Dear Colleagues:

At Pfizer, we are committed to upholding the highest standards when we interact with physicians, healthcare organizations, patients and other stakeholders. Our Healthcare Law Compliance Guide (commonly known as the White Guide) provides an overview of the laws, regulations, Pfizer policies and guidelines that govern our U.S.-based human biopharmaceutical business. It is essential that you familiarize yourself with the White Guide.

Every colleague is accountable for understanding and meeting our company’s compliance requirements. We encourage you to bookmark the White Guide as a reference to help ensure that you remain in compliance with all policies and procedures applicable to your work. Do not hesitate to consult with your team attorney if you have any questions or e-mail the White Guide team at WhiteGuide@pfizer.com.

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

Rady A. Johnson
Douglas M. Lankler
HOW TO USE THE WHITE GUIDE

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

For ease of navigation, the White Guide is embedded with “bookmarks” for each chapter topic and subheading. When you are reviewing the White 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 WhiteGuide@pfizer.com. This will help us continuously improve the White Guide to help meet your needs!

Sincerely,

The White 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.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Chapter</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>OVERVIEW AND KEY PRINCIPLES</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>ADVERTISING AND PROMOTIONAL MATERIALS</td>
<td>17</td>
</tr>
<tr>
<td>3</td>
<td>PROMOTIONAL INTERACTIONS WITH HCPs</td>
<td>36</td>
</tr>
<tr>
<td>4</td>
<td>MARKETING PROGRAMS</td>
<td>44</td>
</tr>
<tr>
<td>5</td>
<td>HCP AND GOVERNMENT OFFICIAL CONSULTING ENGAGEMENTS</td>
<td>62</td>
</tr>
<tr>
<td>6</td>
<td>GOVERNMENT HEALTHCARE PROGRAMS</td>
<td>84</td>
</tr>
<tr>
<td>7</td>
<td>SUPPORT OF EXTERNAL ORGANIZATIONS</td>
<td>101</td>
</tr>
<tr>
<td>8</td>
<td>NON-PROMOTIONAL AND MEDIA ACTIVITIES</td>
<td>128</td>
</tr>
<tr>
<td>9</td>
<td>CLINICAL RESEARCH AND INVESTIGATOR-INITIATED RESEARCH (IIR)</td>
<td>150</td>
</tr>
<tr>
<td>10</td>
<td>PATIENT ASSISTANCE PROGRAMS</td>
<td>174</td>
</tr>
<tr>
<td>11</td>
<td>PRIVACY: PROTECTING PERSONAL INFORMATION</td>
<td>189</td>
</tr>
<tr>
<td>12</td>
<td>PROMOTIONAL INTERACTIONS WITH CONSUMERS</td>
<td>210</td>
</tr>
<tr>
<td>13</td>
<td>PROMOTIONAL INTERACTIONS WITH EMPLOYER GROUPS</td>
<td>224</td>
</tr>
<tr>
<td>14</td>
<td>STARTERS</td>
<td>230</td>
</tr>
<tr>
<td>15</td>
<td>STATE LAWS: HCP AND STATE EMPLOYEE RESTRICTIONS</td>
<td>247</td>
</tr>
<tr>
<td>16</td>
<td>FEDERAL EMPLOYEE INTERACTIONS AND LOBBYING</td>
<td>283</td>
</tr>
<tr>
<td>17</td>
<td>PUBLICATIONS</td>
<td>307</td>
</tr>
<tr>
<td>18</td>
<td>MEALS, EDUCATIONAL ITEMS, AND HCP PAYMENT DISCLOSURE</td>
<td>316</td>
</tr>
</tbody>
</table>
Chapter 1: OVERVIEW AND KEY PRINCIPLES

CONTENTS

Overview and Key Principles

Introduction .................................................................................................................................................................... 3
Overview of Key Healthcare Laws and Regulations .................................................................................................. 4
  Anti-Kickback Laws .............................................................................................................................................. 4
  Safe Harbors from the Federal Anti-Kickback Statute ........................................................................................ 5
Medicaid and Medicare ................................................................................................................................................. 6
  Medicaid Best Price Law ...................................................................................................................................... 6
  Medicare Part D Regulations ................................................................................................................................ 7
FDA Laws and Regulations ............................................................................................................................................ 7
Labeling ......................................................................................................................................................................... 8
Advertising & Promotion .............................................................................................................................................. 8
Starters (Samples) ......................................................................................................................................................... 9
State Pharmaceutical Compliance and Disclosure Laws ............................................................................................ 9
Overview of Other Key Laws and Regulations ........................................................................................................... 10
  False Claims Act ................................................................................................................................................... 10
  Privacy Laws ........................................................................................................................................................ 10
  State Consumer Protection Laws .......................................................................................................................... 11
  Foreign Corrupt Practices Act ............................................................................................................................... 11
Industry Codes, Guidance, and Our Government Agreements ................................................................................ 12
  PhRMA Code ........................................................................................................................................................ 12

Rev. 01/16
PhRMA Guiding Principles – Direct To Consumer Advertisements About Prescription Medicines ..........12
OIG Compliance Program Guidance for Pharmaceutical Manufacturers ........................................ 12
Pfizer’s Government Agreements and Post-CIA Compliance ......................................................... 13
  Pfizer’s Corporate Integrity Agreements .................................................................................... 13
Pfizer’s State Attorneys General Agreements ............................................................................. 14
Violations and Penalties ................................................................................................................ 14
Pfizer’s Compliance Program ....................................................................................................... 15
FOR MORE INFORMATION ......................................................................................................... 16
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:

<table>
<thead>
<tr>
<th><strong>Key Healthcare Laws</strong></th>
<th><strong>Other Key Laws</strong></th>
<th><strong>Industry Codes, Guidance, and Government Agreements</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-Kickback Laws (state and federal)</td>
<td>False Claims Act</td>
<td>PhRMA Code on Interactions with Healthcare Professionals</td>
</tr>
<tr>
<td>Medicaid Best Price Law &amp; Medicare Part D Regulations</td>
<td>Privacy Laws</td>
<td>PhRMA Guiding Principles on Direct to Consumer Advertising</td>
</tr>
<tr>
<td>FDA Laws &amp; Regulations</td>
<td>State Consumer Protection Laws</td>
<td>OIG Compliance Program Guidance for Pharmaceutical Manufacturers</td>
</tr>
<tr>
<td>State Pharmaceutical Compliance and Disclosure Laws</td>
<td>Foreign Corrupt Practices Act</td>
<td>Pfizer’s State Attorneys General Agreements</td>
</tr>
</tbody>
</table>
**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 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. 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.

