s patients or members.

If Pfizer seeks to compensate an Account for sending branded health information:

- The Account must secure individual authorizations from its patients or members before making the communication and must disclose any compensation provided by Pfizer;
- Any compensation provided to the Account must be equal to the Fair Market Value (FMV) cost of developing and conducting the services to be provided (e.g., mailing any program materials or welcome kits, as applicable);
- Only RC-approved Patient Education materials may be used and the materials must disclose Pfizer’s sponsorship.

Any proposed changes to approved materials must be reviewed and approved by the appropriate Pfizer Review Committee before the materials can be disseminated.

Medication Compliance Programs

Medication Compliance Programs, most commonly referred to as “refill reminder” or “adherence call” programs, are outreach programs that provide patients with information about the product they are taking, remind them of the importance of staying on therapy as prescribed, and remind patients to refill their prescriptions. These programs may be implemented without seeking patient authorizations if Pfizer and the Account comply with the requirements of the HIPAA “refill reminder exception.”

The type of compensation permitted under the refill reminder exception depends on whether compensation is provided directly by Pfizer to either the Account or its business associate for the associated communications.
• If Pfizer pays an Account directly, Pfizer may only reimburse the Account for the cost of labor, supplies, and postage related to performing the program.
• If Pfizer pays an Account's business associate, Pfizer may compensate the business associate up to the fair market value of the services provided.

Please note that the following activities are not permitted under the refill reminder exception:

• Communications regarding new formulations of a currently-prescribed drug or biologic;
• Communications about a drug that may be used in conjunction with a currently prescribed drug or biologic; and
• Communications encouraging an individual to switch from a currently prescribed drug or biologic.

For arrangements that do not comply with requirements of the refill reminder exception, the Account would need to collect patient authorizations before disseminating the communications.

All materials provided as part of a Medication Compliance Program must be reviewed and approved by the appropriate Pfizer Review Committee.

Co-Promote Programs

From time to time, Pfizer may enter into Service Agreements with managed care customers ("MCC") that maintain a formulary where Pfizer products are listed. These Service Agreements provide for the distribution of non-routine formulary information about Pfizer products to the MCC’s members. Typically, these contracts compensate an MCC for providing information to its members explaining that a Pfizer product has recently been added to the MCC’s formulary or reminding them of the availability of Pfizer products on formulary. Similar to the Medication Compliance Programs above, these formulary announcements are only permitted without patient authorization if the announcements are targeted to the MCC’s members who are currently prescribed the same drug or biologic and remuneration to the MCC only covers the cost of labor, supplies, and postage. If Pfizer pays the MCC’s business associate for the services provided, fair market value compensation to the business associate may be provided. For broader targeting of formulary announcements, or for arrangements involving greater compensation, the MCC would need to collect patient authorizations before disseminating the formulary information.
Co-Promote agreements cannot compensate an MCC for engaging in routine formulary-related communications. Routine communications are those that the MCC would do even without financial support from Pfizer. Examples of routine communications that cannot be funded may include:

- Monthly patient newsletters;
- The annual mailing of the new formulary guide; and
- Announcements of routine formulary changes (e.g., announcements of all changes to formulary since last update that the MCC could do in the normal course of business).

All Co-Promote programs must be vetted by an Organized Customer Legal attorney to ensure compliance with relevant laws including privacy laws. The privacy analysis may hinge on factors such as the nature of the communication, the manner in which the Pfizer product is identified or implied, the audience to whom the communication would be targeted, the information used to target the message, and the nature of the remuneration or expenses covered by Pfizer.

**Collaborations**

A Collaboration is an arrangement between two or more parties who jointly work together toward a common public health goal. Periodically, Pfizer engages its Accounts in Collaborations on various health initiatives of mutual interest and value to both companies that have potential benefits to the health community at large. Unlike a Service Agreement, which is more of a vendor-type relationship, a Collaboration Arrangement documents a transaction of a more significant nature that involves contributions provided by each party. All Collaborations should be supported by an internal Pfizer business rationale or justification and memorialized in a written contract. Collaborations entered into with Accounts by Account Managers and/or Field Medical colleagues are subject to review and approval by your team attorney or the Intake Committee, as further described in Chapter 5. See Orange Guide Chapter 5: Interactions with Health Systems and Medical Groups for more information on Collaborations. Collaborations with not-for-profit entities are addressed in Pfizer’s Standard Operating Procedure (SOP) Funding Requests for Not-for-Profit Organizations. When entering into Collaborations follow the rules and principles above that apply to non-discount arrangements with Accounts.
FOR MORE INFORMATION

- For more information about HIPAA, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.

- Questions may be referred to your manager, the Payer Brand Customer Marketing Team/Product Team, PCA Customer Marketing, your team attorney, or the Organized Customer Legal Team.
Chapter 16: CONSUMER AND EMPLOYEE INTERACTIONS

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Chapter 16: CONSUMER AND EMPLOYEE INTERACTIONS

Introduction

All colleagues must provide truthful, accurate, and balanced product information to healthcare professionals (HCPs). It is equally important that you understand the rules that govern your interactions with consumers (including patients, potential patients, and all other non-HCPs), as they are distinct from the rules that apply to your interactions with HCPs. Employees of customer organizations may also be considered consumers and must be treated according to the guidelines in this Chapter.

Pfizer interacts with consumers at various types of events including speaker programs, health fairs, public health screenings, and disease management programs. A variety of laws and industry standards specifically govern your promotional interactions with consumers. These differ in some ways from the laws and standards governing your promotional interactions and activities with HCPs. Similar to interactions with HCPs, however, interactions with consumers can involve promotional risks, including the following:

- The U.S. Department of Health and Human Services Office of Inspector General (OIG) has warned that offering incentives, such as remuneration or free services, to consumers may implicate the federal anti-kickback laws.
- Some state 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, the Pharmaceutical Research and Manufacturers of America (PhRMA) has issued guidance to Pfizer and other member companies related to DTC advertising called Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines. This document provides guidance on ways to ensure that DTC communications provide accurate, accessible, and useful information to

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patients and consumers. Pfizer has committed to follow this guidance and has adopted its own Guidance for the Implementation of the Updated PhRMA DTC Principles.

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

As with HCPs, your discussions with consumers must comply with all FDA regulations, and all information provided to consumers must:

- Be consistent with product labeling;
- Be truthful and not misleading;
- Be supported by substantial evidence; and
- Appropriately balance the benefits of the product with its risks.

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

- At consumer events such as community health fairs, health screenings, state fairs, and disease management events where Pfizer has the opportunity to set up a display or exhibit; and
- At speaker programs or presentations organized by Pfizer specifically for consumers, using RC-approved consumer slide decks and contracted speakers.

Non-compliance with the policies in this guide puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination of employment.
**Key Points to Ensure Compliance**

- **When you interact with consumers:**
  - Use only RC-approved materials intended for consumers and limit your discussion to the information contained in these materials;
  - Provide fair and balanced information;
  - Do not provide off-label information;
  - Do not provide advice to consumers about their condition or treatment. Refer consumers to their HCP to discuss treatment options; and
  - Do not discuss competitor products, except to the extent that they have been included in RC-approved consumer materials.

- Pfizer is responsible for speaker conduct and all content presented at Pfizer speaker programs for consumers (whether branded or unbranded). The program and speaker must follow all applicable Centris requirements (Centris has replaced the EZSpeak platform). In addition, the speaker:
  - Must not provide specific medical advice to consumer attendees and should instead refer attendees to their HCP;
  - Must not discuss competitor products, except to the extent that they have been included in the RC-approved consumer slide deck;
  - Must not provide off-label information in any circumstance; and
  - Must not promote his or her practice or attempt to recruit new patients out of the audience.

- Meals at consumer programs may not exceed $50 per person (food, beverages, tax, and tip included).

- Always disclose that you are a Pfizer employee or representative when interacting with consumers. Wear your Pfizer name tag at all times.

- Employees of customer organizations may also be considered consumers. Pfizer interactions with customer employees who are not HCPs (such as at a health fair) must follow the principles applicable to consumer interactions.
Colleague Activities at Consumer Events

Exhibits and Displays

Pfizer is committed to providing information to consumers about their health and Pfizer treatment options. You are sometimes provided with opportunities to interact directly with consumers by working at Pfizer exhibits or displays at consumer events such as health fairs, patient advocacy events, and health screenings. The goal of these interactions should be to foster more informed conversations between patients and their HCPs about the patients’ health and treatment options.

Always disclose that you are a Pfizer employee or representative when interacting with patients. Wear your Pfizer name tag at all times.

Exhibit Fees, Food and Booth Staff

It is permissible to pay fair market value (FMV) for exhibit and display space at a consumer event. Pfizer may provide a very modest snack (e.g., fruit, granola bars, non-alcoholic beverages or pastries) to those consumers who visit the exhibit. You are permitted to provide a snack only to those consumers with whom you interact, and any snack you provide to consumers should be consistent with the level of interaction you are having with them.

People who are not Pfizer employees, including HCPs, should not work or host at the Pfizer booth. Remember that field-based medical colleagues such as Field Medical Directors (FMD) generally have only very limited interactions with consumers, consistent with the Green Guide (e.g., interacting with representatives of patient advocacy groups).
Providing Food to Consumers at a Display

Q. I will be working at a Pfizer display table at a community health fair next week. Can I provide food at my table? What about covering the cost of sandwiches for all the health fair attendees?

A. You can provide modest hospitality snacks at a display table where you are interacting with consumers. Any food you provide to consumers must be consistent with the level of interaction you are having with them. In this case, because you are interacting at a display table, it would be acceptable to provide modest snack items like fruit, granola bars, non-alcoholic beverages or pastries. It would not be appropriate for you to cover the costs of sandwiches or other food items for all attendees since you are permitted to provide food only to those consumers with whom you interact. Remember, even when you have more extensive interactions with consumers (e.g., at a speaker program) the cost of food, beverage, tax, and tip may never exceed $50 per attendee.

Venue

The consumer event where you are displaying must be located at a neutral venue that is open to the public. (Note that a doctor’s office is not considered open to the public). Pfizer-sponsored health screenings cannot be used to direct consumers to particular Pfizer products or to get people to ask their doctors about Pfizer products. Therefore, if Pfizer is also sponsoring a health screening at a consumer event, the exhibit booth and the health screening location must be physically separated, such as by a partition or by being in separate locations. If colleagues are exhibiting at an independent, third party sponsored educational event or conference, Pfizer promotional displays must also be separate from the educational presentation areas.

Materials

You may only use materials that have been RC-approved for use with consumers, and you must follow any accompanying instructions on use of the materials. For example, if only unbranded consumer materials have been RC-approved, you may not discuss or provide product information to consumers at the event.
Materials at a Display

Q. If both consumers and HCPs are expected to attend the event, can materials intended for HCPs be put out on the table for display along with the approved consumer materials?

A. No. You may only place approved consumer materials on the table for display. However, you may have the approved HCP materials available to access and provide to HCPs if any approach your exhibit to speak with you.

Exhibits at Health Screenings

Colleagues may interact with consumers at exhibit booths located at health fairs, patient advocacy events, or health screenings. Screenings promote the early detection of diseases and offer patients a meaningful opportunity to treat a disease or condition. Colleagues who are present during any patient interactions must clearly identify themselves as Pfizer employees. Wear a Pfizer name tag at all times.

Only Payer Channel Access (PCA) group colleagues are permitted to fund health screenings. Please see Orange Guide Chapter 13: Health Screenings for further information.

Interactions

When interacting with consumers, you must adhere to the following guidelines:

- **Limit your discussion to the information contained in RC-approved consumer materials.**

- **Present the risks and benefits of Pfizer products in a fair and balanced manner.** This can be accomplished by providing both the approved indications along with relevant limitations of use and consumer directed safety information found in your RC-approved consumer materials.

- **Do not compare a Pfizer product with a competitor product, unless that specific information is contained in the RC-approved consumer materials.** If a consumer asks you to compare the Pfizer product with a competing product, refer the consumer to his or her healthcare provider.

- **Do not discuss off-label use of a Pfizer product.** If a consumer asks you about off-label use, refer the consumer to his or her healthcare provider.
• Do not provide medical advice to consumers, regardless of your professional training or position within Pfizer. If a consumer asks you for advice or a recommendation as to treatment options, refer the consumer to his or her healthcare provider.

• Do not encourage consumers to switch their medication to a Pfizer product. If asked by a consumer whether they should switch products, refer the consumer to his or her healthcare provider.

• Follow Pfizer's policies on the reporting of adverse events and other reportable safety information. If a consumer shares information about an adverse event, you must report it within 24 hours by phone (800-438-1985) to the Safety group. Refer to the section “Adverse Events and Other Reportable Safety Information” below for an explanation of other reportable safety information.

Educational Presentations to Consumer Audiences

Pfizer Contracted Speaker as Presenter

A speaker program for consumer audiences, just like a speaker program for HCPs, is a promotional activity controlled by Pfizer at which a contracted HCP or a contracted certified nurse educator presents an RC-approved slide deck intended for consumers. Colleagues are not permitted to conduct a consumer program unless the relevant RC expressly allows it. As with speaker programs for HCPs, Pfizer is responsible for the conduct and the content of its promotional speaker programs to consumers and, therefore, colleagues must adhere strictly to Pfizer policies regarding consumer presentations and Centris procedures. An HCP speaker must not use the Pfizer program as an opportunity to promote his or her medical services or practice or to recruit new patients.
Before you hold a speaker program for consumers, review with the speaker these important policies regarding the content of your planned program:

- Speakers must use only RC-approved consumer slide decks, and these slide decks must be used in their entirety. Slides cannot be deleted or created and inserted by the speaker under any circumstance.

- If the speaker is presenting an unbranded consumer slide deck, the speaker cannot discuss information about Pfizer products unless responding to an unsolicited question about the on-label use of a Pfizer product.

- The speaker must remain on-label when providing information about Pfizer products, even if the speaker receives a question from the audience about an off-label use of the product. Consumers are not trained medical professionals; therefore, the dialogue between an HCP speaker and consumers is not considered scientific exchange. The speaker should explain that the product is not indicated for the use described, and the speaker should refer the consumers to their healthcare providers for further information. If the speaker does not appropriately respond to the question, the Pfizer colleague is obligated to make a corrective statement and refer the consumers to their healthcare providers.

- The speaker cannot provide specific medical advice to a consumer attendee, even when the individual requests it. The speaker must refer the consumer to his or her healthcare provider.

- No discussion of competitor products is permitted at branded or unbranded talks unless specifically contained in the RC-approved consumer materials or slide deck.

- As with speaker programs for HCPs, speaker programs for consumer audiences must be a minimum of 45 minutes, inclusive of Q&A, for venue programs, and a minimum of 30 minutes for in-office programs.
Providing Copies of Materials

Q. Can I hand out copies of the consumer slide deck to consumers in attendance at my consumer program?
A. No, you may not hand out copies of the consumer slide deck unless you have received clear guidance from the appropriate RC that this is permissible. However, you may hand out RC-approved consumer materials.

Attendees

The guidelines you must follow related to consumer attendees are somewhat different than those that apply for HCPs in attendance at speaker programs. In addition to the guidelines below, be sure to follow any specific guidelines provided by the brand team.

- **You must make a good faith effort to broadly advertise a consumer speaker program** you are holding, such that it will likely result in an audience of at least 3 patient-consumers. The three required attendees may not be composed of a mix of patients, caregivers, and family members. You must have three patient-consumer RSVPs in order to move forward with a consumer program. It is not permissible to hire a speaker to address a group of his/her own patients, or patients of a health system or practice for which he or she works.

A roster must be completed in Centris for every consumer program held. The rosters may not include the names of any consumer attendees. Only the total number of consumer attendees may be listed in the Consumer Attendance field. For consumer programs, if the HCP is a patient or a family member of a patient or if the HCP does not have a specialty in the disease state and is attending the program as a consumer or care-giver for a patient consumer, then you do not have to capture their name in the Consumer Attendance field. If the HCP has a specialty in the disease state and would be someone a rep would potentially call on or would be able to attend one of our HCP speaker programs due to their specialty in that disease state, then you must record their names in the Consumer Attendance field for disclosure purposes.

- As with speaker programs held for HCPs, the representative and speaker must confirm electronically in Centris that the program was held and that speaking services were provided.

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• If you are distributing invitations for a mixed audience (consumers and HCPs), only consumer-directed invitations should be used (available from your Meeting Planner).

**Presentations to a Mixed HCP and Consumer Audience**

Q. If I organize a speaker program where both HCPs and consumers may be present, does the speaker have to use a Pfizer slide kit approved for a consumer audience?

A. Yes. Pfizer must comply with existing FDA requirements and the PhRMA Code on DTC Advertising Principles when interacting with consumers. Therefore, where both consumers and HCPs attend a program, the speaker must use an RC-approved consumer slide kit to ensure Pfizer product information, particularly safety information, is presented in a way that consumers can understand. In addition, HCPs attending the presentation are subject to Pfizer’s HCP Payment Disclosure policy (See Chapter 18: Meals, Educational Items, and HCP Payment Disclosure).

**Speaker Non-Compliance**

Q. What do I do if a speaker does not conduct a program in compliance with Pfizer’s policies?

A. You must promptly and courteously provide clarification to the audience on any inaccurate or inappropriate information. This should be done immediately after the information has been presented and prior to any Q&A. In addition, if a speaker does not conduct a consumer program in compliance with Pfizer’s policies, you must coach the speaker on the appropriate conduct and report the violation during the Centris closeout. Once you have done this, your manager will receive an e-mail notification regarding the violation.

**Meals**

Providing a modest meal at an educational speaker program is permissible. However, the cost of food, beverage, tax, and tip may not exceed $50 per attendee. Entertainment or recreation may not be provided, and you should make a good faith effort to avoid using venues that provide entertainment (e.g., hotels with casinos). Where there is a mixed HCP and consumer audience, the meal limit remains at $40 per attendee, for both HCP and consumer attendees.