**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 prohibit improper influences on healthcare decisions by making it a criminal and/or civil offense to knowingly and willfully solicit, receive, pay, offer to pay, or provide anything of value 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.

**HHS:** Federal administrative agency that oversees Medicaid, Medicare, and other federally funded healthcare programs.

**OIG:** A legal department within HHS charged with enforcing federal healthcare laws and regulations and negotiating and overseeing Corporate Integrity Agreements.
A number of safe harbors are relevant to our business activities, but three are especially important:

- **Discount safe harbor**: allows Pfizer to discount the price of a product to make it competitive with other products, provided that the discount is properly reported to the government and complies with other safe harbor requirements.

- **Managed Care safe harbor**: permits Pfizer to provide a wide array of discounted items or services to certain eligible managed care organizations under specified circumstances.

- **Personal Services 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 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 accurately account for discounts or other price concessions 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 at a pharmacy trade show, 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 a 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 should 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 promotion 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**: A federal agency responsible for the regulation of most foods, dietary supplements, drugs, vaccines, biological medical products, blood products, medical devices, radiation-emitting devices, veterinary products, and cosmetics.

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**Labeling**

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

**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.

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**Advertising & Promotion**

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.

Any 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 benefits and risks. All promotional materials, unless exempted “reminders,” must also include the product’s package insert or, for certain advertisements, a brief summary relating to side effects, contraindications, and effectiveness.

With respect to interactions involving the promotion of Pfizer products, Field Commercial Colleagues must adhere to the policies set forth in the **Orange Guide Chapter 2: Interactions with HCPs**, and all other colleagues must adhere to the policies set forth in **White Guide Chapter 2: Advertising and Promotional Materials, White Guide Chapter 3: Promotional Interactions with Healthcare Professionals**.
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 personally benefit an HCP 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.

State Pharmaceutical Compliance and Disclosure Laws

In addition to the federal government, a growing number of states are regulating pharmaceutical companies’ interactions with HCPs. These laws and regulations include restrictions and sometimes prohibitions on gifts and meals, disclosure of payments made to HCPs, 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 state pharmaceutical compliance and disclosure laws, see the State Laws: HCP and State Employee Restrictions Chapter and the Meals, Educational Items, and HCP Payment Disclosure 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 also has 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 a violation by the pharmaceutical company. Sales Colleagues must ensure that all HCP interactions comply with Orange Guide Chapter 2: Interactions with HCPs. All other colleagues must ensure that marketing materials and other commercial activities comply with White Guide Chapter 2: Advertising and Promotional Materials and White Guide Chapter 3: Promotional Interactions with Healthcare Professionals.

Privacy Laws

Pfizer and firms engaged by us to perform various services (e.g., advertising and promotion agencies and other vendors) 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 non-U.S. 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 non-U.S. 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 updated Frequently Asked Questions, can be viewed under the Compliance tab on PfieldNet at http://pfieldnet.pfizer.com/Compliance/Pages/Home.aspx and on OpSource at 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 go beyond legal obligations to set forth a method of communicating that will enable DTC communications to serve to educate patients and consumers and encourage them to seek guidance from their healthcare professionals. Pfizer has adopted its 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 Materials.

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 an effective compliance program. 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, generally 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 (or whistleblower suit filed by a private individual on behalf of the government) suit 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 its 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. However, the expiration of our CIA does not mean that Pfizer is lessening its commitment to compliance. In fact, Pfizer had implemented many of the Bextra CIA-required policies, procedures, systems, and controls before entering into the Bextra CIA, and we will continue to conduct our business in a manner that meets or even exceeds the expectations of the OIG and other regulatory bodies. 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 each agreement 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 new and updated 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](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: ADVERTISING AND PROMOTIONAL MATERIALS

CONTENTS

Advertising and Promotional Materials

Introduction ....................................................................................................................................................................2

Key Points to Ensure Compliance ........................................................................................................................3

Core Compliance Principles for Professional and Consumer Promotional Materials ....................................... 4

Pre-Approval Communication ............................................................................................................................. 4

Post-Approval Communications ..........................................................................................................................5

  Core Principle #1: All Claims Must Be Consistent with Product Labeling ................................................. 5

  Core Principle #2: All Claims Must Be Supported by Substantial Evidence .............................................. 5

  Core Principle #3: All Claims Must Be Truthful and Not Misleading .......................................................... 7

  Core Principle #4: All Claims Must Appropriately Balance the Benefits of the Product with Its Risks ... 9

  Core Principle #5: All Promotional Materials Must Be Approved through Review Committee ............. 9

Requirements of Promotional Labeling and Advertising ..................................................................................10

Use of Reprints in Product Promotion ..............................................................................................................15

Direct-To-Consumer and Internet Advertising ..................................................................................................16

  Direct-To-Consumer Advertising ...................................................................................................................16

  Patient Testimonials ....................................................................................................................................17

  Internet Promotion .......................................................................................................................................18

FOR MORE INFORMATION ..................................................................................................................................18

Rev. 01/16
Chapter 2: ADVERTISING AND PROMOTIONAL MATERIALS

Introduction

A fundamental basis for our promotional interactions with healthcare professionals (HCPs) and consumers is to promote our products and provide information about the disease states they treat. Pfizer has five core principles that must be followed to create FDA-compliant promotional materials and messages and to ensure that the information we provide is appropriate. They are:

- All claims must be consistent with product labeling;
- All claims must be truthful and not misleading;
- All claims must be supported by substantial evidence;
- All claims must appropriately balance the benefits of the product with its risks; and
- All promotional materials must be approved through Review Committee (RC).

These principles are set forth in detail in Clinical and Medical Controlled Document (CMCD) REG08-POL: Requirements for the Content and Approval of Promotional Activities and/or Materials.

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

Any exceptions to these policies/principles must be approved in writing by the BU Chief Counsel, after consultation with the Promotional Policy Committee (PPC) and General Counsel.
Key Points to Ensure Compliance

- Pfizer has five core principles that must be followed to ensure that the promotional information we provide is FDA-compliant and appropriate. They are:
  - All claims must be consistent with product labeling;
  - All claims must be truthful and not misleading;
  - All claims must be supported by substantial evidence;
  - All claims must appropriately balance the benefits of the product with its risks; and
  - All promotional materials must be approved through Review Committee.

- A brand Review Committee (RC) may approve clinical reprints for promotional use by Sales Colleagues only if they are consistent with the product’s label. In order for a reprint to qualify as “consistent with the product’s label,” it must satisfy certain conditions, as detailed later in this Chapter.

- Like other forms of promotion, Direct-to-Consumer (DTC) communications must comply with FDA regulations and Pfizer’s five core principles as well as PhRMA’s Guiding Principles. DTC communications should educate patients and consumers and encourage them to seek guidance from healthcare professionals.

- As outlined in White Guide Chapter 4: Marketing Programs, Customer Engagement Programs (CEPs) must be designed, reviewed, approved, and conducted in compliance with Corporate Policy #902: Management of Safety Information for Customer Engagement Programs (CEPs) and Corporate Procedure #902a: Management of Safety Information for Customer Engagement Programs (CEPs).

- As it does with other forms of promotion, the FDA regulates Pfizer’s use of the Internet and social media to promote its products. Websites that contain product information that is deemed promotional must comply with all the laws, regulations, and principles that govern promotional materials created for traditional media, in addition to relevant Pfizer policies and guidelines. See DRT.pfizer.com for guidelines associated with the appropriate use of the Internet and social media channels in advertising and promotion.
Core Compliance Principles for Professional and Consumer Promotional Materials

Pre-Approval Communication

Prior to approval, the Food and Drug Administration (FDA) permits only two types of advertisements for drugs: “Institutional Advertising” and “Coming Soon” advertising. “Institutional Advertising” may announce that a drug company is conducting research in a particular therapeutic area to develop a new drug, but the name of the investigational drug must not be mentioned, and any representation (written, verbal, or graphic) that directly or indirectly identifies the drug must not be included in the advertisement. “Coming Soon” advertising announces the name of the product that will be available soon without any information (written, verbal, or graphic) relating to the therapeutic area, safety, efficacy, or intended use of the drug. “Coming Soon” advertisements are permissible only if the drug is not expected to have a boxed warning. “Coming Soon” advertisements must meet the requirements of a reminder advertisement (described further below) and therefore must not contain any representations about the product. For a particular product, Pfizer can choose only one of these two types of advertising during the pre-approval time period. Companies are not permitted to use both types simultaneously or to alternate between these approaches during the pre-approval time period. Other than these two types of advertising, no promotion may be conducted for a product prior to its approval.

Pre-Approval Communication

Q. When can I meet with customers to begin discussing a new product or new indication?

A. Pfizer is not permitted to promote a new product or indication prior to receiving FDA approval. This means that Pfizer is not permitted to promote the safety and efficacy profile of the product until after FDA approval. In limited circumstances it may be appropriate to discuss an unapproved product or indication with a customer as part of a non-promotional interaction (e.g., advisory board or scientific exchange). All colleagues must receive appropriate approvals before proactively discussing any unapproved product or indication with an HCP or consumer or other customer. See CMCD REG08-POL: Requirements for the Content and Approval of Promotional Activities and/or Materials and White Guide Chapter 8: Non-Promotional and Media Activities, for more information.
Post-Approval Communications

Core Principle #1: All Claims Must Be Consistent with Product Labeling

Pfizer, like all pharmaceutical companies, is permitted to promote only FDA-approved uses of its products in the United States. All promotional statements made about a Pfizer drug must be consistent with the information contained in the product’s labeling. Uses that remain under investigation or that are under FDA review, but have not been approved, are considered off-label and claims about such uses cannot be made in promotion.

Core Principle #2: All Claims Must Be Supported by Substantial Evidence

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

The chart on the following page sets out examples of typical claims and the generally accepted evidence that is required to support the claim being made in approved materials:
<table>
<thead>
<tr>
<th>Type of Claim</th>
<th>Example</th>
<th>Generally Accepted Supporting Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Efficacy or Safety Claim</strong></td>
<td>“Product X has been shown to reduce blood pressure by 30% in most adult patients”</td>
<td>2 adequate and well controlled clinical trials</td>
</tr>
<tr>
<td><strong>Comparative Claim:</strong></td>
<td>Comparing any attribute of the Pfizer product with a competing product “In two studies, Product X reduced high blood pressure as well as competing Product Y”</td>
<td>2 adequate and well controlled clinical trials comparing Product X and Product Y head-to-head (or, in limited circumstances, 1 large, well-controlled head-to-head study) using comparable, approved dosage regimens</td>
</tr>
<tr>
<td><strong>Superiority Claim:</strong></td>
<td>Claiming an attribute of the Pfizer product is better or superior to a competing product “Product X demonstrated superiority in reducing blood pressure over Product Y in two studies”</td>
<td>2 adequate and well controlled clinical trials comparing Product X and Product Y head-to-head (or, in limited circumstances, 1 large, well-controlled head-to-head study) using comparable, approved dosage regimens</td>
</tr>
<tr>
<td><strong>Healthcare Economic or</strong></td>
<td>“Over the course of treatment, Product X may (or on average) reduce hospital costs by Y%”</td>
<td>For claims made to formulary committees that are directly related to the product’s indication, competent and reliable scientific evidence</td>
</tr>
<tr>
<td><strong>Pharmacoeconomic Claim</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Quality of Life (QoL) Claim:</strong></td>
<td>Claiming use of a Pfizer product improves one’s overall quality of life or an aspect of one’s life “Patients on Product X showed improved daily physical function”</td>
<td>2 adequate and well-controlled clinical trials using an appropriate FDA-agreed upon validated Quality of Life instrument</td>
</tr>
</tbody>
</table>

*Healthcare Economics or Pharmacoeconomic Claims are generally limited to use with formulary decision makers*
In addition, as a general rule, product claims must have **clinical as well as statistical significance**. Any exceptions to this rule must be carefully reviewed to ensure the claim does not inappropriately imply greater efficacy or fewer risks than otherwise established by scientific or medical evidence. It is also always important to ensure that each claim is only as strong as the evidence that supports it. In other words, each product claim must be narrowly tailored to match the findings of the data.

For a more complete listing of types of claims and the required evidence to support them, please see CMCD REG08-POL: Requirements for the Content and Approval of Promotional Activities and/or Materials.

**Superlative Claims**

Q. Is it ever appropriate to use superlatives like “best” or “safest”?

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

**Core Principle #3: All Claims Must Be Truthful and Not Misleading**

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

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

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

**Visual Representations**

Q. A brand team wants to include photographs of families (children and parents) in their promotional materials. Are there any concerns with doing this?