Meals may never be provided: (1) to solicit business; or (2) in a manner that might suggest that the recipient was being bribed or improperly influenced.
Adverse Events and Other Reportable Safety Information

Follow Pfizer’s policies on the reporting of adverse events and other reportable safety information. Reportable safety information includes information about the safety, performance, and quality of Pfizer products. There are four categories of reportable safety information, as listed below:

<table>
<thead>
<tr>
<th>TYPES OF REPORTABLE SAFETY INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
</tr>
<tr>
<td>1. Adverse Events</td>
</tr>
<tr>
<td>Any untoward medical occurrence in an</td>
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<tr>
<td>individual administered a Pfizer product, which includes any non-prescription or prescription drug, biologic, biosimilar, medical device, vaccine, cosmetic, or nutritional product.</td>
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<tr>
<td>• Abnormal test findings</td>
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<tr>
<td>• Clinical symptoms and signs and/or new diagnoses</td>
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<tr>
<td>• New diagnoses</td>
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<tr>
<td>• Changes in physical examination</td>
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<tr>
<td>findings</td>
</tr>
<tr>
<td>• Progression/worsening of</td>
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<tr>
<td>underlying disease</td>
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<tr>
<td>• Lack of efficacy for a Pfizer product</td>
</tr>
<tr>
<td>• Drug Abuse</td>
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<tr>
<td>• Death</td>
</tr>
<tr>
<td>2. Unexpected Therapeutic Effect</td>
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<tr>
<td>A beneficial therapeutic effect of a</td>
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<tr>
<td>product aside from the use for which</td>
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<tr>
<td>it had been given.</td>
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<tr>
<td>• Blister pack arrived empty</td>
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<tr>
<td>• Vial is leaking liquid</td>
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<tr>
<td>• Syringe is jammed</td>
</tr>
<tr>
<td>• Product is/may be counterfeit</td>
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<tr>
<td>3. Product/Device Complaints</td>
</tr>
<tr>
<td><strong>Product</strong>: any written, electronic,</td>
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<tr>
<td>or oral expression of dissatisfaction</td>
</tr>
<tr>
<td>relative to the physical properties,</td>
</tr>
<tr>
<td>condition, package insert, and/or</td>
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<tr>
<td>packaging of a product.</td>
</tr>
<tr>
<td><strong>Device</strong>: any written, electronic,</td>
</tr>
<tr>
<td>or oral communication of dissatisfaction</td>
</tr>
<tr>
<td>relative to the appearance, identity,</td>
</tr>
<tr>
<td>quality, durability, reliability,</td>
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<tr>
<td>safety, effectiveness, instructions</td>
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<tr>
<td>for use, or performance of a medical</td>
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<tr>
<td>device or a product with a medical</td>
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<tr>
<td>device component, including software</td>
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<tr>
<td>products that are regulated as</td>
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<tr>
<td>medical devices (e.g. mobile apps,</td>
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<tr>
<td>website functionality, etc.).</td>
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<tr>
<td>A product complaint associated with</td>
</tr>
<tr>
<td>any Pfizer-sponsored medical software</td>
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<tr>
<td>(including websites and mobile apps)</td>
</tr>
<tr>
<td>should also be reported.</td>
</tr>
<tr>
<td>• Blister pack arrived empty</td>
</tr>
<tr>
<td>• Vial is leaking liquid</td>
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<tr>
<td>• Syringe is jammed</td>
</tr>
<tr>
<td>• Product is/may be counterfeit</td>
</tr>
</tbody>
</table>
**TYPES OF REPORTABLE SAFETY INFORMATION**

<table>
<thead>
<tr>
<th>Description</th>
<th>Examples**</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Circumstances That May Lead To Adverse Events</td>
<td>• <strong>Occupational Exposure</strong>: Splashing of oral/injectable solution in the eye</td>
</tr>
<tr>
<td></td>
<td>• <strong>Off-label use</strong>: Prescribed Revatio for a child with hypertension (only approved for adults)</td>
</tr>
</tbody>
</table>

Certain situations should also be forwarded whether or not there are any associated adverse events. They include: drug misuse; drug overdose; exposure during pregnancy or breastfeeding; medication errors; occupational exposure; and off-label use.

**The above are examples only. Please refer to Corporate Policy 903: Your Responsibility to Report Information about the Safety, Quality, and Performance of Pfizer Products for a complete list of reportable information.**

If you become aware of reportable safety information, you must report it to the appropriate Pfizer contact within 24 hours. For product complaints only, please send an e-mail to: PCGCentral@pfizer.com. For all other reportable safety information, submit the report by phone at 800-438-1985, e-mail to: USA.AEReporting@pfizer.com, or through Veeva CRM from your iPad. All reports of safety information should be forwarded regardless of the seriousness of the event, whether or not there is a causal relationship with the Pfizer product and whether or not the event is mentioned in the product label/instructions. Please provide as much information as possible in your report, including the consumer’s name and contact information, if available, along with details of the event and patient’s details (e.g., age, gender). However, do not delay submission of your report even if you have only limited information available.

For further information about your reporting responsibilities, please refer to Corporate Policy 903 or the Pharmacovigilance and Cosmetics Reporting Site at: http://sharepoint.pfizer.com/sites/YRR/SitePages/Home.aspx.

**Employees as Consumers**

Employers are increasingly making decisions regarding the access their employees have to medicine. As a result, colleagues may have an interest in calling on employers to present information about Pfizer products relevant to the employer in making these decisions.
Employers often request that Pfizer interact directly with their employees in the interest of providing health education. These employees are consumers, and it is important that Pfizer treat them as such. Accordingly, Pfizer must ensure that it applies the same principles set forth in this Chapter to its interactions with those employees.

Providing Materials for Non-Pfizer Consumer Events

There are also situations in which colleagues may provide RC-approved consumer materials to third parties such as HCPs or patient groups for use in their patient education efforts. Colleagues can provide RC-approved consumer materials for use at patient education programs that are organized and conducted by third parties. However, slide decks may not be shared unless the relevant RC has specifically authorized dissemination of the slide deck in this manner. You cannot offer any speaker payment or other financial support for these non-Pfizer patient education programs, including, but not limited to, providing food or equipment for these programs.

Consumer Privacy

Pfizer recognizes the importance of safeguarding the confidentiality of Personal Information (PI), including Sensitive Personal Information (SPI). SPI is health-related information that, in combination with certain identifiers, such as name, birth date, or social security number, can be used to identify a specific individual. As a colleague, you must not seek SPI about consumers when you are interacting with them. In the event you encounter SPI in the course of interacting with a consumer, do not disclose or use such information for any purpose or in any manner that would compromise the confidentiality of such SPI. For a detailed discussion of privacy issues, see Orange Guide Chapter 8: Privacy: Protecting Personal Information.

Other Consumer Interactions

Consumer interactions that are not specifically described in the Orange Guide are not appropriate for you to engage in without specific guidance. Before engaging in any consumer interaction other than those outlined, please confer with your manager or team attorney.
FOR MORE INFORMATION

- For more information on handling suspected adverse events, see Corporate Policy 903, Your Responsibility to Report Information about Safety, Quality or Performance of Pfizer Products.

- For more information on speaker programs and additional speaker program resources, please refer the “Help” section in Centris.

- Questions may be referred to your manager or team attorney.
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Chapter 17: STATE LAWS: HCP AND STATE EMPLOYEE RESTRICTIONS

Introduction

States are increasingly enacting laws and regulations that impact our business and restrict our activities, including your interactions with HCPs and state employees. Many of these state laws are more restrictive than federal law and the generally applicable Pfizer policies set forth elsewhere in this Guide.

It is important that all colleagues understand all applicable state laws and policies— and not only the ones applicable to the states where they work because certain state laws may apply regardless of where an interaction occurs. Activities that violate these laws may result in criminal and civil penalties for you and Pfizer.

This Chapter is relevant to all colleagues but particularly those who may interact with HCPs with an active license in the states discussed in this Chapter and with state employees. This includes Account Managers who interact with various Account employees. Depending on the state, the law may apply to interactions with Account employees even when they are not practicing physicians, by virtue of their continuing to be licensed in the state or their responsibilities in the Account. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination of employment.

If you have any questions about state healthcare compliance laws and HCP-related restrictions:

- Consult the State Healthcare Law tab on the PfieldNet Compliance page or on OpSource;
- Send questions to StateHealthcareLawCompliance@pfizer.com; or
- Consult your team attorney.

If you have any questions about state employee gift restrictions:

- Consult with the appropriate Government Relations Director (GRD); or
• Consult your team attorney.

Summary of Key State HCP-related Healthcare Compliance Laws

<table>
<thead>
<tr>
<th>State</th>
<th>Important Provisions of the State Law</th>
<th>Key Points to Ensure Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>California</td>
<td>Companies shall adopt a comprehensive compliance program which sets specific dollar limits on gifts, promotional materials, and activities.</td>
<td>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.</td>
</tr>
<tr>
<td>Chicago</td>
<td>Individuals who market or promote prescription drugs to HCPs in Chicago must obtain a license. Individuals who promote prescription drugs in Chicago for fewer than 15 days per calendar year are exempt from the licensing requirement.</td>
<td>Colleagues responsible for Chicago and who promote Pfizer products in Chicago for 15 days or more per calendar year must obtain a license. Licenses will be required starting July 1, 2017. Licenses must be renewed every year and continuing education requirements must be satisfied. Licensees will also be required to record certain information about their interactions with HCPs.</td>
</tr>
</tbody>
</table>
### Connecticut

- The Connecticut Compliance Program Law requires companies to adopt a marketing code of conduct – the PhRMA Code is acceptable.

- Starting in 2016, companies must begin tracking payments or other transfers of value provided to Advanced Practice Registered Nurses (‘APRN’) authorized to practice independently (i.e., not in collaboration with a physician) for reporting in 2017.

- Follow all Pfizer policies and procedures and the PhRMA Code.

- Accurately and completely record all expenditures to all HCPs, including APRNs.

<table>
<thead>
<tr>
<th>State</th>
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<th>Key Points to Ensure Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Connecticut</td>
<td>The Connecticut Compliance Program Law requires companies to adopt a marketing code of conduct – the PhRMA Code is acceptable. Starting in 2016, companies must begin tracking payments or other transfers of value provided to Advanced Practice Registered Nurses (‘APRN’) authorized to practice independently (i.e., not in collaboration with a physician) for reporting in 2017.</td>
<td>Follow all Pfizer policies and procedures and the PhRMA Code. Accurately and completely record all expenditures to all HCPs, including APRNs.</td>
</tr>
<tr>
<td>State</td>
<td>Important Provisions of the State Law</td>
<td>Key Points to Ensure Compliance</td>
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<tr>
<td>District of Columbia</td>
<td>Individuals engaged in the practice of “pharmaceutical detailing” must secure a license to detail in person in D.C. Individuals who practice “pharmaceutical detailing” in D.C. less than 30 days per calendar year are exempt from this requirement. The D.C. Board of Pharmacy believes that the exemption may be claimed only by individuals detailing in D.C. “once a year for a short duration of time of less than 30 consecutive days.” Companies must report certain marketing costs. Members of the D.C. Medication Advisory Committee must not receive gifts, including meals or remuneration for speaking or consulting.</td>
<td>Colleagues whose territory or geographic responsibilities include D.C. must obtain a detailer license from the D.C. Board of Pharmacy, renew it every even numbered year, and attend Continuing Education courses. Accurately and completely record all HCP expenditures. Do not provide any gift or meal to any member of the Medication Advisory Committee, no matter how nominal the value.</td>
</tr>
<tr>
<td>State</td>
<td>Important Provisions of the State Law</td>
<td>Key Points to Ensure Compliance</td>
</tr>
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<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Massachusetts</td>
<td>Adopt a marketing code of conduct consistent with Massachusetts regulations. Companies may not provide meals (including snacks or other refreshments in non-convention/conference settings) 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 (limited exception for MA HCPs under bona fide service contracts with Pfizer). Pfizer must give HCPs the opportunity to withhold prescriber data. Pfizer must annually report certain HCP expenditures to Massachusetts.</td>
<td>Only provide out-of-office meals and snacks to MA-licensed HCPs at speaker programs (except refreshments or snacks in a convention setting). Accurately and completely record all expenditures on HCPs. If you are unsure whether an HCP has a MA license, check the <a href="#">HCP Lookup Tool</a>. You can also check Veeva CRM, which flags most (but not all) MA HCPs. You must make a good faith effort to determine whether an HCP is licensed in Massachusetts.</td>
</tr>
<tr>
<td>State</td>
<td>Important Provisions of the State Law</td>
<td>Key Points to Ensure Compliance</td>
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</tbody>
</table>
| **Minnesota** | Gifts to practitioners are prohibited.  
Pfizer policy prohibits HCP meals to MN practitioners, including nominal meals and snacks.  
Pfizer policy prohibits providing text books, journal subscriptions, online subscription services (e.g., Epocrates), and anatomical models, to MN practitioners.  
Pfizer policy also prohibits engaging MN practitioners as paid consultants, except for the following type of projects:  
- publications and educational materials 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. | 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 text books, journal subscriptions, online subscription services (e.g., Epocrates, including trial memberships), or anatomical models.  
Do not engage MN HCPs as commercial consultants.  
Accurately and completely record all practitioner expenditures.  
If you are unsure of whether an HCP has a MN license, you can check the HCP Lookup Tool. Also, Veeva CRM flags most (but not all) HCPs with MN licenses.  
You must make a good faith effort to determine whether an HCP is licensed in Minnesota. |
<p>| <strong>Nevada</strong> | Nevada Marketing Code of Conduct requires companies to adopt a marketing code of conduct – the PhRMA Code is acceptable.                                                                                                                | No specific guidance, other than to follow all Pfizer policies and procedures.                                                                                                                                                  |</p>
<table>
<thead>
<tr>
<th>State</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Vermont</td>
<td>Vermont prohibits all HCP meals, including in-office meals and meals of nominal value (there is a limited exception for: (i) bona fide service contracts; and (ii) refreshments or other snacks at a convention/congress booth). Vermont also prohibits paid market research surveys involving VT-licensed HCPs. The restriction applies whether the survey is conducted directly by Pfizer or through an independent third party survey research organization. Pfizer must report certain HCP expenditures, as well as samples, coupons, and vouchers, to Vermont. Price Disclosure Forms must be provided to HCPs when detailing and posted on Pfizer's website.</td>
<td>Do not invite VT HCPs to any speaker programs that provide meals or snacks (even if the program is conducted outside of VT). Do not provide VT HCPs with meals or snacks (except refreshments or snacks in a convention setting). Do not engage VT HCPs as part of any paid marketing research surveys. Accurately and completely record all HCP expenditures, as well as samples, coupons, and vouchers provided to VT-licensed HCPs. Provide VT Price Disclosure Forms to HCPs as appropriate (available on PfieldNet). If you are unsure of whether an HCP has a VT license, you can check the HCP Lookup Tool. Also, Veeva CRM flags most (but not all) VT HCPs. You must make a good faith effort to determine whether an HCP is licensed in Vermont.</td>
</tr>
</tbody>
</table>
Summary of Key State Employee Gift Laws

Almost all states have restrictions on interactions with state employees (including HCPs employed by state institutions). Consult the appropriate Government Relations Director (GRD) for the state employee restrictions in your state. A summary of the most significant state restrictions is provided below.

<table>
<thead>
<tr>
<th>State</th>
<th>Important Provisions of the State Law</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Colorado</td>
<td>State employees may not receive anything of value worth more than $59 from a company (as a whole, not by employee) per year.</td>
<td>Accurately and completely record all expenditures on state employees.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Monitor spending per state employee and coordinate with your colleagues to ensure Pfizer is not spending beyond the $59 annual limit.</td>
</tr>
<tr>
<td>Louisiana</td>
<td>State employees are prohibited from performing certain compensated services for pharmaceutical companies. State employees have a $60 cap on food, drinks, and refreshments provided during a single event.</td>
<td>Before considering engaging a state employee to perform a compensated service, consult with your manager.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Before providing a meal or refreshments to state employees, coordinate with your colleagues to ensure the employee is not receiving value greater than $60 during the event.</td>
</tr>
<tr>
<td>New York</td>
<td>State and local employees are prohibited from receiving gifts.</td>
<td>Do not provide meals or educational items to state or local employees.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>
Key Points to Ensure Compliance

- Understand the laws and policies of the states in which you work and the states where the HCPs with whom you interact hold licenses. Always remember that several state laws may apply regardless of where an interaction occurs.

- Before providing a meal or educational item to an HCP, know where the HCP is licensed and follow any applicable state restrictions. For example, regardless of where the interaction takes place, significant restrictions apply to HCPs with active VT, MA, and MN licenses. These restrictions apply to all Pfizer colleagues.

- Conduct your activities in accordance with the relevant state laws described in this Chapter, as well as general Pfizer policy found in this Guide.

- Be aware of and abide by all spending limits and restrictions in your state.

- Follow and complete all process steps required to track and report expenditures.

- Remember that federal government employees, such as those working for the VA or DoD, must follow federal gift restrictions, which include restrictions on meals. For further information on these restrictions, see the Federal Employee Interactions and Lobbying Chapter in this Guide.

- Almost all states impose restrictions on what may be provided to state and local employees (including HCPs employed by state institutions). You can direct any specific questions on state laws that are not addressed in this Guide to the relevant team attorney or to StateHealthcareLawCompliance@pfizer.com. For information about state employee restrictions, consult with your Government Relations Director.

California

The Law: The California Drug Marketing Practices Law

The California Drug Marketing Practices Law requires that each pharmaceutical company:
• Establish, at a minimum, a comprehensive compliance program that complies with the requirements set forth in the OIG’s Compliance Program Guidance for Pharmaceutical Manufacturers and PhRMA’s Code on Interactions with Health Care Professionals;
• Set an annual aggregate limit for spending on meals, promotional items, and other activities provided to covered HCPs; and
• Declare annually, on its public website, that it is in compliance with California Law.

**Definition of Healthcare Professional**

Covered HCPs include any CA-licensed prescriber of human drugs, medical student, or member of a formulary committee. Non-prescribing pharmacists, nurses, and office staff, who are not medical students or formulary committee members, are not included in the annual aggregate limit on spending to covered HCPs.

**How the Law Impacts Pfizer Colleague Activities**

Pfizer has set its annual aggregate limit on covered promotional expenditures at $3,500 per covered California HCP. This limit does not apply to CA-licensed HCPs practicing in other states.

The value of the following items must be included when calculating the annual aggregate limit:

• PhRMA Code compliant meals, including all food and beverage in and outside a medical office or hospital, in connection with any promotional activity; and
• Pfizer Review Committee (RC) approved educational items. The value of the following items are not included when calculating the annual aggregate limit:
  • Starters;
  • Fair market value payments for services, such as speaking and consulting payments;
  • RC-approved promotional literature such as clinical reprints and slim jims;
  • Independent educational grants (financial support for continuing education forums);
  • Financial support for educational scholarships; and
• Pfizer RC-approved educational items.
All colleagues who engage in activities in California should be aware that their expenditures which meet the criteria above will be included when calculating the annual aggregate limit. Colleagues must ensure that their records on these expenditures are accurate and complete.

The State of California can impose significant penalties on Pfizer for failure to comply with this law. If you have any questions concerning the California Pharmaceutical Sales and Marketing Disclosure Law, please contact the team attorney with responsibility for California.

**Chicago**

**The Law: Pharmaceutical Representative Licensing Ordinance**

The Chicago Pharmaceutical Representative Licensing Ordinance requires individuals who market or promote prescription drugs to HCPs in Chicago to obtain a license. Individuals who promote prescription drugs in Chicago for fewer than 15 days per calendar year are exempt from the licensing requirement. Licenses will be required beginning July 1, 2017.

**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. Licenses will be required starting July 1, 2017. License applications will require the following:

- The applicant’s full name, residence address, and residence telephone number;
- The applicant’s business address and business telephone number;
- A description of the type of work in which the applicant will engage;
- Affirmation that the applicant completed the required professional education course; and
- $750 licensing fee.

Licenses must be renewed every year and continuing education requirements must be satisfied to renew a license.
Licensees will be required to abide by a code of ethics. Licensees will also be required to record certain information about their interactions with HCPs, including:

- A list of health care professionals within Chicago contacted;
- The number of times the health care professionals were contacted;
- The location and duration of contact;
- The pharmaceuticals promoted;
- Whether product samples, materials, or gifts of any value were provided to the health care professional and the value of the samples, materials, or gifts; and
- Whether and how the health care professional was compensated for contact with the pharmaceutical representative.

Chicago can impose significant penalties on Pfizer colleagues for failure to comply with this law, which may include fines of no less than $1,000 and no more than $3,000 per violation. If you have any questions concerning the Chicago Pharmaceutical Representative Licensing Ordinance, please contact the Sales and Marketing Attorney with responsibility for Chicago.

**Colorado**

*The Law: Restrictions on Gifts to State Employees*

Colorado law prohibits any state employee from soliciting, accepting, or receiving, directly or indirectly, any gift or other item of value (including meals), regardless of form (e.g., money, service loan, travel, entertainment, hospitality, or promise) worth more than $59 in any calendar year.

As with any other customer, colleagues may not provide any type of gift, regardless of value, to a Colorado state employee if the gift is intended or expected to influence or reward that employee in the performance of any activity related to his or her official duties.
**Definition of Healthcare Professional State Employee under the law**

A Colorado state employee includes any HCP employed, *either full-time or part-time*, by the State of Colorado, any community healthcare providers employed by a Colorado county or municipal government, and any physicians employed at the University of Colorado Health Sciences Center.

**How the Law Impacts Pfizer Colleague Activities**

Collectively, Pfizer colleagues are prohibited from providing gifts, including meals, which have a total value over $59 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 $59 in items and meals from Pfizer as a company during any calendar year. (The $59 annual limit is not per Pfizer colleague.) Pfizer RC-approved educational items of more than nominal value (e.g., anatomical models) may not be provided to Colorado state employees who are healthcare providers, even though they are RC-approved items. This limitation applies to all Pfizer colleagues who interact with employees of the State of Colorado.

The following items are exceptions to the annual $59 limit for Colorado state employees:

- Unsolicited PhRMA Code compliant food and beverage snack items of nominal value (e.g., doughnuts and non-alcoholic beverages such as soft drinks and coffee) which are not part of a meal;
- Unsolicited RC-approved educational items of nominal intrinsic value; and
- Fair market value payments for an employee’s provision of services, such as speaking or consulting services.

**Helpful Point**

If you are not sure whether an HCP is employed by the State of Colorado or just affiliated with a state institution, you must confirm his or her relationship with the state prior to providing any meals or items of more than nominal value to the HCP. If the HCP receives regular compensation directly from a state institution, he or she is likely considered a state employee and is therefore subject to the restrictions discussed in this section.
If you have any questions, please contact the team attorney with responsibility for Colorado.

**Connecticut**

*The Law: Connecticut Compliance Program Law & APRN Disclosure Law*

- Requires pharmaceutical, biological, and medical device companies to adopt and implement a marketing code that is at least as restrictive as the PhRMA Code and a comprehensive compliance program.

- Connecticut Department of Consumer Protection has authority to investigate alleged violations of the code-adoption requirement and alleged failures to conduct any training program or regular audit for compliance with the adopted code. Violations of the provisions would subject a company to a civil penalty of up to $5,000.

Connecticut law also requires manufacturers to disclose payments and transfers of value provided to Connecticut-licensed Advanced Practice Registered Nurses (APRNs) who practice not in collaboration with a physician (i.e., independently). Definition of Advanced Practice Registered Nurse below for purposes of the Connecticut disclosure law is defined as:

- An APRN who practices “not in collaboration with a physician” (i.e., an APRN who practices independently); and


*How the Law Impacts Pfizer Colleague Activities*

All colleagues who engage in activities with Connecticut APRNs should be aware that their expenditures on APRNs will be reported and ensure that transfers of value, including their reporting of attendees at speaker programs, is accurate and complete.
District of Columbia

The Law: Prescription Drug Marketing Costs Disclosure Law

The District of Columbia (D.C.) Prescription Drug Marketing Costs Disclosure Law requires Pfizer to report all marketing costs for prescription drugs to the D.C. Department of Health, including the value, nature, purpose, and recipient of all expenses associated with advertising, marketing, and direct promotion to D.C. residents through radio, television, magazine, newspaper, direct mail, and telephone.

Specifically, costs associated with the following activities are required to be reported:

- Direct-to-consumer advertisements targeting D.C. residents;
- Educational or informational programs, materials, or seminars provided to healthcare professionals, pharmacies, clinics, health plans, and other healthcare providers;
- Remuneration for promoting or participating in educational or informational sessions;
- Food, entertainment, gifts, and anything else provided to HCPs valued at more than $25 or provided for less than market value;
- All expenses associated with HCP trips and travel;
- Starters (unless they are for distribution to patients at no charge); and
- The aggregate cost of all employees and contractors engaging in drug advertising and promotion in D.C.

The following marketing expenses do not have to be reported:

- Expenses of $25 or less per day per HCP;
- Compensation for bona fide clinical trial activities;
- Scholarships and expenses for attending educational, scientific, or policy conferences if attendee is selected by the sponsoring organization; and
- Payments to D.C.-licensed HCPs for participating in blinded market research, if: a) the research is conducted by an “independent survey research organization;” b) the
pharmaceutical client does not know the identity of the practitioners participating in the research; and c) the payments are determined and made by the survey research organization.

**Definition of Healthcare Professional**

The law applies to expenditures provided to persons and entities who are licensed to provide healthcare in D.C., including healthcare professionals and persons employed by them who work in D.C., licensed insurance carriers, health plans and benefit managers, pharmacies, hospitals, nursing facilities, clinics, and other entities licensed to provide healthcare in D.C.

**How the Law Impacts Pfizer Colleague Activities**

All colleagues who engage in activities in D.C. should be aware that expenditures which meet the criteria above will be reported to the D.C. Department of Health. Colleagues must take special care to ensure that their reporting of attendees is accurate and complete. The District of Columbia can impose significant penalties on Pfizer for failure to comply with this law.

**The Law: Pharmaceutical Detailer Licensing Law**

The Pharmaceutical Detailer Licensing Law requires licensure for any colleague or speaker who communicates with a licensed HCP located in D.C. for the purpose of promoting a pharmaceutical product. However, the law exempts individuals who engage in “pharmaceutical detailing” less than 30 days per calendar year from the requirement to obtain licensure.

The D.C. Board of Pharmacy interprets the exemption as only applying to individuals detailing in D.C. “once a year for a short duration of time of less than 30 consecutive days."

**Gifts to D.C. Medication Advisory Committee Prohibited**

D.C. law also prohibits offering a gift or remuneration of any kind to a member of the D.C. Medication Advisory Committee (DCMAC). Colleagues must not give anything of value to any DCMAC member (even if the item is RC-approved or would be acceptable for non-DCMAC members), including:

- Speaking and consulting fees;
• Food or beverage, whether inside or outside the office, or in connection with a promotional program or otherwise; and
• Educational items (e.g., textbooks, and anatomical models).

However, colleagues may provide starters to DCMAC members who are licensed physicians engaged in the practice of medicine and who intend to distribute them free of charge to patients.

For a list of DCMAC members, please consult the Department of Health Care Finance FAQ (Question 27).

How the Law Impacts Pfizer Colleague Activities

Colleagues whose territory or geographic responsibilities include D.C. and who detail HCPs in D.C. must complete and submit a license application to the D.C. Board of Pharmacy. These colleagues must have a valid pharmaceutical detailer license before calling on an HCP in D.C. It is your responsibility to apply for your license, and application costs will be reimbursed by Pfizer.

The license application materials are available online at the District of Columbia Board of Pharmacy website. The license application requires submission of an affidavit to abide by a Code of Ethics, which prohibits, along with other requirements: (1) sending messages of disappointment for failing to prescribe certain medications; and (2) continuing to make sales calls after the healthcare professional has requested in writing not to receive further calls.

The following materials are necessary to complete the application:

• A completed, signed D.C. application form;
• Two (2) recent passport photos (2x2);
• One (1) clear copy of a U.S. government-issued photo ID;
• Social Security Number or a Sworn Affidavit;
• Name Change Documents (Marriage Certificate, Divorce Decree, or Court Order) if applicable;
• Official certificate of graduation in a sealed envelope or notarized Waiver of Educational Requirements form;
• Notarized Affidavit to Abide by Code of Ethics form;
• A criminal background check; and
• $175 for the Application and License Fee in the form of a check, money order or certified check payable to the D.C. Treasurer, which you should submit for reimbursement in PT&E.

Impacted colleagues will need to renew their license each even numbered year prior to the end of February. Colleagues should plan to submit their application by December 31st of the preceding year to allow adequate time for review and processing of your application prior to the deadline. As part of the license renewal application, you will need to attest that you have completed a minimum of 15 hours of continuing education during the two year period preceding the date the license expires. You must register for a “SafeRx Pharmaceutical Detail Licensing CE Program” through P2L. Once registered, you will receive a list of CMR training courses that are approved for CE under the SafeRx Pharmaceutical Detail Licensing Program. It can take up to two months to complete each course offered, and Pfizer will pay directly for home study courses taken with the CMR SafeRx Pharmaceutical Detail Licensing CE Program. If you have completed a CMR Certification or CMR Flex course post receipt of your pharmaceutical detailer’s license, you should contact CMR at (800)328–2615 or program@cmrinstitute.org to determine if you already received renewal credit.

The District of Columbia can impose significant penalties on Pfizer colleagues for failure to comply with this law, which may include a fine of up to $10,000 as well as penalties and sanctions. If you have any questions concerning the D.C. Prescription Drug Marketing Costs Disclosure Law or SafeRx please contact the Sales and Marketing Attorney with responsibility for the District of Columbia.

Louisiana

The Law: Code of Governmental Ethics

The Louisiana Code of Governmental Ethics prohibits HCPs who are “public servants” from performing certain compensated services for Pfizer, such as receiving fees for speaking services or reimbursement for associated expenses. In addition, Louisiana imposes a $60 cap on food, drink, or refreshment
provided to a public servant for a single event. The amount should be calculated by dividing the total cost of the food by the total number of persons (including non-public servants) at the event.

**Definition of “Public Servant”**

“Public servants” are either public employees or elected officials. They include, amongst others, persons who are employees at any of the following institutions:

- Louisiana State University (LSU) and affiliated hospitals and clinics;
- Charity hospitals and other state hospitals;
- Medicaid P&T Committee members;
- State prisons; and
- State rural health clinics.

**How the Law Impacts Pfizer Colleague Activities**

Louisiana public servants cannot be engaged as promotional speakers for Pfizer.

The Louisiana Board of Ethics has stated, however, that a public employee can serve as a consultant (e.g., at a marketing advisory board) as long as the consultant services are related to his or her academic discipline or area of expertise and prior approval has been granted. For example, at LSU, the LSU chief administrative officer would need to approve such a consultancy. Further, if a public servant is involved in research with Pfizer, he or she can in most circumstances receive reimbursement for travel expenses for a Pfizer-sponsored clinical trial. Lastly, the Code of Governmental Ethics and Board of Ethics’ rulings do not prohibit a public servant from speaking at a conference where Pfizer has provided an independent educational grant since Pfizer does not control the selection of the speaker or the content of the presentation, and the expenses at such an event would be paid by the conference organizer directly.
**Helpful Point**

If you are not sure whether a potential speaker is a Louisiana public servant, you must confirm their status prior to engaging the person as a speaker. If the person receives regular compensation directly from one of the institutions above, they are probably a “public servant” and would be prohibited from receiving compensation from Pfizer for speaking.

The cap on meal expenditures at any program where Pfizer is providing a meal and where there is at least one public servant present is $60.

The law applies to any event where Pfizer is providing food or drink, and where a public servant is present, including speaker programs, advisory board meetings, and speaker training meetings. It would not, however, apply to an event funded through an independent educational grant, where Pfizer provides financial support for the event and the grant recipient provides the meal.

The State of Louisiana can impose significant penalties on Pfizer and individual Pfizer employees for failure to comply with the law.

If you have any questions concerning the Louisiana laws discussed here, please contact the team attorney with responsibility for Louisiana.

**Massachusetts**

*The Law: Pharmaceutical and Medical Device Manufacturer Conduct Law (Massachusetts Marketing Code of Conduct)*

The Massachusetts Marketing Code of Conduct restricts Pfizer’s ability to provide meals and other items of value to HCPs licensed in Massachusetts (MA). The law also requires Pfizer to disclose payments and items provided to “Covered Recipients” (further defined below) that have a value of $50 or more. These laws are more restrictive than the PhRMA Code. They apply to all colleagues and extend to interactions with Massachusetts HCPs that occur outside of Massachusetts.
In summary, the law requires Pfizer to:

- Adopt the Massachusetts Marketing Code of Conduct;
- Establish a compliance program and conduct an annual audit and training;
- Disclose annually certain financial interactions between Pfizer and Covered Recipients; and
- Provide Massachusetts HCPs the opportunity to withhold their prescriber data from use by sales and marketing.

Failure to comply with any provision of the law can subject Pfizer to a penalty of $5,000 per violation.

**Definition of Healthcare Professional**

The Massachusetts definition of a healthcare professional (HCP) is broad. It includes any person who prescribes prescription drugs and is licensed to provide healthcare in Massachusetts, including a partnership or corporation comprised of such persons, as well as employees and agents of such persons (e.g., nurses, office staff, etc.). Examples of Massachusetts HCPs include:

- Physicians;
- Physician Assistants;
- Certified nurse midwife;
- Psychiatric nurse mental health specialists;
- Nurse Practitioners; and
- Employees and agents of such persons (e.g., nurses, office staff, etc.).

Massachusetts HCPs do not include hospitals, nursing homes, pharmacists, health benefit plan administrators, healthcare professionals not licensed in Massachusetts, and other entities if they are not agents, employees, etc. of a MA-licensed HCP. However, such entities and individuals are considered Covered Recipients for MA disclosure, as described below. As a result, T&E submissions for permitted meals to Massachusetts HCPs and Covered Recipients must list all recipients individually.
How the Law Impacts Pfizer Colleague Activities

All colleagues (regardless of division, business unit, or role) who engage in activities with Massachusetts-licensed HCPs, regardless of where the HCP practices or where the interaction occurs, should be aware that Massachusetts laws restrict Pfizer’s ability to provide meals and other items of value to Massachusetts HCPs. In addition, certain expenditures have to be reported, so all colleagues must ensure that their records on these expenditures are accurate and complete.

You must make a good faith effort to determine whether an HCP is licensed in Massachusetts. To help you determine whether an HCP holds a MA license, you should check the HCP Lookup Tool. Sales Colleagues can also access this information on Veeva CRM.

Meals

The Massachusetts Marketing Code of Conduct is more restrictive than the PhRMA Code with respect to the provision of meals to HCPs. Subject to the other requirements of Pfizer’s policies, meals may be provided to MA HCPs in certain limited situations that are specifically identified in the following guidance.

- “On-Site” meals are permissible during informational presentations in an HCP office or in-hospital setting (a cafeteria located within a hospital would generally qualify as a hospital setting). Meals must be modest and occasional.
- Pfizer may also provide modest meals to MA-licensed HCPs at out-of-office speaker programs.
- A limited exception for meals provided as compensation to Massachusetts HCPs who are consulting pursuant to a bona fide contract with Pfizer exists as well.
- In addition, refreshments such as coffee and snacks provided by Pfizer at a booth at a convention/congress are also permissible.

As a general matter meals are prohibited in all other situations that are not specifically identified in the guidance above.