A. Visual representations, artwork, and graphics must be taken into consideration when determining whether material is false and misleading. Visuals can imply claims about the product and must be consistent with the product’s labeling. For example, if a product is indicated for adults, including pictures focusing on children in the advertising could lead viewers to mistakenly believe that the product is indicated for use in children. Accordingly, all visuals must be reviewed to ensure they are not misleading in light of the product’s indication or any claim made about the product.
Core Principle #4: All Claims Must Appropriately Balance the Benefits of the Product with Its Risks

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

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

Fair Balance

Q. Can promotional materials for a product claim that the product is “safe?”

A. No. The word “safe” should not be used without qualification since all products have risks. A product may, however, be described as having a “well-studied safety profile” if it can be substantiated by medical evidence. Appropriate safety information, such as boxed warnings, contraindications, warnings/precautions, and side effects must also always be provided to balance and provide context to such a statement.

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

All materials intended to promote our products for use in the United States (including disease awareness and pre-launch materials prepared in anticipation of FDA approval), all materials required to be filed to the FDA’s Office of Prescription Drug Promotion (OPDP) by Date Of First Use, and all pieces being submitted to OPDP for Advisory Comments, must be approved through RC. For more information on the RC Process, see CMCD REG08-WI-US01: Process Governing Review and Approval of United States Product Team Advertising and Promotional Materials. The Review Committee tab on...
OpSource includes RC training materials and other helpful documents. The Advertising and Promotion Guidelines tab on OpSource also provides links to general and platform specific guidelines.

Sales Colleagues on Veeva CRM are expected to utilize the digital materials on their approved device (i.e., tablet or iPad) whenever possible when engaging in detailing HCPs (see Orange Guide Chapter 2: Interactions with HCPs). Pfizer product teams requesting exceptions from this general rule must seek approval from Legal (i.e., Global Product Counsel) and Compliance. In addition, Pfizer product teams seeking to utilize paper materials only and not develop any digital materials for detailing purposes must also seek approval from Legal and Compliance.

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

Requirements of Promotional Labeling and Advertising

OPDP regulates two categories of promotional materials which have slightly different requirements: promotional labeling and advertisements. OPDP uses the term “promotional labeling” to apply to a broad array of materials used in marketing a product, including, for example, brochures, mailing pieces, detailing pieces, price lists, exhibits, literature reprints, and similar pieces of printed, audio, or visual matter descriptive of a drug.

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

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

- **Proprietary Name & Established (Generic) Name**;
- Approved indication(s) for use (including any limitations of use);
- Dosage form(s) and dosage(s);
• Quantitative amounts of active ingredients in combination products;
• Name of the company responsible for marketing the product and its agent (co-promote partner);
• Boxed warning (where applicable), contraindications, warnings/precautions, and side effects; and
• Appropriate labeling: 1) Full prescribing information, including Patient Package Insert (or Medication Guide and/or Instructions for Use) for promotional labeling; 2) appropriate brief summary for print advertisements, and 3) adequate provision for broadcast advertisements such as television, radio, and telephone.

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

• Professional print advertisements must include a Professional Brief Summary.
• Consumer print advertisements must include the Professional Brief Summary, Important Facts Brief Summary, the Patient Package Insert, or the Medication Guide, as determined by the RC.
• Broadcast advertisements (television, radio, or telephone) must include the Major Statement and ensure adequate provision of the full prescribing information.

Moreover, the full prescribing information – both the Package Insert (PI) and the Patient Package Insert (PPI) or Medication Guide and/or Instructions for Use, as appropriate – must accompany promotional labeling (with the exception of some reminder ads). This requirement applies to both professional and consumer labeling. These concepts are explained in the tables on the following pages.
• **Proprietary (Brand) Name & Established (Generic) Name** is required on all promotional labeling and advertising. The established (generic) name must be included at the most prominent mention of the proprietary (brand) name.
  
  o There must be no intervening matter between the brand and generic name. The established name must be used in type at least half as large as the type used for the most prominent presentation of the proprietary name. For example, in a logo, the generic name must be included and the type size used must be at least half the size of the type used for the brand name.
  
  o On any page of an advertisement or promotional labeling in which the proprietary name or designation is not featured but is used in the running text, the established name shall be used at least once in the running text, typically at first mention or otherwise prominently.
  
  o In television advertisements, the generic name should be included immediately following the most prominent display of the brand name on the screen (i.e., through supers that are used as headlines or taglines).
  
  o In radio advertisements and telephone scripts, the generic name should be included at the first mention of the brand name.
  
  o In electronic media, the generic name should accompany the brand name at the most prominent mention, and the generic name should also appear at least once in the running text. For electronic media, including websites and presentations, the generic name has to be visible on the screen at all times.

• **Professional Brief Summary** typically includes all risk information from the full prescribing information regarding the product including, but not limited to, boxed warning (where applicable), contraindications, warnings/precautions, and side effects, and information under headings such as cautions, special considerations. The Brief Summary typically excludes the pharmacokinetics, pharmacology, and dosage information from the full prescribing information unless there is important risk information included in these sections. Consult with your brand Regulatory team member, for further guidance.
• **Important Facts Brief Summary** is a consumer-friendly version of the Brief Summary that is generally derived from the PPI (or Medication Guide) and is used in consumer print DTC advertisements.

• **Major Statement** conveys a drug’s most important risk information in consumer-friendly language during a broadcast advertisement. A product’s Major Statement is typically crafted with significant input from the FDA’s OPDP through the request for advisory comment process.

• **Adequate Provision** is applicable in the context of broadcast advertisements only. The term refers to providing the audience with a reasonably convenient way to obtain the drug’s full prescribing information. One acceptable approach to disseminating the product’s approved labeling for broadcast advertisements is to include each of the following components:
  - Providing a toll-free telephone number in the advertisement for consumers to call to request the full prescribing information or to have it read to them over the phone;
  - Providing an Internet web page (URL) address where the full prescribing information can be viewed;
  - Identifying at least one publication that is concurrently running a consumer print advertisement in the marketplace where the broadcast ad is running that provides more detailed safety information, along with a toll-free telephone number and address for further consumer access to full prescribing information; OR making full prescribing information available (when the advertising campaign has a relatively limited audience reach) at publicly accessible sites (e.g., pharmacies, doctors’ offices, grocery stores, public libraries); and
  - Disclosing that HCPs may provide additional product information.