Please see the Disclosure section below for T&E requirements for meals provided to Massachusetts HCPs and Covered Persons.

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Helpful Points

Colleagues may provide modest meals to MA-licensed HCPs at Pfizer speaker programs and as part of an informational presentation in an HCP’s office or a hospital setting.

There are also exceptions for meals provided as compensation under valid consulting agreements and for refreshments provided in a convention/congress booth.

Colleagues must make a good faith effort to determine whether an HCP is licensed in MA before inviting an HCP to a speaker program and can consult the HCP Lookup Tool or Veeva CRM. The meal and gift restrictions apply even when a MA-licensed HCP is located in another state.

Other Prohibited Items of Value and Activities

Generally, educational items may be provided to Massachusetts-licensed HCPs as long as they are RC-approved and consistent with the PhRMA Code.

Colleagues are prohibited from making expenditures on behalf of any Massachusetts HCP for:

- Entertainment or recreational items of any value;
- Grants, scholarships, subsidies, or educational items offered with the intent to encourage or modify prescribing behavior; or
- Residents, fellows, and HCPs to attend educational conferences (where funding comes directly from Pfizer and Pfizer chooses the recipient).

In addition, Pfizer may only provide CME support (through the process and standards associated with Independent Grants for Learning and Change (IGLC)) to conference organizers that meet ACCME standards or equivalent standards. Pfizer may not, however, provide funding directly to support meals for HCPs or compensate HCPs for attending CME events.

Disclosure

Pfizer must track and report annually all expenditures made to MA 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, unless they would be employees or agents of MA HCPs), 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.

As noted above, T&E submissions for permitted meals to Massachusetts HCPs and Covered Recipients must list all recipients individually. Effective July 8, 2012, co-pay cards, coupons and free trial vouchers may be provided to MA residents or to providers or pharmacies for distribution to MA residents, subject to the following:

- Distribution of these offerings is prohibited for drugs that have an AB-rated generic equivalent (e.g., Lipitor).
- Colleagues must accurately record and track in Veeva CRM the distribution of these items to any HCPs.
- Marketing and other HQ teams developing these programs must abide with the other parameters outlined in the Massachusetts Update on Loosened Co-pay, Coupon and Free Trial Voucher restrictions, dated August 8, 2012.

**Non-patient Identified Prescriber Data**

Before using non-patient-identified prescriber data, Pfizer must give Massachusetts HCPs the opportunity to request that their prescriber data be withheld from Sales and Marketing and not be used for marketing purposes. The Commercial Operations group within Pfizer is responsible for ensuring that any prescriber data provided by Pfizer to Sales representatives complies with state law.

**Minnesota**

**The Law: Gift Restriction Law**

Minnesota prohibits Pfizer from offering or giving any gift of value to a Minnesota healthcare practitioner, as defined below in this section. The definition of “gift” includes any thing or service that is given and received for less than fair market value unless it is specifically permitted under the statute.
The restrictions apply to all colleagues (not only Sales) and extend to interactions with Minnesota practitioners that occur outside of Minnesota.

The following are not considered “gifts” under the statute and may be given to Minnesota practitioners:

- Free drug samples for free distribution to patients (i.e. starters);
- Payment to sponsor a medical conference, professional meeting, or other educational program, provided no payment is made directly to a practitioner;
- Reasonable fees and expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting;
- Compensation at fair market value in connection with a genuine research project;
- Certain publications and educational materials, including most (but not all) RC-approved educational materials (e.g., Pfizer-created branded and unbranded promotional materials, reprints, literature, and other printed materials); and
- Salaries or other benefits paid to employees.

**Educational Items**

Educational reference items which provide general medical or drug information are not considered to be “publications and educational materials” and may not be provided. Examples of prohibited items include textbooks, journal subscriptions, online subscription services (such as trial memberships for Epocrates), and anatomical models. If you are unsure about whether an RC-approved item can be provided to a Minnesota practitioner, check with your manager or your team attorney.

**Meals**

As of May 31, 2010, Pfizer prohibits all colleagues from providing meals to Minnesota practitioners, subject to a very limited exception for meals provided as a reasonable expense to practitioners who serve on the faculty at a Pfizer professional or educational conference or meeting who are receiving compensation for services pursuant to a contract with Pfizer. A modest meal is not considered a “gift” under the law in these circumstances. Where a Minnesota practitioner is serving as a speaker at a Pfizer promotional program, for example, his or her meal does not constitute a gift and may be provided.
meals must, however, comply with all Pfizer policies on providing meals to HCPs, including the policy that meals should be modest and not exceed $135 in value.

Companies are required to submit annual reports to the Minnesota Board of Pharmacy of non-gift payments to practitioners, such as consulting fees, speaking honoraria, and related expenses, if the payments total $100 or more per year per practitioner.

**Consulting Engagements with MN HCPs**

Pfizer policy prohibits engaging MN-licensed practitioners as consultants except with respect to the following types of projects:

- Publications and educational materials
- Substantial professional or consulting services of a practitioner in connection with a genuine research project
- Speaking and speaker training.

Engaging MN practitioners as consultants for any other purposes is prohibited without prior Legal approval.

**Definition of Practitioner**

A “healthcare practitioner” is essentially *anyone who is able to prescribe a prescription drug in Minnesota* regardless of whether the practitioner actively prescribes. Physicians, nurse practitioners, physician assistants, dentists, dental therapists, optometrists, podiatrists and veterinarians are all included in the definition of practitioner in Minnesota. Pharmacists, however, are not included in the definition of practitioner and are therefore not covered by the law.

You should treat any Minnesota healthcare practitioner as if they are subject to the Minnesota gift law *regardless of the state in which the practitioner works or where the practitioner is geographically located*. For example, if a Minnesota-based practitioner is attending a speaker program in another state, the Minnesota state gift law still applies. If a physician who lives and practices in Florida is dual licensed in
Minnesota, the Minnesota gift law is deemed to apply. Therefore, meals cannot be provided to any Minnesota-licensed practitioner, regardless of his or her location except as noted herein.

**How the Law Impacts Pfizer Colleague Activities**

All colleagues are prohibited from providing meals to Minnesota-licensed practitioners, unless the meal is provided as a reasonable expense to a practitioner in connection with serving on the faculty at a Pfizer professional or educational conference or meeting, or performing bona fide services under one of the permitted consulting engagements, and who is receiving compensation for services pursuant to a contract with Pfizer. These types of meals are not considered a “gift” under the state statute. Similarly, gifts (as defined above) to practitioners are also prohibited.

You must make a good faith effort to determine whether a practitioner is licensed in Minnesota. To help you determine whether a practitioner holds a Minnesota license, you can check the [HCP Lookup Tool](#). Sales Colleagues can also access this information by looking up the HCP on their Veeva CRM tablet or iPad. Note that Veeva CRM flags most (but not all) MN HCPs.

Minnesota can impose significant penalties on Pfizer as well as criminal misdemeanor penalties for failure to comply with this law. If you have any questions concerning the Minnesota Gift Law, please contact the team attorney with responsibility for Minnesota.
Helpful Points

Colleagues must not offer or give any gift of value to a Minnesota HCP, including certain educational items (e.g. textbooks).

Colleagues must not provide meals or refreshments to Minnesota HCPs, except in the limited instance for certain HCPs under contract with Pfizer, as detailed above.

Colleagues must not engage Minnesota HCPs as consultants, except under the limited circumstances detailed in this Chapter.

You are required to make a good faith effort to determine whether an HCP is licensed in Minnesota before providing a gift or a meal to the HCP. You can consult the HCP Lookup Tool for a list of Minnesota HCPs, as noted above.

The meal and gift restrictions apply even when a Minnesota HCP is located in another state.

Nevada

The Law: Nevada Marketing Code of Conduct

The Nevada Marketing Code of Conduct requires all manufacturers and wholesalers who sell or market a drug in Nevada to:

- Adopt a written marketing code of conduct (the current PhRMA Code is acceptable);
- Adopt a training program to provide regular training to appropriate employees on the marketing code of conduct;
- Conduct annual audits to monitor compliance with the marketing code of conduct;
- Adopt policies and procedures for investigating instances of noncompliance with the marketing code of conduct;
- Identify a compliance officer responsible for the marketing code of conduct; and
- Submit certain information annually to the Nevada State Board of Pharmacy (including the marketing code of conduct, description of the training program; description of the

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investigation policies; contact information for the Compliance Officer; and certification of the company’s annual audit and compliance with its marketing code of conduct).

**New York**

**The Law: Restrictions on Gifts to State and Local Officers and Employees**

New York prohibits all NY elected officials, state officers and employees, state legislators, state legislative employees, municipal officers, and municipal employees from receiving (directly or indirectly) any gift. “Gift” includes anything of value given in any form, including any money, service, loan, travel, entertainment, hospitality, or promise, unless an exception applies. Colleagues may not provide any item to a New York State or local officer or employee if the item is intended or expected to influence or reward the New York State or local officer or employee in the performance of any activity related to his or her official duties.

**Definition of Officer or Employee**

A New York officer or employee includes, amongst others, any HCP employed, either full-time or part-time, by any New York State or county hospital, New York State Medicaid Board, or any other New York State or county agency. Bear in mind that an HCP with a private practice could also be a New York officer or employee.

**How the Law Impacts Pfizer Colleague Activities**

Pfizer colleagues may not provide any gift, including meals, to a New York State officer or employee. Additionally, Pfizer colleagues may not provide gifts, including meals, to any New York local officer or employee. In addition, even PhRMA Code compliant RC-approved educational items such as anatomical models or textbooks may not be provided.

Pfizer colleagues may continue to provide PhRMA-compliant food and beverage items of nominal value (e.g., doughnuts, cookies, and non-alcoholic beverages such as soft drinks and coffee) which are not part of a meal. New York interprets “nominal” as a value of $15 or less.
Helpful Point

If you are not sure whether an HCP is employed by the State of New York or a municipal institution, or is just affiliated with such an institution, you must determine the relationship prior to providing any item of value to the HCP. If the HCP receives regular compensation directly from one of these institutions, he or she is likely a state official and would be governed by the restrictions discussed in this section.

If you have any questions, please contact the team attorney with responsibility for New York.

Vermont

The Law: The Prescribed Products Law

The Vermont Prescribed Products Law significantly restricts Pfizer’s ability to provide meals and other items of value to Vermont healthcare providers (HCPs). These laws are more restrictive than the PhRMA Code. They apply to all colleagues and extend to interactions with Vermont HCPs occurring outside of the State of Vermont. Pfizer is required to disclose these expenditures to the State of Vermont.

In certain circumstances, Pfizer has an obligation to self-report to the State of Vermont if any colleague inadvertently provides a prohibited gift or meal to a Vermont HCP. If you become aware of any such occurrence, you must report it immediately to StateHealthcareLawCompliance@pfizer.com.

Definition of Healthcare Provider

Healthcare provider is defined very broadly in Vermont. It includes:

- Any person licensed to prescribe products or authorized to recommend prescribed products (“healthcare professionals”);
- Partnerships and corporations comprised of healthcare professionals;
• Officers, agents, and employees of healthcare professionals (e.g., nurses, office staff, etc.); and
• Hospitals, nursing homes, pharmacists, and any other person authorized to dispense or purchase for distribution prescribed products.

Examples of HCPs in Vermont include:

• Physicians;
• Nursing Homes;
• Nurse Practitioners;
• Dentists;
• Healthcare professional office staff;
• Physician assistants;
• Hospitals;
• Pharmacists;
• Licensed Clinical Social Workers and Psychologists;
• Health plan benefit administrators; and
• Members of the Green Mountain Care Board (whether or not they are licensed HCPs).

_How the Law Impacts Pfizer Colleague Activities_

All colleagues (regardless of division, business unit or role) who engage in activities that involve Vermont HCPs, regardless of where the HCP practices or where the interaction occurs, should be aware that Vermont prohibits Pfizer from providing meals and certain other items of value to Vermont HCPs. In addition, certain expenditures have to be reported, so all colleagues must ensure that their records on these expenditures are accurate and complete.

You must make a good faith effort to determine whether an HCP is licensed in Vermont. To help you determine whether an HCP holds a VT license, you can check the [HCP Lookup Tool](#). Sales Colleagues
Meals

All meals to Vermont HCPs are prohibited. This prohibition includes the provision of coffee and doughnuts, or other food items of nominal value, even if these items are for non-prescribing staff in a physician’s office. There is a limited exception for meals provided as compensation to Vermont HCPs who are providing services pursuant to a bona fide contract with Pfizer. In addition, refreshments such as coffee and snacks provided by Pfizer at a booth at a convention/congress are also permissible.

Gift Ban

In addition to the prohibition on meals, colleagues cannot provide Vermont HCPs with any item of value unless the item is explicitly allowed under the law.

The following items are allowed under Vermont law:

- Starters;
- Peer-reviewed academic, scientific, or clinical articles or journals that have been RC-approved;
- Articles, journals, and other educational items;
- Certain conference sponsorships;
- Rebates and discounts;
- Authorized expenditures related to clinical trials; and
- Compensation at fair market value for bona fide consulting services, including research and product development meetings.

Marketing Research

The Prescribed Products Gift Ban and Disclosure Law prohibits Pfizer from providing payments to VT-licensed HCPs in connection with marketing research surveys (including blinded surveys).
Paid market research surveys involving VT-licensed HCPs are banned. The restriction applies whether the survey is conducted directly by Pfizer or through an independent third party survey research organization.

**Helpful Points**

Vermont prohibits all meals with VT HCPs (regardless of where the meal takes place) except as noted below.

Snacks of nominal value (e.g., coffee, drinks, cookies, etc.) are also prohibited, except when provided at a booth at a convention/congress.

You must not invite VT HCPs to Pfizer speaker programs at which food is provided even if the program is conducted outside of Vermont.

There is an exception for meals provided as compensation for services performed under a bona fide consulting contract.

You are required to make a good faith effort to determine whether an HCP is licensed in VT before inviting an HCP to a speaker program. You can consult the HCP Lookup Tool for a list of VT HCPs or by looking up the HCP in the Veeva CRM tablet or iPad, as noted above.

The meal and gift restrictions apply even when a VT HCP is located in another state.

**Disclosure of Expenditures to Vermont HCPs**

Most allowable expenditures to Vermont HCPs, or other institutions covered by the law (e.g., Vermont academic institutions, Vermont nonprofit hospital foundations, and professional, educational, and patient organizations representing or serving health care providers or consumers in Vermont), must be disclosed, regardless of the amount.

This includes tracking and disclosing the distribution of samples, coupons, and vouchers. Vermont’s law defines “sample” as a unit of a prescription drug, biological product, or medical device that is not intended to be sold and is intended to promote the sale of the drug, product, or device, including starter packs and coupons or vouchers that allow any individual to receive a prescribed product for free or at a discounted price.

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Items exempt from disclosure are:

- Refreshments and other snacks provided at a booth at a convention/congress;
- Rebates and discounts;
- Royalties and licensing fees for patent rights;
- Labels on prescribed products;
- Reasonable expenses related to an interview by a manufacturer in connection with a bona fide employment opportunity; and
- Prescribed products distributed free of charge or at a discounted price pursuant to a Pfizer Patient Assistance Program.

**The Law: Vermont Price Disclosure Law**

The Vermont Price Disclosure Law requires that, when marketing directly to Vermont authorized prescribers, Pfizer disclose the Average Wholesale Price (AWP) “per pill” of each drug marketed, as well as the prices of other drugs in the same therapeutic class. Two types of disclosure are required:

- **Long Form Disclosure**: Disclosure of price-related information posted on Pfizer’s website; and
- **Short Form Disclosure**: Written disclosure of price information which must be provided to the prescriber at the point of specific detailing or promotional activity (whether in person, by mail, by telephone, or electronically).

Both the long and short Vermont price disclosure forms may be accessed at [http://www.pfizer.com/vtprescribers/](http://www.pfizer.com/vtprescribers/).
The following table identifies which forms are required in connection with typical promotional activities.

<table>
<thead>
<tr>
<th>Promotional Activity</th>
<th>Action Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Face-to-face meeting with prescribers (detailing, exhibit booths, professional conferences) in Vermont.</td>
<td>Provide short form to each prescriber for each product promoted or detailed.</td>
</tr>
<tr>
<td>Mailing to prescribers.</td>
<td>Include short form with mailing for each product promoted.</td>
</tr>
<tr>
<td>Telephone calls.</td>
<td>Inform Vermont prescriber that short form will be mailed; mail short form for each product promoted to business address within 24 hours.</td>
</tr>
<tr>
<td>E-mails or electronic communications.</td>
<td>Include short form for each product promoted as an attachment or as conspicuous and separate section of the e-mail.</td>
</tr>
</tbody>
</table>

Marketing activities which do not require price disclosure in Vermont include placement of advertisements and marketing to state or private payers as well as hospitals.

Vermont can impose significant penalties on Pfizer for failure to comply with this law. If you have any questions, please contact the team attorney with responsibility for Vermont.

**FOR MORE INFORMATION**

- Refer any questions to the team attorney with responsibility for the relevant state.
Chapter 18: MEALS, EDUCATIONAL ITEMS, AND HCP PAYMENT DISCLOSURE

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

Introduction

The Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals (PhRMA Code) provides that occasional meals may be offered to U.S. healthcare professionals (HCPs) in connection with informational presentations and discussions, so long as the meal is modest as judged by local standards and occurs in a venue and manner conducive to communication that provides scientific or educational value. The PhRMA Code also restricts who may provide out-of-office meals to U.S. HCPs. In addition, it allows colleagues to give occasional approved educational items to U.S. HCPs if the items are valued at $100 or less.

As of August 1, 2013, pharmaceutical manufacturers operating in the United States are required to report to the government payments and other transfers of value made to U.S.-licensed physicians and teaching hospitals in accordance with the transparency provisions of the Patient Protection and Affordable Care Act (PPACA), which are commonly referred to as “the Sunshine Act” or “Open Payments” provisions. These disclosure obligations are reflected in Pfizer’s HCP Payment Disclosure and State Reporting SOP, which is broader than the Sunshine Act provisions because certain states have different definitions on HCPs and reporting standards, and individuals other than those described in the Sunshine Act can influence or cause the administration, prescription, purchase, or recommendation of prescription medicines.

Certain state laws and federal institutions create additional restrictions and disclosure obligations regarding payments and other items provided to U.S. HCPs, as described in the State Laws: HCP and State Employee Restrictions Chapter and the Federal Employee Interactions and Lobbying Chapter in this Guide. HCP payment disclosure is just one of the many ways Pfizer is fulfilling its commitment to increased transparency and public candor.

This Chapter addresses Pfizer policies regarding the provision of payments, meals, educational items, or anything else of value to U.S. prescribers or U.S. teaching hospitals. Non-compliance
with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination of employment.

**Key Points to Ensure Compliance**

- Except where restricted by law or Pfizer policy, a Pfizer colleague may provide food and beverage to HCPs if the value is modest by local standards. For out-of-office meals, the total cost cannot exceed $135 per attendee, including tax, tip, and delivery charges. For in-office or in-hospital meals, the total cost, including tax, tip, and delivery charges, may not exceed $40.

- When providing a modest meal in connection with product promotion, the meal must never be the primary focus of the interaction – it should be incidental to the dissemination of approved information and must comply with the PhRMA Code.

- It is improper for colleagues to provide “take out” meals to HCPs or their staff members. Only individual HCPs and office staff members who engage in an educational discussion with a Sales Colleague can partake in the meal.

- The PhRMA Code prohibits Sales representatives and their immediate supervisors from hosting out-of-office meals for HCPs, outside of speaker programs. Senior Sales Colleagues (above District Manager level) and non-Sales colleagues (including Marketing colleagues) are not subject to this restriction and may host restaurant or other meals as long as there is a legitimate business reason. Account Managers (see chart below for definition) may provide out-of-office meals to HCPs who do not regularly treat patients.

- The PhRMA Code prohibits non-educational items from being offered to U.S. HCPs or members of their staff. Accordingly, only Pfizer Review Committee-approved (“RC-approved”) educational items may be provided to HCPs and their staff.

- Pfizer’s payment disclosure policy applies to payments, meals, snacks, reimbursable travel expenses, approved educational items, and other transfers of value provided to U.S.-licensed physicians and other HCPs. Pfizer also discloses payments to U.S. teaching hospitals, as well as payments related to clinical research, which are attributed to the principal investigators.
Key Points to Ensure Compliance

- HCPs who are currently licensed in Minnesota or Vermont, or employees of a Vermont HCP, may not be invited to any speaker program (in-office or out-of-office) if food will be provided. Other HCPs or physicians have the option to “opt out” of eating a meal at a speaker program where a meal is provided, in which case the value of the meal will not be reported for them.

- HCPs may permanently “opt out” of being offered meals, snacks, or educational items by contacting PTI@Pfizer.com. If a prescriber has permanently “opted out” but nonetheless accepts payments, meals, or other disclosable items of value from Pfizer, they will be subject to disclosure. Disclosures pursuant to the Sunshine Act are posted on the Open Payments website maintained by CMS at http://www.cms.gov/OpenPayments/index.html.

- Colleagues who interact with HCPs are responsible for verifying their “opt out” status. Sales Colleagues should consult the physician profiles on their Veeva CRM to view an HCP’s “opt out” status. A permanent “opt out” list, accessible to all colleagues, is also available on OpSource and PfieldNet.

- Colleagues must correctly record in the applicable finance and payment system(s) information necessary to identify teaching hospitals and HCPs and the payments or items of value provided to them.

- Certain state laws and federal institutions (e.g., VA/DoD) also limit and/or require the disclosure of payments and items of value provided to HCPs. These laws and restrictions are described in the State Laws: HCP and State Employee Restrictions Chapter and the Federal Employee Interactions and Lobbying Chapter in this Guide. Additional information is also available on OpSource under the State Healthcare Law Compliance tab and on PfieldNet under the Compliance tab.

- In-scope payments or other transfers of value provided to U.S.-licensed physicians and U.S. teaching hospitals through external parties, such as Contract Research Organizations (CROs) and Contract Sales Organizations (CSOs), are also subject to disclosure.
Meals to HCPs

General Rules and Restrictions

Pfizer policy and the PhRMA Code permit colleagues to provide meals to U.S. HCPs on occasion in appropriate circumstances – such as meals in connection with informational presentations or discussions providing scientific or educational value – so long as the meal is modest as judged by local standards, never is the primary focus of the interaction, and occurs in a venue and manner conducive to informational communication. Recreational and entertainment venues are prohibited. In addition, under Pfizer policy, out-of-office meals to U.S. HCPs cannot exceed $135 per attendee (including the cost of food, beverage, tax, tip, and delivery charges) and meals in an in-office or in-hospital setting cannot exceed $40 (including food, beverage, tax, tip, and delivery charges). Further, providing alcoholic beverages to HCPs in excess or not as part of a meal is prohibited, as it is not conducive to providing scientific or educational information or other business purposes.

The PhRMA Code restrictions on out-of-office meals apply only to Field Sales Colleagues and their immediate managers. If and when Pfizer colleagues are permitted to provide meals to HCPs varies based on each colleague’s role, but always requires a legitimate business reason. The table below provides a high-level summary:

<table>
<thead>
<tr>
<th>Host restaurant meals?</th>
<th>Host in-office meals?</th>
<th>Host in-hospital meals?</th>
<th>Host speaker programs?</th>
<th>Host meals at conventions?</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHR, TSR, IHR, and any other Sales representative</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>District Manager</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Regional Manager, Regional Business Director, Regional Presidents</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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### Host Meals

<table>
<thead>
<tr>
<th>Host restaurant meals?</th>
<th>Host in-office meals?</th>
<th>Host in-hospital meals?</th>
<th>Host speaker programs?</th>
<th>Host meals at conventions?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Account Manager, including AD, DE, KAM, VAM, ADM (only if such colleague does not directly supervise Sales representatives)</strong></td>
<td>Only for non-HCPs or HCPs who do not regularly treat patients</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>HQ Marketing/Medical</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### Several states and the U.S. Department of Veterans Affairs (VA)/Department of Defense (DoD) Restrictions

Several states and the U.S. Department of Veterans Affairs (VA)/Department of Defense (DoD) also impose meal limitations and reporting requirements that are stricter than the PhRMA Code and/or Pfizer’s [HCP Payment Disclosure and State Reporting SOP](#). For instance, with very limited exceptions, no meals (in- or out-of-office) may be provided to physicians licensed to practice in Vermont or Minnesota unless specifically approved by Legal. Further, no out-of-office meals may be provided to physicians licensed to practice in Massachusetts (subject to a limited exception for meals provided in connection with speaker programs). The VA also prohibits colleagues from providing food items of any type or value to VA staff (including volunteers) at VA facilities, or bringing food into VA facilities for use by non-VA staff, even if a colleague receives approval from on-site staff.

Before providing any meals or other items of value to HCPs, colleagues should refer to the State Laws: HCP and State Employee Restrictions Chapter and the Federal Employee Interactions and Lobbying Chapter in this Guide. To determine whether an HCP is licensed in Massachusetts, Minnesota, or Vermont, Sales Colleagues should consult the physician profiles on their Veeva CRM, and other colleagues should search the HCP lookup tool found at [http://hcplookup.pfizer.com/Pages/search.aspx](http://hcplookup.pfizer.com/Pages/search.aspx). Additional information on state law restrictions and other tools are available under the Compliance tab on PfieldNet and under the [State Healthcare Law Compliance tab on OpSource](#).

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Account Manager Out-of-Office Meals with HCPs

Q. Can a KAM host an out-of-office meal with a physician who serves as the medical director of a hospital system?

A. It depends. Account Managers such as KAMs can provide out-of-office meals to a physician who is not regularly treating patients. Typically, an HCP who treats patients one day per week or less (i.e., no more than 20% of the time) is not “regularly treating patients.” As always, there must be a legitimate business reason (related to the physician’s responsibilities outside of treating patients) for meeting over a meal, and the interaction must be conducted in accordance with the provisions of this Chapter, including any other state law or restriction.

Meals Provided by Field Sales Colleagues and Their Immediate Managers

Under the PhRMA Code, meals provided to U.S. HCPs by Sales representatives and their immediate managers in connection with informational presentations must be limited to in-office and in-hospital settings. The only times a Sales representative or their immediate manager may provide restaurant meals to HCPs are at Pfizer speaker programs where trained speakers (generally paid external HCPs) present RC-approved information about Pfizer products, disease states, or other healthcare topics, using content controlled by Pfizer. Sales representatives and their immediate managers are prohibited from providing out-of-office meals to HCPs under any other circumstances. Further, it is impermissible to pay for HCP meals at an activity such as independent continuing medical education (CME) where the content is not controlled by Pfizer. For more information about speaker programs, see Orange Guide Chapter 9: Speaker Programs for HCPs and White Guide Chapter 4: Marketing Programs.

It is inappropriate for a Pfizer colleague to include an HCP’s spouse or other guest in any Pfizer-provided meal, unless the spouse or guest is otherwise an appropriate attendee under Pfizer policies.

It is never appropriate for a Pfizer colleague to offer “take-out” meals or meals to be eaten without the Pfizer colleague present. Meals must be incidental to the provision of informational presentations and discussions. Therefore, only individual HCPs and office staff members who engage in an educational discussion with the Pfizer colleague can partake in the meal. For this reason, and to ensure proper reporting for disclosure purposes, Pfizer colleagues should instruct HCPs and their staff not to unwrap or consume meals provided by Pfizer prior to the arrival of a Pfizer colleague.
“Meals” Defined

Q. What is considered a “meal?”
A. Anything more than a nominal food or beverage item is considered a meal and, thus, may not be provided by Sales representatives or their immediate managers outside of an office or hospital setting except in connection with an appropriate speaker program.

Q. Does taking an HCP out for a cup of coffee constitute a meal?
A. No. Under Pfizer policy, food or beverage items of nominal value ($10 per attendee or less) – such as coffee, other non-alcoholic beverages, or pastries, are considered a snack and not considered a meal. Pfizer policy permits a Sales representative or their immediate manager to make an occasional educational presentation to an HCP out of the HCP’s office or hospital (such as in a coffee shop near the HCP’s office), along with offering a snack (not a meal), unless further restricted by state law or other laws or policies.

In general, offering a snack (as defined above) out of an HCP’s office or hospital should be reserved for situations in which it is not possible to provide food or beverage in an in-office setting and limited to only one or two HCPs at a time. It should not replace an in-office educational presentation incidental to a meal.

In all cases, the value of any food or beverages provided to a U.S.-licensed physician, regardless of amount, is potentially subject to public disclosure by Pfizer. Thus, the Pfizer colleague providing the item of value must properly record the expense as described later in this Chapter.
Providing a Meal to Office Staff

Q. If a Pfizer colleague is bringing lunch to a medical office for HCPs to eat during a product discussion, can the colleague also provide lunch to non-HCPs (e.g., office staff) in attendance?
A. Yes, the PhRMA Code provides that when conducting in-office (“lunch and learn”) programs for HCPs it is permissible to provide the meal to members of an HCP’s staff who also attend the presentation or otherwise receive educational information.

Q. Can a Pfizer colleague provide lunch to HCPs or medical office staff who do not attend the informational presentation or receive educational information?
A. No, “take-out” meals are prohibited.

Q. A medical clinic will only accept appointments from Pfizer colleagues who agree to bring lunch to the clinic. They have offered to schedule a recurring lunch appointment for a Pfizer colleague on the first and third Wednesday of each month. Can the Pfizer colleague accept this offer?
A. No. Under the PhRMA Code and Pfizer policy, meals may only be provided to HCPs on an occasional basis. Such a recurring lunch appointment would be improper.
Providing “In-Office” Meals to Remotely-Based Customers

Q. How is “in-office” meal defined for customers who are based remotely? Can a Sales Colleague or their immediate manager host a non-restaurant meal in temporary meeting space rented by customers who do not have a corporate office?

A. Sales Colleagues and their immediate managers are limited to providing an “in-office” meal under the PhRMA code to ensure the meal is incidental to a substantive interaction and in the setting where the HCP typically conducts professional conversations. Some HCP customers are field-based without a formal corporate office, e.g., retail pharmacy managers (licensed pharmacists who manage a territory of chain pharmacies for large retailers). These customers occasionally rent hotel or other meeting space to conduct business. In such instances, the customer-rented space, excluding all restaurants and restaurant meeting rooms, may be considered “in-office” for purposes of this Chapter, as that is where the customer conducts professional conversations.

If the customer-rented space is at a restaurant or restaurant meeting room, it is not considered “in-office,” and you may not provide a meal at such a location. Sales representatives and their immediate managers may only expense a meal at the customer-rented location incidental to a promotional presentation and in accordance with all requirements of this Chapter; no other expenses such as the meeting space rental may be incurred. As with other “in-office” promotional opportunities, Pfizer colleagues must follow all Pfizer policies for detailing and should leave the customers’ meeting space after the promotional discussion and incidental meal are concluded, in no way involving themselves in the customers’ other business dealings. If colleagues have questions or concerns about promotional opportunities with remotely-based customers, including the provision of meals, they should consult with their team attorney.

Providing in-Hospital Meals

Q. 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?

A. 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.
Providing Meals to Pharmacists

Q. Do the same rules apply to pharmacists and pharmacy technicians?
A. Yes. While the PhRMA Code does not define “healthcare professional,” Pfizer policy requires colleagues to treat pharmacists as HCPs and to treat pharmacy techs as office staff. However, pharmacists generally do not need to be named individually (as “HCPs”) in colleagues’ meal expense reports – with the exception of Massachusetts, Vermont, and D.C. pharmacists, who must be identified and tracked for state law reporting purposes.

Meals Provided by Senior Sales Colleagues and Headquarters Colleagues

All colleagues are subject to the general rules and restrictions set forth at the beginning of this section. However, the PhRMA Code restriction on restaurant meals is not applicable to senior Sales Colleagues above District Manager level nor to non-Sales colleagues. These colleagues, including those in Marketing, 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. Sales representatives and their immediate managers may attend meals hosted by such colleagues if there is a legitimate business need and as long as the topic of discussion is appropriate for their attendance, but they should not use them as a means to conduct promotional activities that they cannot host on their own. The ratio of Pfizer colleagues to HCPs should be conducive to the business discussion. Further, for all Sales Colleagues, it is presumed that discussions regarding unapproved indications for Pfizer 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 a meal for an HCP. Colleagues should consult their team attorney for any questions regarding whether the topics to be discussed at a proposed meal with an HCP are appropriate.
**Orange Guide - Chapter 18: Meals, Educational Items, and HCP Payment Disclosure**

**Colleagues Permitted to Host Non-Speaker Program Restaurant Meals**

Q. The PhRMA Code states that meals offered in connection with presentations by Sales representatives and their immediate managers (except for speaker programs) should be limited to in-office or in-hospital settings. To which types of colleagues does this apply?

A. The following colleagues are prohibited from providing restaurant meals to HCPs outside of speaker programs: Healthcare Representatives, Therapeutic Specialty Representatives, District Managers, Clinical Specialists, and all other Sales Colleagues who either call on HCPs or who directly supervise colleagues who call on HCPs.

Q. Does that mean that all colleagues who meet with customers are prohibited from providing these types of presentations in restaurants?

A. No. The following senior Sales Colleagues may host modest restaurant meals with HCPs at appropriate venues, if there is a legitimate business reason to do so: Regional Managers, Regional Directors, and Regional Presidents. Non-Sales colleagues, such as those in Marketing, are likewise permitted to provide restaurant meals, subject to the legitimate business reason standard. Meanwhile, the following colleagues may host restaurant business meals for non-HCPs and HCPs who do not regularly treat patients: Account Managers, Account Directors, Directors of Employers, Key Account Managers (KAMs), VAMs, and Alliance Development Managers.

**Sales Colleagues Attending Non-Speaker Program Restaurant Meals**

Q. May a Sales representative or District Manager attend a restaurant meal with an HCP that is hosted by an appropriate colleague?

A. Yes. Sales representatives and DMs may attend meals that are hosted by an appropriate colleague (e.g., restaurant meals hosted by RMs and RDs at conventions or congresses), as long as they do not use the meal as an opportunity to conduct promotional activities that they could not host on their own. This means that Sales representatives and DMs may not use the meal to provide a product presentation to attendees (i.e., detail). In addition, the legitimate business reason of the meal should be to meet the objectives of the hosting Senior Sales or Headquarter colleague, not the objectives of the Sales representative or DM in attendance.

Q. May a Sales representative or District Manager attend a restaurant meal with an HCP if there is no appropriate colleague present, but the parties each agree to pay their own way?

A. No, this would not be in the spirit of the PhRMA Code or Pfizer policy.
Legitimate Business Reason

To determine whether the legitimate business reason requirement is satisfied, colleagues hosting such meals should determine whether the proposed interaction and meal are consistent with their role and responsibilities and would help them achieve their goals and objectives in a legitimate manner. The central focus must be the business interaction, with the meal being incidental to that primary purpose. At all times, colleagues must exercise sound judgment and discretion when providing meals in conjunction with a business interaction. Any questions about whether a meal can be provided to an HCP should be directed to the relevant team attorney.

Q. An Account Manager plans to provide a restaurant meal to an HCP C-Suite executive who does not regularly treat patients for an appropriate business discussion. Would it be acceptable for a Sales representative to accompany the Account Manager to provide the latest approved clinical information on a Pfizer product as part of the discussion?

A. No. While a Sales representative or District Manager may join an Account Manager who is permitted to provide restaurant business meals, information provided over the meal should not be focused on presentation of the clinical benefits of a Pfizer product geared toward influencing prescribing practices. Rather, all discussions with those HCPs who are not regularly treating patients should focus on more general business matters associated with the delivery of patient care or similar topics related to the HCP’s central and primary role as an administrator or executive.