For telephone advertisements, see “PI/PPI Treatment in Consumer Labeling, Multicultural Items, and IVRs” for more information on OpSource.
• **Reminder Advertisements and Reminder Labeling** are short promotional pieces that contain a drug’s proprietary (brand) name and established (generic) name and may contain dosage form and strength, as well as pricing information or formulary coverage. A reminder cannot mention or imply the drug’s indication, effectiveness, safety, uses, or dosing regimen. Nor can a reminder give any representation of the drug, either direct or implied. The inclusion of any such information could transform a reminder into a full advertisement or promotional labeling. Because reminders call attention to the name of the drug product but do not include indications or dosage recommendations, they are not required to carry the full prescribing information or brief summary. Reminder ads also do not include safety disclosures since there are no efficacy or other claims to balance. **Pursuant to FDA regulations (with a limited exception for “price reminders” subject to strict requirements including disclosure of the price paid by the consumer), reminders cannot be used for products that carry a boxed warning.**

• **Help Seeking or Disease Awareness Advertisements** are communications disseminated to consumers or HCPs that discuss a particular disease or health condition, but do not mention any Pfizer drug or make any representation or suggestion concerning a particular Pfizer drug.

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**FDA Submission of Promotional Materials**

**Q.** When do promotional materials need to be sent to OPDP?

**A.** All branded promotional materials for Pfizer drugs must be filed with OPDP before or at the time that Pfizer first uses the materials. Except in the case of drugs approved via the Subpart H accelerated approval process, OPDP is not required to review the materials prior to first use. A company may choose to seek advisory comments from OPDP on materials prior to their first use. This is typically done prior to the launch of a new product or new indication so that the company may receive guidance from OPDP on the promotional presentation including claims of efficacy and fair balance when particular claims are made. Moreover, pursuant to the PhRMA DTC Guiding Principles, Pfizer has committed to seek advisory comments on new television broadcast ads.

Promotional materials for biologics and vaccines are sent to the Advertising & Promotional Labeling Branch (APLB) of the Center for Biologics Evaluation and Research.
Use of Reprints in Product Promotion

A brand Review Committee may approve clinical reprints for promotional use by Sales Colleagues only if they are consistent with the product’s label. In order for a reprint to qualify as “consistent with the product's label,” (for indication, efficacy, and safety) it must satisfy **ALL** of the following conditions:

1. The primary message must fall within the product’s label;
2. It contains, at most, only an insignificant amount of information that is inconsistent with the label; and
3. Any information that is inconsistent with the label must not be reasonably likely to be used to support an inappropriate promotional message.

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

- Pfizer is prohibited from disseminating information regarding an off-label use of a Pfizer product if that use was submitted to the FDA for approval and the FDA either (1) refused to approve the application; or (2) indicated that FDA-identified deficiencies must be resolved before approval can be granted, unless the information clearly and conspicuously discloses to the recipient that the FDA has issued that advice regarding the off-label use.
- Pfizer is prohibited from distributing reprints containing off-label information about any Pfizer product to physician specialties who do not customarily prescribe the product if the distribution of the reprint, combined with other promotional activities, promotes off-label use of the product.
- **Geodon-specific restrictions:** Before approving the potential distribution of any reprint containing off-label information about Geodon, it is important to consult your team attorney.
- **Lyrica- and Zyvox-specific restrictions:** Only Medical colleagues may identify, select, approve, and disseminate reprints containing off-label information regarding Zyvox and Lyrica (beyond insignificant references to off-label information). MOS colleagues may disseminate reprints relating to pharmacoeconomic or health outcomes to healthcare organizations. Sales Colleagues are prohibited from disseminating such reprints.

Rev. 01/16

Page 15 of 19
Any reprint approved for Sales Colleague use must include an implementation guide or be addressed specifically in an existing implementation guide.

Before approving a reprint, the product Review Committee should carefully consider additional risk mitigation measures that may be appropriate, such as carriers, wrappers, backgrounders, and/or enhanced training, on a case-by-case basis. In accordance with CMCD REG08-WI-US01: Process Governing Review and Approval of United States Product Team Advertising and Promotional Materials, any reprint reviewed for approval under this guidance may be referred to the relevant Business Unit Review Committee (BURC).

Any reprint that does not satisfy this guidance may not be approved for promotional use. It may qualify for non-promotional dissemination only with approval from the relevant BURC.

Direct-To-Consumer and Internet Advertising

Direct-To-Consumer Advertising

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

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

Pfizer has also agreed to abide by additional terms governing its DTC television advertising that require Pfizer to:

- Submit all new DTC television advertising campaigns for a Pfizer product to OPDP for advisory comment;
Wait a reasonable time (not less than 45 days) until Pfizer receives a response from OPDP prior to running the advertising campaign; and

If Pfizer receives a response within 45 days, modify such advertising consistent with any written comments from OPDP.

If OPDP does not provide Pfizer with a response within the 45-day waiting period, Pfizer may run the television advertising campaign but it must provide written notice and a copy of the advertising to certain state Attorneys General. Pfizer must also notify OPDP that it is proceeding to run the television campaign.

In addition, following the initial approval of any product indicated for pain relief, Pfizer shall delay DTC television advertising if the FDA recommends a delay in writing to Pfizer. Pfizer must delay the advertising for as long as recommended by the FDA, but not longer than 18 months from approval. If Pfizer decides to run the television advertising contrary to the FDA’s recommendation after the expiration of the 18-month waiting period, Pfizer must provide written notice and a copy of the advertising to certain state Attorneys General.

**FDA Submission of Promotional Materials**

Q. The PhRMA Guiding Principles for DTC Communications do not specify a time that companies need to wait after submitting television advertising to the FDA for review. Why are we required to wait 45 days?

A. As part of Pfizer’s settlement with several state Attorneys General, Pfizer agreed to undertake additional obligations with respect to its television advertising. One of those obligations was to submit all new television advertising to the FDA for review and wait at least 45 days for comments. Pfizer is obligated to modify its advertising consistent with written comments it receives.

**Patient Testimonials**

Like all other advertising and promotion, testimonials must follow the core principles outlined above. Any testimonial used by Pfizer must be consistent with the product label and must include fair balance. Testimonials must not include any claims that Pfizer could not make directly. Moreover, in accordance with our agreements with state Attorneys General, Pfizer cannot disseminate in a promotional context any patient testimonial relating to a Pfizer product that does not clearly and conspicuously disclose

Rev. 01/16
what the generally expected performance would be in the depicted circumstances or clearly and
conspicuously disclose the limited applicability of the experience described by the patient testimonial
to what consumers may generally expect to achieve. Please refer to the Guidance for the
Implementation of the Updated PhRMA DTC Principles. Please also refer to Testimonials: Patient
Recruitment and Engagement, available on OpSource, for further guidance on specific requirements for
using patient testimonials in promotion.