Q. Pfizer is hosting a promotional booth staffed by Marketing colleagues at a medical conference. Can a Marketing colleague take a group of physicians out to a restaurant meal to discuss new Pfizer RC-approved data on a Pfizer product?

A. Yes. This would be considered a legitimate business purpose since it is permissible for Marketing colleagues to discuss RC-approved content with HCPs so long as they adhere to the Four Core Compliance Principles. Marketing colleagues may provide a modest meal incidental to the discussion, unless restricted by state law. For more information, see the State Laws: HCP and State Employee Restrictions Chapter in this Guide.

Educational Items to HCPs

In accordance with the PhRMA Code and Pfizer policy, RC-approved educational items valued at $100 or less may be provided on occasion to HCPs or members of their staff. Non-educational items are prohibited from being offered, even if the items are practice-related and of minimal value (such as
pens, pads, mugs, etc.). Educational items that do not directly benefit a patient or are not intended to be used by or with a patient, such as textbooks and reprints, are reportable under the Sunshine Act. If you have a question about whether a specific educational item is approved to be provided to HCPs, consult the relevant product Legal or Regulatory colleague, or submit your question to StateHealthcareLawCompliance@pfizer.com or PhRMACode@pfizer.com.

Further, as with meals, several states and the VA/DoD also impose limitations which are stricter than the PhRMA Code or Pfizer policy on educational items (and other items of value) that may be provided to HCPs. For instance, to ensure compliance with Minnesota state law, Pfizer policy prohibits colleagues from providing educational items to physicians licensed to practice in that state. Before providing educational items to HCPs, colleagues should refer to the State Laws: HCP and State Employee Restrictions Chapter and the Federal Employee Interactions and Lobbying Chapter in this Guide. For further information, and to determine where an HCP is licensed to practice, consult the HCP Customer Master at http://hcplookup.pfizer.com/Pages/search.aspx and the other references available on OpSource under the “State Healthcare Law Compliance” tab and on PfieldNet under the Compliance tab. Sales Colleagues should also consult the State Law Restriction field in Veeva CRM.

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 expended personally, including meals. Remember that The Summary of Pfizer Policies on Business Conduct (the "Blue Book") and Corporate Policy (CP) #203: Conflicts of Interest require you to avoid even the appearance of a conflict of interest.

HCP Payment Disclosure Policy

Overview

Consistent with its commitment to transparency, in 2009, Pfizer committed to publicly disclose payments and the value of meals, reimbursable travel expenses, and educational items that it provides to U.S.-licensed prescribers and to U.S. institutions in connection with clinical research, along with the names of the associated principal investigators. Pfizer disclosed on its public website payments and the
value of meals, reimbursable travel expenses, and educational items that it provided to U.S.-licensed prescribers and institutions between 2010 and 2014.

Since the Sunshine Act became effective, Pfizer has been disclosing payments in accordance with that law. These disclosures are available on CMS’s Open Payments website at http://www.cms.gov/OpenPayments/index.html.

Pfizer’s disclosure policy is broader than the requirements of the Sunshine Act, and defines “HCP” more broadly than the definition found in the Act. This is so because certain states have different reporting standards, and individuals other than those described in the Sunshine Act can influence or cause the administration, prescription, purchase, or recommendation of prescription medicines. The disclosure policy affects any colleague who provides payments, meals, or non-cash items or services of any value to healthcare professionals (including, among others, licensed U.S. prescribers and U.S. clinical investigators) or to U.S. institutions who may employ such healthcare professionals. Colleagues must be familiar with the policy and should proactively discuss our disclosure policies with all U.S. healthcare professionals and institutions to whom they intend to provide disclosable payments or items of value, to ensure they are aware that such payments and other transfers of value will be disclosed.

**Items Included in Reporting**

Pfizer’s disclosures may include the following types of payments and non-cash items provided directly or indirectly to a broad range of U.S. healthcare professionals and institutions:

- Meals (including snacks/refreshments);
- Business travel expenses;
- Educational Items (e.g., textbooks and reprints);
- Research support (all payments or transfers of value related to R&D, such as clinical site payments, study drug, and equipment that is leased, loaned, or given):
  - Investigator-Initiated Research (IIR);
  - Non-interventional/Observational Studies;
  - Pre-clinical Research;
  - Phase I-IV Pfizer-Sponsored Clinical Studies;
  - Clinical Research Collaborations (CRCs); and
Outcomes Research Studies.

- Consulting Fees and Honoraria;
- Promotional Speaking Fees;
- Publication support (e.g., payments to an agency);
- Charitable Contributions;
- Grants; and
- Royalty and License Payments.

Reporting of Indirect Payments or Other Transfers of Value

Under the Sunshine Act, Pfizer must report any indirect payment or transfer of value it requires, instructs, directs, or causes to be provided to a covered recipient. That includes payments where Pfizer knows or expects that a covered recipient would receive any portion of its payment or transfer of value, even if Pfizer does not specify or know the identity of the recipient.

For instance, in-scope payments and transfers of value to U.S.-licensed physicians or teaching hospitals that are processed through third-party entities, such as **Contract Research Organizations (CROs)** or **Contract Sales Organizations (CSOs)**, are disclosable under the Sunshine Act. Also, if Pfizer were to give a medical professional society funds that were earmarked for the purpose of awards or grants to U.S.-licensed physicians, the awards or grants would be indirect payments to covered recipients and thus subject to the reporting requirements, even if Pfizer did not influence or know which physicians would receive a grant or award.

Disclosure of Monetary Compensation and Business Travel Expenses

Pfizer may directly or indirectly provide **fair market value compensation** to U.S. HCPs in connection with a number of activities, including consulting and advisory boards, promotional speaking, clinical trials, and other studies or projects. Pfizer may also compensate HCPs by paying or reimbursing reasonable travel expenses incurred in connection with these activities and others, such as employment interviews, including airfare, hotel accommodations, and ground transportation. Disclosable travel expenses reflect either the actual sums expended for a specific HCP’s accommodations or, if the activity or event requires the attendance of multiple HCPs, may reflect a proportionate allocation of travel expenses.
All compensation to U.S. HCPs is required to correspond to **bona fide services** provided pursuant to **written agreements**. See White Guide Chapter 5: HCP and Government Official Consulting Engagements and the Clinical Research and Investigator-Initiated Research (IIR) Chapter in this Guide for more information on common engagements involving monetary compensation.

**Disclosure of the Value of Meals**

As described in this Chapter, colleagues are permitted to provide occasional modest meals to U.S. HCPs in appropriate circumstances. Currently, subject to state laws that may also impose meal limitations and reporting requirements that are stricter than the PhRMA Code or Pfizer policy, Pfizer’s disclosures include all meals provided to U.S.-licensed HCPs, regardless of value. Although not treated as “meals,” snacks and refreshments of nominal value ($10 or less per attendee) must be appropriately recorded in expense reports, as directed in this Chapter.

When meals are provided in connection with an informational presentation to a group, the disclosable value is calculated by taking into account both actual and expected attendees. Therefore, to ensure appropriate accounting for the per-person value, all attendees who partake in the meal (HCPs and non-HCP office staff), as well as all expected attendees and those who do not partake in the meal but did attend, should be tracked. (See [http://pfieldnet.pfizer.com/workspace/Documents/PTE_Promotional_Meals_Recordings_no_show_no_eat.doc](http://pfieldnet.pfizer.com/workspace/Documents/PTE_Promotional_Meals_Recordings_no_show_no_eat.doc) for additional information on how to track your attendees).

**Tracking and Calculating the Disclosable Value of Meals**

**Q.** I am planning for 10 U.S.-licensed HCPs to attend a speaker program at a restaurant that, as part of its room reservation contract, requires a $75 cost per attendee commitment ($75 x 10 = $750), regardless of actual attendance. If 2 HCPs do not show up, will that increase the reported meal value ($750 / 8 = $93.75)?

**A.** No. If a restaurant requires Pfizer to pay a fixed “per person” meal fee based on estimated attendance at a speaker program, that “per person” fee will be allocated to across all attendees (regardless of actual consumption). In this example, Pfizer would report $75 for each of the 8 HCPs who attended and ate the meal.
Disclosure of Snacks and Refreshments Provided at Exhibit Booths

Q. We are planning to have an exhibit booth at a state physicians’ annual convention, at which we intend to make coffee and pastries of nominal value ($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?

A. Yes. Snacks and refreshments of any value (including nominal value) must be tracked and reported. You should ensure that you can screen out HCPs who must be excluded under state law, and accurately record the full name, title, state license number, and address of each HCP that accepts a refreshment, including the value of the items provided.

Disclosure of the Value of Educational Items and Non-Disclosure of Patient Materials

As discussed in this Chapter, under Pfizer’s policies and PhRMA Code guidelines, RC-approved educational items valued at $100 or less may be provided on occasion to U.S.-licensed HCPs. The value of these educational items (such as textbooks) is included in Pfizer’s public disclosures. Note that reprints and other educational materials that enhance an HCP’s skills are considered reportable transfers of value under the Sunshine Act.

Generally, Pfizer-created branded and unbranded promotional materials, literature and other leave-behind written materials are NOT subject to disclosure under the Sunshine Act. Likewise, items that are to be used by or with patients, such as an anatomical model or patient education materials, are NOT disclosable under the Sunshine Act. However, some of these items are subject to disclosure under state laws (e.g., Vermont). Accordingly, all of these items must be tracked for business purposes. Such items include:

- Co-pay cards;
- Savings cards;
- Pill dispensers;
- Brochures;
- Vouchers;
- Prescription stamps; and
- Pamphlets.
Recording Disclosable Payments and Items

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

- Obtain full and complete names, titles, addresses, and state license numbers for all U.S.-licensed HCPs receiving payment for, or otherwise participating in, activities involving disclosable items, including attendees at meetings, presentations, and speaker programs where meals are provided;
- Ensure that information about payments and non-cash items given to U.S.-licensed HCPs is accurately recorded in the appropriate system (e.g., Ariba ePay and Purchase Orders; PT&E’s “My HCP” category; Centris’s “Attendee” section; GEMS’ Attendee registry StarCite; Veeva CRM);
- Classify budgets and expenses using the appropriate codes and ensure invoices can be attributed to the HCP through the Pfizer Physician ID Number; and
- Never approve expense reports or invoices that lack full names and appropriate expense allocation.
Identifying HCP Meal Attendees in Sales Colleague Expense Reports

Q. A Sales Colleague has provided an in-office meal to a mixed group including both physicians who are on and not on her TCL, as well as office staff. Which individuals must the Sales Colleague identify by name in her meal expense report?

A. All individuals who are licensed to prescribe medicines in the United States must be identified by name in the meal expense report, regardless of whether they appear on the colleague’s TCL. These include doctors of medicine or osteopathy, medical residents, dentists, podiatrists, optometrists, chiropractors, and advanced practice nurses, such as nurse practitioners and physician assistants, who are legally authorized to prescribe by the state in which they practice. Non-prescribers, including registered nurses and office staff, do not need to be identified by name, except that any individuals who are employees or agents of Massachusetts-licensed, or Washington, D.C.-licensed prescribers (including non-prescribing nurses and office staff), as well as M.A. and D.C. pharmacists, must be named for state reporting purposes.

For further information regarding appropriate use of the travel & expense system, Sales Colleagues should consult the Pfizer Travel & Expense guidelines available on PfieldNet. Please also see the State Laws: HCP and State Employee Restrictions Chapter in this Guide, for further details on who qualifies as an HCP in Massachusetts and D.C.

Opting Out of Receiving Disclosable Items

If a U.S.-licensed HCP expresses a desire to opt out of receiving food, beverages, or other disclosable items, the notified colleague must: (1) immediately make Pfizer aware of the opt out by e-mailing all relevant information to PTI@Pfizer.com; and (2) inform other colleagues who may interact with that HCP, so that the HCP’s request can be honored. The HCP may also submit questions or an opt out request directly to PTI@Pfizer.com.

It is critical for Pfizer colleagues to make sure that the U.S.-licensed HCPs with whom they interact are aware of Pfizer’s disclosure policy and the meaning of an “opt out.” An HCP who does not want to have items reported should not be offered – and must not accept – any payments, food, or other disclosable items from Pfizer. Pfizer maintains a record of HCPs who have “opted out” of receiving disclosable items from Pfizer on PfieldNet and OpSource.

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.

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If an HCP who has opted out subsequently chooses to opt back in, the notified colleague or the HCP should contact PTI@Pfizer.com.

Access and Use of Open Payments and other Transparency Data

Disclosures made pursuant to the Sunshine Act are available on CMS’s Open Payments website at http://www.cms.gov/OpenPayments/index.html. If you have questions about the data or want to use or perform analyses using these data, please contact the Transparency Team at GlobalTransparencyAnalytics@pfizer.com.

Understanding the Opt Out Process

Q. 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?
A. Generally, yes. However, any HCPs in the office who have opted out must not be provided the meal.

Q. 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?
A. The HCP must be informed that any meals consumed will be reported, and the HCP’s name must be included in the list of attendees in the relevant expense system (e.g., PT&E), so that an appropriate portion of the meal expense can be allocated to that HCP.

Q. An HCP is willing to provide consulting services for zero compensation, including no travel expense reimbursements. Will this arrangement be subject to disclosure?
A. Probably not. The HCP should still sign a “zero fee” consulting agreement to memorialize the terms. Please contact ENGAGE2@pfizer.com or your team attorney with any questions.
The Disclosure Process

Q. Will U.S-licensed HCPs have the opportunity to review their Sunshine Act data before it is posted on the CMS Open Payments website?
A. 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.

Q. How should I handle complaints by HCPs about Pfizer’s disclosure policy? What if an HCP believes that the information in Pfizer’s disclosures is incorrect?
A. Pfizer has a dedicated staff to address transparency questions and concerns raised by HCPs. You should send an e-mail to PTI@pfizer.com and copy your manager on the communication. The HCP may also send an e-mail directly to PTI@pfizer.com.

FOR MORE INFORMATION

- For more information 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 OpSource and under the Compliance tab on PfieldNet, or e-mail StateHealthcareLawCompliance@pfizer.com or PhRMACode@pfizer.com.
- For more information regarding processes for capturing and recording promotional meals in PT&E, refer to the guidance available on PfieldNet at http://pfieldnet.pfizer.com/workspace/Documents/PTE_Entering_in_a_Promotional_Meal_Expense.pdf.
- To determine whether an HCP is licensed in Massachusetts, Minnesota, or Vermont, Sales representatives should consult the physician profile within Veeva CRM, and other colleagues should consult the HCP Lookup Tool at http://hcplookup.pfizer.com/Pages/search.aspx. Additional information on state law restrictions and other tools is available under the Compliance tab on PfieldNet and under the State Healthcare Law Compliance tab on OpSource.
• For more information on Pfizer’s HCP transparency practices, including its U.S. HCP Payment Disclosure and State Reporting SOP, refer to the Compliance tab on PfieldNet and the HCP Payment Disclosure tab on OpSource or e-mail PTI@Pfizer.com.

## Chapter 19: SALES ACTIVITIES: GREENSTONE AND PFIZER INJECTABLES

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Chapter 19: SALES ACTIVITIES: GREENSTONE AND PFIZER INJECTABLES

Introduction

Sales of Pfizer Injectables (including legacy Hospira products) and Greenstone products to customers, including Accounts such as pharmacies, wholesalers, hospitals, and group purchasing organizations (GPOs), are important to Pfizer's success. To fulfill our legal and regulatory responsibilities, it is also vital that sales activities be conducted according to Pfizer policy and procedures.

This Chapter is applicable to all Greenstone and Pfizer Injectables (including legacy Hospira) Colleagues. Non-compliance with these policies puts the Company at risk and can subject colleagues to disciplinary action up to and including termination of employment.

For the purposes of this Chapter, the term “healthcare professional” (HCP) is defined broadly to include any individual who interacts directly with patients or has a role in patient diagnosis or treatment. It includes nurses, nurse practitioners, physicians, and dispensing pharmacists. It also may include individuals who do not work directly with patients but have influence over the recommendation, purchase, or prescribing of Pfizer products – such as health plan administrators, Pharmacy & Therapeutics Committee members, and Formulary Committee members who do not see patients. Generally, the term HCP does not include administrative staff such as receptionists, office managers, and case or file managers. It is important to note, however, that the definition of HCP may differ in certain contexts as demonstrated throughout this Orange Guide (including, for example, how states define HCPs in the context of applicable state laws). Generics purchasers at wholesale and retail customers are not considered HCPs for the purposes of this Chapter.
Key Points to Ensure Compliance

- Never engage in any actual or perceived quid pro quo. Anything given to or received from a customer must be considered in light of anti-kickback laws as well as Pfizer's policies.
- Any payment or gift to customers may implicate pricing and discount considerations.
- Any items you provide to customers must be Review Committee-approved and comply with the policies in this Chapter.
- All meals, including meals provided in conjunction with any customer or other meeting, must adhere to the policies in this Chapter.
- The proper process must be followed when purchasing exhibit or display space at a conference, trade show, or other event in accordance with this Chapter.

Never Engage in Actual or Perceived Quid Pro Quo

Anti-Kickback Laws

Quid pro quo is Latin for “this for that.” This means offering or appearing to offer any remuneration or item of value in exchange for purchasing, prescribing, dispensing, formulary positioning or formulary acceptance. The decision of an HCP to prescribe, recommend, or dispense a Pfizer product must be based on the best interests of the patient and not on any item of value offered to the prescriber.

This principle governs the relationships between Greenstone and Pfizer Injectables and their customers. Any remuneration from a manufacturer provided to a purchaser that is expressly or impliedly related to the purchase of a Greenstone or Pfizer Injectables product potentially implicates the anti-kickback laws. Providing a donation or any funding, including sponsoring any customer event, also may implicate the anti-kickback laws. This includes charitable contributions if the contribution is given to a customer or a charity affiliated with a customer as well as donations to patient awareness programs run by customers.

Please review Orange Guide Chapter 1: Overview and Key Principles for more information on the anti-kickback laws.

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Pricing Considerations

Any amount of money or items of value given to a customer, no matter how small, may implicate pricing considerations. Any donation, funding, or sponsorship to a customer could be considered to be a “discount.” A discount offered to one customer may have to be offered to other customers.

The Robinson-Patman Act prohibits a seller from discriminating among its commercial customers with respect to price, or promotional allowances or services, in certain circumstances. “Price” in this situation means transactional, or net, price, taking into account discounts, rebates, prompt payment terms, and other factors affecting price.

The government’s increased role as a purchaser of prescription medicines in the past few years has heightened its attention to enforcement of the laws and regulations concerning the Medicaid Drug Rebate Program. Under the law, manufacturers have certain reporting responsibilities and are required to provide the federal government with a rebate for each unit of product paid for by State Medicaid agencies.

Please review the Overview and Key Principles Chapter and Orange Guide Chapter 2: Interactions with HCPs for information on the Medicaid Best Price Law and the False Claims Act, as well as Corporate Policy 603: Compliance with Antitrust Laws.
Providing Funding to Customers

Q. What are the considerations involved in deciding whether I can approve a donation to a pharmacy’s patient awareness program? The money would fund the distribution of sunscreen to patients when they fill prescriptions for medications that increase photo-sensitivity.

A. This request might be considered a discount, which Pfizer Injectables or Greenstone might then need to offer to other customers or consider for its government price reporting. Any payment or gift to customers also must be considered in light of potential anti-kickback concerns. Consult with your team attorney about the propriety and potential implications of making such a donation.

Q. What if the donation requested would be paid to a foundation or other not-for-profit organization?

A. Donations to not-for-profit organizations must follow the procedures set out in the Standard Operating Procedure on Funding Requests for Not-for-Profit Organizations. However, if a not-for-profit organization is affiliated with a customer (such as a foundation established by a pharmacy), a donation may raise potential anti-kickback concerns, and you should consult with your team attorney.

When a funding request relates to a not-for-profit organization, please refer to Orange Guide Chapter 3: Support of External Organizations. The Standard Operating Procedure (SOP) on Funding Requests for Not-for-Profit Organizations, available on Opsource, applies to all funding to not-for-profit organizations.

Giveaway Items

Items of nominal value, such as pens, may be distributed by Greenstone and Pfizer Injectables at booths at trade shows and conferences, provided the criteria listed below are met. Such items must not, under any circumstances, be distributed in the field (e.g., at hospitals or to practicing pharmacists), nor may these items be made available through the PROMOS online catalog or other sources accessible by all colleagues.

The following criteria must be met for non-Hospital Surgical Sales Colleagues to distribute items of nominal value at a trade show, meeting or convention:

- No “detailed” products are displayed (e.g., no Thrombin-JMI or Dyloject);
The majority of attendees at the trade show must be non-HCPs or non-practicing HCPs (e.g., GPO meetings, wholesaler trade shows, pharmacy buyer conventions);

No clinical information will be discussed; and

No other Pfizer brands with clinical detailing messages are represented at the event.

### Providing Give-aways to Customers

Q. Can we give away Pfizer Injectables pens to our customers in the field or on sales calls?

A. No. Pfizer Injectables may only give away the pens (and similar approved reminder items) at the Pfizer Injectables booth or table at meetings and conventions if no Pfizer brands currently promoted with clinical detailing messages are represented at the same event, no “detailed” products are displayed, the majority of the attendees at the meeting or convention are non-HCPs and/or non-practicing HCPs, and no clinical information will be discussed. There are certain local or regional meetings that Pfizer Injectables will attend and other Pfizer brand teams will not. It is OK for the Pfizer Injectables team to distribute pens at these local or regional meetings when Pfizer Injectables is the sole Pfizer group attending and no “detailed” Injectables product is being displayed. Prior to arranging to distribute reminder items at an event, please contact the convention or meeting organizers to confirm that no other Pfizer teams will be attending or exhibiting.

You must never tie giving something of value – even something of nominal value – to an HCP’s or other recipient’s purchasing, prescribing, dispensing, or recommendation of a product. Doing so exposes both you and Pfizer to substantial legal risk and is strictly prohibited.

### Business Meals Provided by Greenstone and Pfizer Injectables Colleagues

Greenstone and Pfizer Injectables Account Managers, excluding the Hospital Surgical Team and any other colleague who provides clinical “detailing” of a product, may host business meals at restaurants for non-HCP customers and HCPs who hold administrative positions and dedicate very little time, if any, to seeing patients or filling prescriptions. For purposes of this Chapter, “Greenstone and Pfizer Injectables Account Managers” include persons titled Director - National Accounts, Regional Business Manager, Territory Business Manager, and Territory Representatives. The Pfizer Injectables Hospital

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Surgical Team (including legacy Hospira Sales Colleagues) and any colleague who provides clinical “detailing” of a product must comply with the business meals guidance provided in Chapter 18: Meals, Educational Items, and HCP Payment Disclosure.

Inclusion of a customer’s spouse or other guest in the meal is not appropriate unless the spouse or guest is an individual who has a legitimate business reason to attend.

Meals must be modest by local standards and cannot exceed an amount of $135 per attendee — including the cost of food, beverage, tax, and tip. A meal should never be the primary focus in speaking with customers. The central focus must be the business discussion, with the meal being incidental to that primary purpose. In addition, providing excessive or solely alcoholic beverages is prohibited, is considered not conducive to a business discussion, and is presumed recreational.

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<td>Greenstone and Pfizer Injectables Account Managers: Director – National Accounts, Regional Business Manager, and Territory Representatives</td>
<td>Only for non-HCP customers and HCPs who do not regularly see patients or fill prescriptions</td>
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You cannot provide any food or other support in connection with an accredited continuing medical education activity (ACCME, ACPE, or ANCC). Note that “medical education” is not limited to medical education for physicians but includes education for other HCPs, including pharmacists. Even if you are offered time to promote while providing a meal to attendees at an accredited medical education conference, you must decline the opportunity since providing a meal could be considered inappropriate support for that conference. Any type of financial support for accredited continuing education, including payment for event expenses or meals, must be funded through an independent professional education grant. Requests for these grants should be sent by the requestor through Pfizer’s

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Independent Grants for Learning & Change group (IGL&C) website. For more information, see Orange Guide Chapter 3: Support of External Organizations. If certain prerequisites are met, there may be an opportunity for an exhibit or display to promote Pfizer Injectables or Greenstone products at an accredited continuing medical education activity. For more information, see Exhibits and Displays below; Funding Requests for Not-for-Profit Organizations, USFR-SOP-01-02; and Exhibits and Displays SOP 2-01.

Activities in Connection with Customer and Other Meetings

Customer-sponsored meetings of customers, such as trade shows and member or affiliate meetings, may provide an excellent opportunity to promote Pfizer Injectables and Greenstone products to those in attendance.

When deciding whether to conduct legitimate sales activities in connection with such meetings you must evaluate your goals, determine whether your business purpose is appropriate, and exercise good judgment. Conducting a sales activity, such as an exhibit or display, in this circumstance must be based on a legitimate business purpose to present information about Pfizer Injectables or Greenstone products and cannot be based on a desire to support or otherwise fund an independent meeting or entertain customers.

Follow these key principles to ensure that the promotional activities you conduct in conjunction with customer-sponsored meetings are appropriate:

- If a meal is being provided, adhere to all Pfizer policies and processes regarding business and speaker program meals; and
- Make it clear to the customer or organization that Pfizer Injectables or Greenstone is funding or participating in specified, permitted activities and will receive specified, permitted tangible benefits.

It is important to remember that if a Pfizer Injectables or Greenstone Colleague participates in any way in the content of a non-Pfizer meeting, the entire meeting may be considered a promotional event, in which case it would be governed by the same promotional rules that apply to all Pfizer promotional activities.

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Exhibits and Displays

Pfizer is often given the opportunity to promote Pfizer Injectables and Greenstone products and provide approved information and materials to customers by paying for an exhibit, display table, or booth at an event. An exhibit or display opportunity can occur at a variety of venues and programs, but the key principle for you to remember is that Pfizer or Greenstone is paying for the space to promote our products (and in some cases our name) and must not pay more than fair market value for the display opportunity.

Money allocated to fund an exhibit or display at independent educational programs may not be used to fund other aspects of the program (e.g., speaker honoraria, requestor's rental expenses, and food). Likewise, you should never try to bypass the grant approval process by submitting an exhibit or display request when the funding is really going to the non-promotional aspects of a program. Promotional and non-promotional funding must always be separated, easily identifiable and tracked for auditing purposes. The location of the display should also be separate and apart from any independent educational activity.

The same criteria apply to all exhibits and displays, regardless of their cost. In addition to appropriate legal review and approval, your manager(s) must also approve the request before the day of the event.
Key Factors to Consider when Evaluating Fair Market Value

- The opportunity for promotion to large numbers of people or an audience that is difficult to access without the display opportunity;
- The size of the table or booth and the number and the roles of colleagues who may work the table or booth;
- The length of time given to Pfizer to engage in promotional discussions with event attendees;
- The physical location of the table or booth in relation to those attending an event;
- Availability of electricity or internet and computer connections; and
- Whether setup and cleanup are included in the exhibit and display fee.

In addition to these factors, you must make sure that if other companies are displaying, all exhibitors are being charged consistent amounts for the same type of space. It is also acceptable if all exhibitors are being charged the same fee but Pfizer has negotiated to pay a discounted rate.

Often the event brochure or prospectus will list the cost levels of exhibit and display opportunities and describe the space and services that are being purchased at each level. This type of brochure or prospectus should accompany your exhibit or display request whenever possible because it helps to validate the fair market value of the exhibit opportunity.

Please refer to the Exhibits & Displays SOP for the procedure to be followed.

Also refer to OpSource when:

- The space purchased is at an event held by a not-for-profit organization, and
- Either: (a) the request is initiated by someone other than a U.S. Sales Colleague; or (b) a U.S. Sales Colleague purchases a package from a third party not-for-profit organization that includes other benefits in addition to the exhibit and display space.
State Laws

State laws on providing meals and other items of value

Note that the rules in certain states may be more restrictive than the PhRMA Code. For example, Vermont, Minnesota, and Massachusetts significantly restricts Pfizer's ability to provide meals and other items of value to HCPs. These laws apply to all colleagues and extend to interactions occurring with HCPs licensed in those states even if they are practicing outside the state. Further, the definition of an HCP is certain states much broader than the PhRMA Code definition. E.g. The Vermont definition of an HCP includes any person licensed to prescribe products or authorized to recommend prescribed products, officers, agents, and employees of HCPs, any person authorized to dispense or purchase for distribution prescribed products, and members of the Green Mountain Care Board (whether or not they are licensed HCPs). For more information on whether your activities are affected by state laws, see Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions or contact your team attorney.

State pharmaceutical compliance and disclosure laws

A growing number of states are requiring companies to monitor their annual expenditures relating to marketing activities to comply with annual spending limits and disclosure requirements. Since the passage of Minnesota's marketing disclosure and restriction law in 1993, several other states including California, Connecticut, Nevada, Maine, Massachusetts, Vermont, and West Virginia, as well as the District of Columbia, have enacted laws imposing varying spending limitations and disclosure requirements on companies that market prescription products in those states. In addition, some states require price reporting of AMP and Best Price to state government agencies. For more information on whether your activities are affected by state pharmaceutical compliance and disclosure laws, see Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions or contact your team attorney.
State law example: Vermont law

Q. Does the law apply to account directors who support our generics business and who deal with buyers at large customers?
A. Yes. The Vermont restrictions apply to all colleagues interacting with any persons authorized to dispense or purchase prescribed products for distribution because these persons are included in the definition of HCP.

FOR MORE INFORMATION

- For more information on anti-kickback laws, the Medicaid Best Price Law, and the federal False Claims Act, see Orange Guide Chapter 1: Overview and Key Principles.

- For more information on funding requests, see Orange Guide Chapter 3: Support of External Organizations.

- For more information on the PhRMA Code, including FAQs, see the Compliance tab on PfieldNet.

- For more information on whether certain activities implicate state laws, see Orange Guide Chapter 17: State Laws: HCP and State Employee Restrictions.

- Questions may be referred to your manager or team attorney.
Chapter 20: HEALTH INFORMATION TECHNOLOGY ENGAGEMENTS

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Chapter 20: HEALTH INFORMATION TECHNOLOGY ENGAGEMENTS

Introduction

Pfizer’s customers are increasing their use of Health Information Technology (“HIT”), particularly Electronic Health Records (“EHR”) systems. Pfizer engages with customers regarding their EHR systems in many ways, offering both branded and unbranded resources (“HIT Tools”) and associated messaging. HIT engagements seek to provide education about products or disease states, to promote Pfizer products, or to expand the market in therapeutic areas where Pfizer has a public health goal as well as a business interest.

In order to manage legal risks appropriately, it is important for all Field Commercial Colleagues to understand: (a) what HIT Tools Pfizer may provide to customers; (b) which Pfizer Field Commercial Colleagues may provide HIT Tools to customers; and (c) appropriate messaging about HIT Tools:

- If a colleague gives – or could be perceived as giving – a customer an HIT Tool or expertise as an inducement for prescribing or recommending a Pfizer product, then that could implicate state and federal anti-kickback statutes.
- Further, if an offering of value inadvertently affects or could appear to affect the prices of Pfizer products that a customer is purchasing, that could cause Pfizer to inaccurately report the price of its products in its submissions to the federal government under the Medicaid Drug Rebate Program and other health care programs (e.g., Best Price).
- Field Commercial Colleagues should deploy only those HIT Tools approved by the relevant RC specifically for their role. RC approval of HIT Tools is tailored to both the customer type and the role of the Pfizer colleague delivering the Tools based on their HIT expertise. Some HIT Tools are intended for Sales Colleagues, while others are only appropriate for use by Account Managers. Implementation of and messaging about these Tools should remain within the scope of their intended audience and purpose.
- Discussion around and implementation of both branded and above-brand HIT Tools must be consistent with any relevant Pfizer product’s FDA approved labeling.
Pfizer has payment disclosure obligations under the Sunshine Act and in some States. Generally, the HIT Tools are designed not to have value that would require a disclosure. In certain circumstances involving HIT Specialists, the provision of HIT Tools and expertise may constitute a reportable transfer of value to the customer. When a disclosure may be necessary, you should discuss the matter with the customer prior to the provision of the Tools in question.

Since HIT engagements with customers carry legal risk, require proper training and expertise, and potentially require a disclosure, Field Commercial Colleagues must always take care to ensure that any customer engagement regarding HIT is consistent with Pfizer policy and is properly implemented.

**Key Points to Ensure Compliance**

- You may use approved HIT Tools. It is your responsibility to ensure the material you intend to use has received appropriate approval before use with customers, and that the material remains current and approved for your intended use. Additionally, ensure that you use the materials in accordance with any guidance or instructions relating to the use of such materials.
- When offering or providing approved HIT tools or resources, do so without any expectation of financial return to Pfizer. Do not condition the offer or provision of a program on increased prescribing or improved formulary status.
- To avoid implicating pricing concerns, avoid combining types of transactions. Do not discuss HIT tools and resources with formulary discussions. Do not attempt to leverage any additional (e.g., non-formulary) arrangements in order to secure preferential formulary status.
- Ensure that your use of HIT Tools is consistent with their approved purpose and your role as a Field Commercial Colleague. Do not engage in HIT related medical activities that MOS or FMD Colleagues typically engage in, such as discussing appropriate diagnostic codes. Similarly Sales Colleagues and Account Managers should not engage in technical discussions around HIT Engagements that HIT Specialists typically conduct.
Core Compliance Principles for HIT Engagements

The Core Compliance Principles apply to HIT engagements. As a reminder, those Core Compliance Principles as applied here are as follows:

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

Use only RC-Approved Materials

Both Pfizer and you could be held responsible for what you say or show to customers in the scope of your employment, and that could include HIT Tools and related messaging. When engaging a customer on any HIT topic, whether branded or unbranded, you must adhere to the following guidance:

- Use with customers only materials that have been approved by the relevant Review Committee (RC) for that use.
- HIT Tools should be used only by the Field Commercial Colleagues for whom they are approved. Sales Colleagues should only use RC-approved HIT Tools available to them through PROMOS or Veeva CRM. Similarly, Account Managers and the members of their Account Team (which can include Medical Outcome Specialists or your Business Unit’s equivalent) and HIT Specialists should only use RC-approved HIT Tools available on the Customer Resource Center (CRC).
- Colleagues may not alter RC-approved materials except where specifically authorized by the RC. For example, an RC approved template may permit a colleague to customize an HIT resource by inserting the customer’s name.
- Approval for one purpose does not mean approval for all purposes. Resources approved for a particular customer may only be used with that customer.
- Customer discussion and implementation of some HIT Tools will require input from Medical colleagues. See below for further discussion and consult your team attorney if you require guidance on when to involve field-based Medical.
- In limited circumstances, your team attorney may allow for the use of certain customized resources that have not been RC approved. This will occur most frequently in the context of

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workflow assessments collaborations, and discussions leading to a collaboration. See below for additional information on workflow assessments and collaborations with an HIT component.

**Stay On-label**

Pfizer may only promote FDA-approved products and FDA-approved uses and dosing of its products, and you may only discuss approved products, indications, and dosing in accordance with RC-approved materials. This guidance applies to your discussions with customers about HIT Tools.