Internet Promotion

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

Pfizer websites that contain product information that is deemed promotional must comply with the
laws, regulations, and principles that govern promotional materials made for traditional media. This
means that any discussions of the product’s uses or indications must adhere to FDA-approved labeling.
Websites must appropriately balance any claims of efficacy with the relevant risk information, and the
risk information should be presented in a manner similar to the presentation of efficacy information.
For example, if the efficacy presentation is active (e.g., an audio component), then the risk information
should likewise have an active element. Similarly, if efficacy or benefits claims are made on a page,
balancing safety information must be incorporated into that page with comparable prominence. There
is no “one click” rule for the provision of safety information; rather, safety information must be
incorporated into websites without the user needing to click to view it. Branded websites may not
include or imply any product claims (including the indication) unless fair balance is provided on that
same page. In addition, the website must contain a link to the product’s package insert.

Detailed information on the requirements of Internet promotion, including on YouTube and Facebook,
can be found under the Advertising & Promotion Guidelines tab on OpSource. This information can
also be found at DRT.Pfizer.com. Promotional teams with questions regarding implementation of
social media guidelines can seek a concept review with the Digital Review Team (DRT).

FOR MORE INFORMATION

- Refer any questions to your team’s Regulatory colleague or product attorney
• **CMCD REG08-POL: Requirements for the Content and Approval of Promotional Activities and/or Materials**

• **CMCD REG08-WI-US01: Process Governing Review and Approval of United States Product Team Advertising and Promotional Materials**

• **PhRMA Guiding Principles on Direct to Consumer Advertising about Prescription Medicines**

• **Pfizer’s Guidance for the Implementation of the Updated PhRMA DTC Principles**

• CEP Resource Center at [http://cep.pfizer.com](http://cep.pfizer.com)

• OpSource internal website at [http://opsource.pfizer.com](http://opsource.pfizer.com)

• The Digital Review Team website at [http://drt.pfizer.com/](http://drt.pfizer.com/)

• Compliance Division internal website (for state Attorney General agreements) at [http://corporatecompliance.pfizer.com/Resources/Pages/StateAGAgreements.aspx](http://corporatecompliance.pfizer.com/Resources/Pages/StateAGAgreements.aspx)
Chapter 3: PROMOTIONAL INTERACTIONS WITH HEALTHCARE PROFESSIONALS

CONTENTS

Promotional Interactions with Healthcare Professionals

Introduction ....................................................................................................................................................................2

   Key Points to Ensure Compliance ........................................................................................................................................ 3

Four Core Compliance Principles for Successful Product Promotion .......................................................................................................................... 3

   Use Only RC-Approved Materials and Selling Statements ...................................................................................................................... 3

   Stay On-Label and Discuss Only Approved Products and Indications ......................................................................................... 4

   Provide an Accurate and Balanced Presentation .......................................................................................................................... 6

   Never Engage in Actual or Perceived Quid Pro Quo Arrangements ............................................................................................. 7

FOR MORE INFORMATION .......................................................................................................................................... 7
Chapter 3: PROMOTIONAL INTERACTIONS WITH HEALTHCARE PROFESSIONALS

Introduction

Pfizer Sales Colleagues have primary responsibility for promoting our products to health care providers (HCPs). However, non-Sales colleagues, including Marketing and Medical colleagues, may also interact with HCPs in various promotional settings such as congresses, conventions, symposia, and “ride-a-longs” with Sales Colleagues. Other interactions with HCPs may be considered promotional, as well, depending on the content and context of the interaction. The “Four Core Compliance Principles” reviewed in this Chapter are applicable to any Pfizer colleague engaged in a promotional interaction with an HCP. Additional guidance for Field Medical Directors (FMD), Medical Outcomes Specialists (MOS), and other Field Medical Colleagues as well as U.S. Business Unit (BU) Medical Affairs/Engagement colleagues when interacting with HCPs can be found in the Green Guide: Governance for External Medical Activities. For a more detailed discussion of the policies applicable to Sales Colleagues, see Orange Guide Chapter 2: Interactions with HCPs.

This Chapter summarizes Pfizer policies regarding promotional interactions with healthcare professionals and is relevant to non-Sales Colleagues who engage in promotional interactions as part of their roles and responsibilities. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination.
Key Points to Ensure Compliance

- Use only Pfizer Review Committee (RC) approved materials with HCPs.
- All promotional statements must be on-label (consistent with the product’s package insert) and based entirely upon approved information. All inquiries about off-label information or unapproved clinical data must be referred to Pfizer’s Medical Information Department (1-800-438-1985).
- Do not discuss new products or indications before they are FDA-approved and on-label.
- Always give a fair and balanced presentation of the benefits and risks of any Pfizer product for the approved indication.
- Never engage in any actual or perceived quid pro quo arrangement.

Four Core Compliance Principles for Successful Product Promotion

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

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

Use Only RC-Approved Materials and Selling Statements

Each Pfizer product has a multi-disciplinary Pfizer Review Committee (RC) that reviews and approves all sales and marketing materials for the product. Any written materials that you use in a promotional interaction, whether a marketing visual aid, a clinical reprint, or anything else, must be approved by the relevant product RC. You may not alter RC-approved materials in any way. In addition, promotional pieces or background materials marked “DO NOT DETAIL” must not be shared with HCPs. For more information on the review and approval of promotional materials, see White Guide Chapter 2: Advertising and Promotional Materials.
It is critical that you only make promotional statements that are 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 minimize risk.

Each colleague is responsible for the appropriate promotion of products in a manner consistent with RC-approved materials and FDA-approved labeling. Suggesting or using inappropriate selling statements, whether intentionally or not, can have far-reaching consequences for Pfizer, and may result in disciplinary action.