Some HIT Tools are branded and mention a specific Pfizer product. Other HIT Tools will be “above brand” and have no Pfizer product mentioned but rather discuss a therapeutic area or HIT generally. It is essential that you adhere to the RC-approved messages when using HIT Tools, whether the HIT Tool contains branded content or is unbranded but addresses a therapeutic area for which a Pfizer product might be prescribed. Remember that it is possible to promote a Pfizer product inappropriately without mentioning the product and when speaking “above-brand.” Therefore, Field Commercial Colleagues must not encourage or implicitly suggest off-label use of a Pfizer product in any unbranded HIT discussion. In all cases, HIT Tools have been RC-approved to help ensure consistency with the FDA-approved labels for our products.

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**Listing of Pfizer Products in an EHR System**

Q. 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 prescriber can find it easily on their screen. I know that a Pfizer product is expected to be approved by the FDA in the near future. Am I permitted to speak with my customer about how to list the product in the EHR, so it will be listed in their EHR system as soon after it has been approved as possible?

A. Generally, it is not appropriate for commercial colleagues to discuss a product with a customer prior to FDA approval. If no RC-approved materials or messaging exist, such discussions are not permitted.
**Fair Balance**

The FDA requires that product presentations include “fair balance” and therefore presentations about Pfizer’s products must include a discussion of a product’s benefit and risks. Similarly, HIT Tools that are branded, and some that are not branded but are closely associated with a product, may also require that Field Commercial Colleagues provide the relevant safety information to “balance” any statements regarding a product’s efficacy. For example, a conversation about securing the listing of a product in an EHR may include express or implied statements about the efficacy of a product. In those instances, fair balance would be required. The HIT Tool and any associated implementation guidance provided by the relevant RC should provide instructions on whether fair balance is necessary.

**Never Engage in Actual or Perceived quid pro quo**

You must never offer nor appear to offer any remuneration, service, or item of value to induce or influence an HCP to prescribe a product or position it on formulary. The decision to prescribe or recommend a product must be based on the best interests of patients and not on anything of value offered by or on behalf of Pfizer. This is of particular concern when engaging customers on HIT.

You may only provide customers with HIT Tools for reasons consistent with the purpose for which the resource was approved. Branded HIT Tools may be offered to educate customers about the appropriate use of our products. Above-brand HIT Tools may educate customers about improving patient outcomes and promoting quality healthcare without referring to particular Pfizer products.

HIT Tools have been RC-approved to ensure that they do not constitute an inappropriate quid pro quo when delivered in a manner consistent with implementation guides and other RC-approved instructions. Under no circumstances should any Pfizer colleague, including an HIT Specialist, conduct any programming, coding, or actual operation of the customer’s HIT system.

You must not present or characterize HIT Tools as assisting customers in obtaining financial incentives, reimbursements, or increased revenue.
HIT Engagements and Meaningful Use Requirements

Q. I’m a KAM and I’d like to work with a customer to develop an improved workflow for identifying smokers and providing smoking cessation treatment where appropriate. I’ve consulted with my HIT Specialist and would like to engage the customer on the HIT-related aspects of this project. The customer is unsure if it wants to work with us on this. In explaining why this might be of interest, can I or the HIT Specialist explain how Pfizer can help the customer improve its ability to satisfy Meaningful Use requirements?

A. No. Providing HIT Tools or expertise with the express or implied purpose of aiding the customer in satisfying Meaningful Use requirements could expose Pfizer to liability under the anti-kickback laws. In this instance, the proper approach would be to avoid the topic of Meaningful Use, except where expressly permitted in RC-approved materials and instead focus on how Pfizer and the customer can work together to ensure better care for the customer’s patients.

Q. I understand that I cannot proactively initiate that discussion, but what if the customer asks about how Pfizer can help it satisfy Meaningful Use requirements? At that point, can we discuss Meaningful Use strategies?

A. 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 Meaningful Use. Although the appropriate use of some Pfizer resources could potentially affect whether a customer meets some Meaningful Use criteria, Pfizer should never deliver these resources with the purpose of helping the customer to increase its revenue, reimbursements, or eligibility for financial incentives. See the FAQs in Chapter 5 for additional details on Collaborations that could positively impact a customer’s reimbursement.

Your Role in an HIT Engagement

As our customers’ breadth and depth of EHR use increases, Pfizer seeks to educate customers about its products and improve patient care through appropriate and compliant engagement on HIT issues. This section provides an overview of how different Field Commercial Colleagues may pursue these HIT engagements. If you are unsure whether a certain activity might be in scope for your role, contact your team attorney.
Sales Colleagues

Traditional Sales Colleagues – most notably sales representatives and district business managers – may only engage customers on HIT topics in two ways. They may deploy RC-approved HIT Tools approved specifically for use by Sales Colleagues. Examples may include pieces that explain how to place Pfizer products in their bookmarks or favorites list. All HIT Tools approved for Sales Colleagues are available on PROMOS. If a resource is not available on PROMOS, it is not approved for use by Sales Colleagues. Secondly they may engage a customer on HIT issues is in identifying leads and introducing Account Team members to key customer contacts. Sales Colleagues may play a critical role in connecting Pfizer Account Team Colleagues with the key individuals at customers who have account management responsibilities, which may include responsibilities directly or indirectly related to HIT. This role may require limited discussion of HIT to gauge interest and determine the appropriate contact, but it should not involve the use of any HIT Tools not approved for Sales Colleagues.

Sales Colleagues Role in Introductions

Q. I am a sales representative, and I recently learned that a doctor I have called on for years has taken on a key HIT role in his medical group. May I ask her if she would be interested in discussing HIT and quality initiatives with a Pfizer KAM? Could I sit in on the meeting?

A. This would be a good example of where it is appropriate for the sales representative to assess the HCP’s interest in meeting with the Account Team to cultivate a lead. And to the extent it would help facilitate the meeting, the representative may show up in person at the first meeting to introduce the KAM.

Q. I am a sales representative and I was speaking with a KAM in the lobby of a hospital when an HCP I know with HIT responsibilities came walking by. I introduced the HCP to the KAM, and the two of them agreed to meet next week to discuss HIT issues. May I join them for that first meeting?

A. No. At this point, the KAM and the HCP have already met each other, and the presence of the sales representative at the scheduled meeting would not do anything further to facilitate the introduction. There is no other proper justification for the sales representative to sit in on the meeting, so he/she should not attend.
Account Managers

As discussed in Chapter 1, Account Managers are Field Commercial Colleagues with account management responsibilities, such as KAMs, Oncology KAMs, and VAMs. Account Managers may deliver branded and unbranded HIT Tools and associated messaging approved for their use and consistent with the training they have received. An example of a branded HIT Tool is a piece to educate HCPs on how to bookmark a Pfizer product in an EHR system. An example of an unbranded HIT Tool is a value proposition deck about incorporating above-brand screeners and patient education materials into an EHR. All customer-facing content must be RC-approved for use by account managers. This means that the resource in question should be available on the Customer Resource Center at crc.pfizer.com. Account Managers should take care to ensure that the piece they would like to use not only has been approved by an RC but also that the piece has not expired.

Using Approved HIT Resources

Q. In discussing a quality initiative relating to fibromyalgia, one of my fellow KAMs recently told me that she had a positive experience sharing a particular RC-approved resource with the customer. She sent it to me by e-mail and told me that it is approved to show a customer on the iPad, but it is not approved to leave behind. May I show this to my customer at my next meeting about fibromyalgia?

A. Maybe, but you should not use an e-mailed copy. Before using the resource, you should first check to see that the piece is currently available on the CRC. 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 the CRC.

Some of the HIT Tools approved for Account Manager use are designed to spur discussion about how Pfizer can work with the customer to improve patient care. These HIT Tools may set the stage for more advanced discussions that may require the involvement of an HIT Specialist. To ensure consistency and availability, Account Managers should always confer with their HIT Specialist before proposing the use of any HIT Tools to a customer.

HIT Specialists

HIT Specialists are a type of Account Manager and member of the Account Team with advanced HIT expertise as well as account management training in relevant therapeutic areas. Accordingly, there are
certain HIT Tools, including some unbranded, disease-state specific resources that only an HIT Specialist may share with a customer. Except as described below, these HIT Tools must be RC-approved for the intended use, and HIT Specialists may only use them if they are available on the CRC. These Tools may include value proposition decks focusing on a particular therapeutic area, as well as screeners, questionnaires, and patient education materials that may be incorporated into a customer’s workflow and/or EHR system.

HIT Specialists work with Account Teams to build on discussions initiated with a customer by the Account Team. Accordingly, Account Team Colleagues must consult with their HIT Specialist to anticipate those situations where the HIT Specialists’ expertise may be necessary to engage the customer on topics involving HIT. This consultation ensures that the Account Team and the HIT Specialist are providing an appropriate, consistent, and compliant HIT message, and it also confirms that the HIT Specialist will be available to work with the customer in a timeframe that works for all parties.

HIT Specialists are not intended to be general HIT consultants for customers. Instead, HIT Specialist engagements with customers should be limited to approved HIT Tools and messaging. In many cases, this means the deployment of RC-approved HIT Tools found on the CRC. In other instances, an HIT Specialist may participate in the development of customized solutions for the customer under an approved collaboration agreement. Furthermore, while they may discuss with the customer how best to develop, build, and deploy these HIT Tools, Pfizer HIT Specialists are not authorized to perform the actual computer programming or coding necessary to implement the resource.

**Appropriate Interaction with HIT Specialists**

**Q.** I am a district manager, and I want my representatives to learn more about HIT so that they may properly deploy approved HIT Tools as well as identify leads for the Account Team. May I invite an HIT Specialist to provide training to my sales representatives team on EHRs and other HIT topics?

**A.** No, that would not be an appropriate request of an HIT Specialist. Field Commercial Colleagues seeking additional HIT training should reach out to the training team to find the appropriate training resources and to identify additional learning needs.
Role of Medical in Account Team Activities Involving HIT

Some HIT engagements may require discussion of clinical topics with the customer. In those instances, the Field Medical Colleagues for your Business Unit (such as a MOS) should be involved early in the process to ensure that they can provide appropriate input. For example, if an HIT Specialist is providing an RC-approved screener to the customer for insertion into the EHR, and the screener requires the customer to make certain clinical decisions about what kinds of information should be factored into the screening process, then it would not be appropriate for the HIT Specialist to discuss those clinical decisions. The HIT Specialist and the account manager have a duty to work with their MOS to anticipate those situations where the MOS’s clinical expertise may be necessary to assist the customer with the proper implementation of the Pfizer resource.

Consultation with MOS

Q. How do I know if the implementation of a screener might require clinical decisions?
A. In the absence of specific RC guidance on this topic, always consult your MOS before working with the customer to implement the screener. There may be instances where decisions have to be made about what diagnostic codes provide appropriate sources of data, and the MOS may be best equipped to make those decisions.

HIT Engagements

The length, structure, and complexity of an HIT Engagement can vary with the objectives of Pfizer and the customer. A simple HIT Engagement may consist of one face to face meeting using a single approved HIT Tool. A more complex engagement may require the expertise of an HIT Specialist. The complexity of the HIT Engagement will most often depend on the customer’s level of sophistication with regard to HIT. Below outlines a typical HIT engagement where the involvement of an HIT Specialist is necessary to determine whether opportunities exist to implement an HIT Tool.

Account Engagement

In this first step, an Account Manager will work with the customer to understand customer needs, and whether those needs overlap with Pfizer business objectives. In the event the customer and Pfizer can
agree upon mutually aligned business objectives intended to improve patient care (e.g., smoking cessation), the Account Manager will further determine whether an opportunity exists to engage the customer around HIT. It is at this point the Account Manager should coordinate with the HIT Specialist to determine what steps, if any, may be taken towards an HIT engagement.

**Workflow Assessments**

Assuming customer agreement and proper coordination between the customer, Account Manager and HIT Specialist, the next step may be for the HIT Specialist to conduct a workflow assessment. A workflow assessment is an in-person evaluation of how a customer’s patients flow through its HIT system and how the use of the system affects the identification and management of patients in a designated therapeutic area. The HIT Specialist conducts the workflow assessment to identify opportunities to incorporate Pfizer-approved HIT Tools designed to improve patient care in the therapeutic area in general. The workflow assessment should not be remunerative and should not constitute a transfer of discernible value to the customer. It is not appropriate for HIT Specialists or Account Team Colleagues to provide expertise on the overall use of the customer’s HIT system or otherwise provide general HIT consulting services. Rather, the HIT Specialist should narrowly tailor the assessment and its recommendations to customers to further the implementation of approved HIT Tools in a relevant therapeutic area.

**Workflow Assessment and HIT Specialist**

**Q.** Who may conduct an HIT workflow assessment?

**A.** Only an HIT Specialist may conduct a workflow assessment. While other Account Team members may possess substantial experience with HIT, only the HIT Specialists have the training, guidance, and experience to perform this assessment.

To conduct the workflow assessment, the HIT Specialist will likely meet with the customer in person and review how the customer interfaces with the electronic health record for a hypothetical patient (i.e., test patient) in the therapeutic area in question. Under no circumstances should an HIT Specialist observe the treatment of actual patients or the protected health information of any patient. It is the responsibility of each Pfizer colleague to ensure that they are not exposed to protected health information. A confidentiality agreement will not address patient privacy concerns and does not permit

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Pfizer employees to receive protected health information. Furthermore, Pfizer does not act as a business associate for purposes under HIPAA. If you are asked to sign a confidentiality agreement or business associate agreement, contact your team attorney.

**Purpose of a Workflow Assessment**

**Q.** I’m an HIT Specialist, and I worked with a KAM to schedule an assessment of an integrated delivery network’s workflow for patients with diabetic pain and for patients with atrial fibrillation, two therapeutic areas for which Pfizer has approved HIT Tools and resources. The customer has also asked that we provide feedback on the workflow for obesity as well as general connectivity problems with different locations. Can I provide the customer the information it seeks?

**A.** Absent an approved collaboration or other unique arrangement approved by management and legal for the proposed purpose, an HIT Specialist should not provide the requested feedback on obesity and connectivity. The HIT Specialist should confine the workflow assessment to the topics of diabetic pain and atrial fibrillation, where Pfizer has an appropriate interest in patient care and also has approved tools and resources. A workflow assessment for obesity would likely be inappropriate, as it is not a therapeutic area aligned to Pfizer interests, nor do approved tools and resources exist. Workflow assessments should focus on opportunities to implement approved HIT tools. Similarly, addressing general connectivity problems is neither aligned to Pfizer strategy nor tailored to improving patient care. Instead, assessments in those areas could be construed as inappropriate HIT consulting services that could expose Pfizer and the HIT Specialist to liability under the anti-kickback laws.

Upon completion of a workflow assessment, the HIT Specialist may draft a report of the findings. The report should be high-level, describing opportunities where Pfizer and the customer might work together to improve patient care, but it should not contain detailed recommendations or solutions. Workflow assessment reports should not contain any guidance regarding the achievement of Meaningful Use guidelines, earning or obtaining financial incentives, or otherwise improving reimbursement. The scope of the workflow assessment report should be limited to the relevant therapeutic area and should not go beyond the implementation of Pfizer approved HIT Tools or the use of existing functionality necessary to implement the approved HIT Tool.
Workflow assessment reports do not require RC approval, but they must be approved by the appropriate team attorney. HIT Specialists also should consult the other Account Team members to ensure that the report: (1) is consistent with Pfizer strategies in the relevant therapeutic area; and (2) contains accurate and appropriate feedback with respect to any clinical or medical topics.

**Post-Workflow Engagement**

Once completed, the workflow assessment will be delivered to the customer and assist the Account Team and customer in identifying next steps in the engagement. In many instances, the workflow assessment will recommend delivery of one or more RC approved materials available on the CRC. When this occurs, the HIT Specialist, in consultation the other Account Team members may provide those HIT Tools to the customer. Where implementation of an approved HIT Tool requires discussion of clinical or disease concepts with the customer, the MOS should be consulted. As always, Account Team coordination is key.

In other instances, the workflow assessment may identify broader opportunities for customer engagement. When the workflow assessment suggests a more complex arrangement, requiring numerous approved tools, customization of existing tools, or significant time investment from both Pfizer and the customer, the Account Team should consider a collaboration. A collaboration, including one with 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. Chapter 5 of the Orange Guide sets out the factors by which one determines whether an engagement is a collaboration that requires Intake Committee approval and a collaboration agreement between Pfizer and the customer. Account teams should refer to Chapter 5 and consult with their team attorney to determine if an HIT engagement would be a collaboration and, if so, the process for ensuring compliance. In the absence of a collaboration agreement, HIT Specialists may only deliver RC-approved HIT Tools found on the CRC and associated messaging.

Collaborations are intended to be unbranded. Where a proposed collaboration may implicate a Pfizer product (for example, where the Pfizer product is the only product on the market with an approved indication in the relevant therapeutic area, or where the Pfizer product is the exclusive option for that customer’s patients), the Account Manager should consult with his or her team attorney before proceeding with the engagement.
Regardless of whether they are acting pursuant to a collaboration agreement with a customer, neither the HIT Specialists nor any other Account Team colleague may conduct any programming, coding, or actual operation of the customer’s HIT system. They may offer guidance to the customer regarding the design, build, and/or implementation of HIT Tools, but they must remain in an advisory role.

Additionally, HIT Specialists must be aware that their interactions with customers may, in certain instances, be subject to disclosure requirements under the Sunshine Act and some State laws. They should make sure that the customer is aware that Pfizer may have to disclose the time and value of their work, and they also should be sure to keep appropriate records of their time and the nature of their work. In order to assess the fair market value of programs an interactive Excel based worksheet tool has been developed to quantifying the value of certain activities. HIT Specialists should contact their team’s point of contact for assistance with use of the tool and to establish the value of a program.

**FOR MORE INFORMATION**

- For more information about when an engagement may become a collaboration, see Orange Guide Chapter 5: Interactions with Health Systems and Medical Groups.
- For more information about collaborations and collaboration agreements involving KAMs, including how to get them approved and prepared, see the Organized Customer Collaborations Process Guidelines.
- For information on the appropriate use of patient information, please see Orange Guide Chapter 8: Privacy – Protecting Personal Information.