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

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

Examples of appropriate on-label and impermissible off-label claims are provided in the table on the following page.
### Detailing and Sales Materials: Examples of On-label vs. Off-label Claims

<table>
<thead>
<tr>
<th>On-label Claims</th>
<th>Off-label Claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statements about a product’s efficacy for the approved indication, supported by an approved promotional piece</td>
<td>Statements about a product’s efficacy for an unapproved use</td>
</tr>
<tr>
<td></td>
<td><em>E.g., “Lyrica can help your patients with insomnia to sleep better”</em></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></td>
<td><em>E.g., “Pristiq can be used in pediatric patients”</em></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 misstate, minimize, or are inconsistent with the information in the package insert</td>
</tr>
<tr>
<td></td>
<td><em>E.g., “Patients taking Toviaz do not really experience side effects”</em></td>
</tr>
<tr>
<td>Statements that accurately reflect an approved indication</td>
<td>Statements that inappropriately broaden an indication</td>
</tr>
<tr>
<td></td>
<td><em>E.g., “Lyrica is effective across the full spectrum of painful neuropathic conditions”</em></td>
</tr>
</tbody>
</table>

Prior to FDA approval of a product or the approval of a new indication for the product, a claim by the manufacturer (or its representatives) that the product is efficacious and/or safe for such use could be deemed illegal. **Pre-approval promotion** can jeopardize the approval of a new product/indication and may result in severe penalties. Therefore, you may only discuss approved products and indications in accordance with RC-approved promotional materials. No matter how compelling the scientific evidence, you must not discuss any product or indication with customers until it is approved by the FDA.
Additionally, you can only make **comparative claims** (comparing an attribute of a Pfizer product to an attribute of another product) when you use Pfizer RC-approved promotional materials that expressly make such claims and you follow all relevant directions provided in applicable Implementation Guides. The FDA considers promotional materials or claims to be false and misleading if they state or suggest that a drug’s safety or efficacy is comparable or superior to that of another drug without “substantial evidence” to support such statements or suggestions. It is not appropriate to make comparative claims based on the data in products’ 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 clinical trials.

If an HCP asks you an **unsolicited question** about unapproved products or indications, or asks for information outside of, or inconsistent with, a product’s approved labeling or Pfizer RC-approved materials, the question must be referred to Pfizer’s **Medical Information Department (1-800-438-1985)**. Sales Colleagues enabled to use Veeva CRM may only facilitate HCP Medical Inquiry submissions using that tool.

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

**Provide an Accurate and Balanced Presentation**

All promotional materials, selling statements, and presentations about Pfizer products must be truthful and not misleading, be supported by substantial scientific evidence, and 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 such **“fair balance”** in the presentation of a product’s benefits and risks and it is necessary to provide this information so that the HCP can make an informed treatment decision. The more robust the efficacy statements, the more risk information needs to be provided to balance the information. This means providing the relevant boxed warning (where applicable), contraindications, warnings/precautions, side effects, and other material information, such as relevant clinical trial exclusion criteria, that are necessary for a prescriber to make an informed decision about whether to
prescribe the product. Balanced presentations demonstrate Pfizer’s commitment to improving patient care and are required under the law.

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

*Quid pro quo* is Latin for “this for that.” Never offer or appear to offer any payment or item of value in exchange for prescribing or formulary acceptance of a Pfizer product. The decision of an HCP to prescribe or recommend a Pfizer product, or put it on a formulary, must be based on the best interests of patients and not on any payment or value offered by Pfizer.

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

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

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

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**FOR MORE INFORMATION**

- Refer any questions to your Regulatory colleague or team attorney
- [Orange Guide Chapter 2: Interactions with HCPs](#)
- [Green Guide: Governance for External Medical Activities](#)
- [White Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure](#)
• **White Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure**
Chapter 4: MARKETING PROGRAMS

CONTENTS

Marketing Programs

Introduction .................................................................................................................................................................... 3

Key Points to Ensure Compliance ........................................................................................................................ 4

Speaker Programs .......................................................................................................................................................... 5

Content Development .............................................................................................................................................. 6

Speaker Program Topics and Invitations ............................................................................................................. 8

Speaker Recruitment & Contracting ................................................................................................................... 8

Speaker Training .................................................................................................................................................. 10

Program Execution .............................................................................................................................................. 10

Promotional Opportunities at Third-Party Meetings and Conventions ................................................................. 10

Symposia Programs ............................................................................................................................................ 11

Initiating Symposia Programs ............................................................................................................................ 12

Content Development ........................................................................................................................................ 12

Invitations, Logistics, and Meals .......................................................................................................................... 13

Exhibit/Display & Other Advertising Opportunities .......................................................................................... 13

External Websites and Other Digital Activities .................................................................................................. 14

Customer Engagement Programs (CEPs) ......................................................................................................... 14

Co-pay Relief Programs ........................................................................................................................................ 15

Quality Programs ................................................................................................................................................ 15

Commercial E-mail .......................................................................................................................................... 16

Rev. 01/16

Page 1 of 18
Chapter 4: MARKETING PROGRAMS

Introduction

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

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

- Pfizer marketing programs, including those executed by an advertising agency or other vendor working on Pfizer’s behalf, must adhere to FDA regulations and other rules governing promotion and must be approved by the relevant Review Committee.

- The main objective of all speaker programs must be to meet an educational need by providing truthful and non-misleading, scientific, and educational information consistent with FDA guidelines on the appropriate utilization of Pfizer products and/or on relevant disease areas.

- Each brand team must follow the “Speaker Program Needs Assessment Guidance” to obtain approval and funding for the use of speaker programs as a promotional tool.

- Pfizer policy requires that speakers engage attendees for a minimum of 45 minutes, inclusive of Q&A, or a minimum of 30 minutes for programs in an in-office setting. Marketing must be mindful of these requirements when developing content in order to ensure that a sufficient amount of content is provided to support program duration requirements.

- Speakers may only be selected based on their expertise, credentials, and ability to communicate with the target audience.

- Prior to providing any speaking services, all speakers must have a signed agreement with Pfizer which documents the fair market value rate to be paid.

- Prior to engaging in any speaker program, all new speakers are required to complete training on: (1) the brand’s core product or topic slide kit (as applicable); and (2) Pfizer compliance policies (annually).

- Brand teams should design, review, approve, and conduct Customer Engagement Programs in compliance with Corporate Policy (CP) #902: Management of Safety Information for CEPs Policy and Corporate Procedure (CP) #902a: Management of Safety Information for CEPs Procedure.

- At many third-party meetings and conventions, Pfizer may pay for space or for an opportunity to promote its products (or, in some cases, to promote Pfizer), but Pfizer must not pay more than fair market value for the opportunity.
Key Points to Ensure Compliance

- Marketing Teams must follow the guidelines posted under the “Internet – Social Media – Digital” section within the Advertising & Promotion Guidelines tab on OpSource when developing digital content.
- Co-pay, rebate, and other similar programs offered by U.S. teams (including brand teams and non-brand teams, such as the U.S. Trade Group) must be developed and implemented in accordance with Pfizer’s policy on Free Trial Vouchers, Co-Pay Relief, and Similar Consumer Programs, New Limitations Regarding Free Trial Voucher Programs, and related guidance and FAQs.

Speaker Programs

A speaker program is a promotional activity controlled by Pfizer in which a speaker (typically an external HCP) presents educational information on products, disease states, or other healthcare topics, consistent with Pfizer’s policies on advertising and promotion, to a group of invited HCPs or consumers. Even though an external HCP is engaged to speak, Pfizer is responsible for the conduct and content at promotional speaker programs since the FDA considers HCP speakers to be representatives of Pfizer. This section focuses on speaker programs for HCPs. For more information on speaker programs for consumers, see White Guide Chapter 12: Promotional Interactions with Consumers.

If a brand team wishes to conduct speaker programs, it must coordinate with Legal and Medical to prepare a Speaker Program Needs Assessment (SPNA). The SPNA must be approved and submitted along with the brand team’s request for funding as part of their proposed Operating Plan for the upcoming year following the requirements and processes outlined in the Speaker Program Needs Assessment Guidance (SPNA Guidance). Because of the heightened risk associated with speaker programs, the use of such programs must be carefully considered and approved only if the use of other promotional strategies with lower compliance risk would not be sufficient to accomplish the educational goal. The SPNA must set forth a valid objective (as defined in the SPNA Guidance) for conducting a speaker program series. In general, the goal of all speaker program initiatives may only be to meet an educational need by providing truthful and non-misleading, scientific, and educational information on the appropriate utilization of Pfizer products. It is against Pfizer policy to design a
speaker program strategy for the purpose of inducing speakers to prescribe Pfizer products or to affect their placement on a formulary.

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

### Speaker Programs

**Q.** If a Pfizer Sales or Marketing colleague initiates a promotional speaker program, what responsibilities does he or she have?

**A.** Regardless of who funds the event (Sales or Marketing), the Program Host is responsible for the overall compliant management of the event. Generally speaking, the Sales or Marketing colleague chooses the venue and presentation topic (from the list of RC-approved topics in EZSpeak), selects an appropriate speaker, and contacts that speaker. The Sales or Marketing colleague must review Pfizer's speaker policies and the speaker's slide deck with the speaker prior to the event to ensure that the speaker understands that he or she must present in accordance with the product’s approved labeling and is using an approved slide deck that does not contain any unapproved slides. Colleagues may e-mail slide decks to the speaker for the sole purpose of the pre-program review discussion with the speaker only if the speaker is not in a position to download the deck. The slide deck in this instance must be already RC-approved, locked, and available in EZSpeak. The Program Host must monitor the program, make any needed corrections or clarifications, and identify any potential compliance violations committed by the speaker as part of the EZSpeak close-out process. For more information on Program Host colleague responsibilities when conducting a speaker program, see Orange Guide Chapter 9: Speaker Programs for HCPs.

### Content Development

All speaker program initiatives must be aligned to an approved SPNA which will identify the legitimate educational objectives (as defined in the SPNA Guidance) for a proposed speaker program series. Marketing, with input from Medical, is responsible for developing speaker program content which must be designed to meet the educational objectives identified in the SPNA. Examples of legitimate educational needs are:
• A gap in knowledge about a Pfizer product or related disease state within an appropriate target audience, as supported by appropriate data or objective information; and
• Promotional education for HCPs about a new product, new indication, significant change to a product’s risk/benefit profile, or significant new safety or efficacy data.

If there is no identifiable legitimate educational need for the speaker program initiative – for example, in cases in which the information is already well known and understood by the target audience – then it may not be appropriate to include the initiative in the SPNA or execute the initiative. For example, if the product has been on the market for many years and HCPs are generally familiar with the information proposed to be presented and there is no data or information demonstrating a need for more education, then the likelihood of identifying appropriate audiences for programs decreases.

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

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

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

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

**Brand teams should generally avoid using product names (either branded or generic) in speaker program topics**, since such references can trigger additional legal and regulatory requirements which Pfizer’s systems and processes are not routinely set up to manage. To be clear, while a speaker program title reflecting a product name (e.g., “Calmia: A treatment for mild anxiety”) may be appropriate as part of a slide deck containing balance and Important Safety Information, it may constitute an unbalanced product claim on a stand-alone branded speaker program invitation if it lacks Important Safety Information or is not accompanied by a PI.

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

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

**Speaker Recruitment & Contracting**

The **Pfizer Customer Engagement (CE) team** maintains a list of “active” Pfizer speakers. These are speakers that: (1) have a signed contract with Pfizer; (2) have completed compliance training; (3) have completed training on a core product or topic slide kit (either live or online, as applicable); and (4) have not yet reached Pfizer’s annual promotional speaker payment cap. An HCP’s promotional speaking contract with Pfizer is valid for one year and is typically automatically renewed.

*Rev. 01/16*
The two main analyses relevant to the speaker recruitment process are: (1) determination of the number of speakers reasonably required to execute the number of expected speaker programs (in order to determine if new speakers need to be recruited for the initiative in addition to speakers already trained and active); and (2) identification of the qualifications and expertise of the speakers necessary to execute the planned programs.

Speakers may only be selected based on their expertise, credentials, and ability to communicate with the target audience. Brand teams, along with input from Medical, if requested, must review nominees against these criteria and work with the CE team to submit the nominations through EZSpeak. In a similar manner, brand teams, along with input from Medical, review and evaluate: (1) KOL designations against qualifications of speakers for KOL status; and (2) National/Regional utilization of speakers to ensure payment amounts for KOLs are commensurate with appropriate KOL designation. In addition to doctors, speakers may be nurses, pharmacists, or any other person with the requisite subject matter expertise and credibility to speak on a particular topic. Sales nominations are processed directly through EZSpeak. Consult the CE team for more information on Speaker Nominations.

Prior to providing any speaking services, all speakers must have a signed agreement in place with Pfizer that documents the speaker’s fair market value (FMV) payment rate. In determining an individual speaker’s FMV payment rate, the speaker’s specialty, credentials, and expertise must be considered. For more guidance and details on how to determine FMV rates for speakers, consult the CE team. Typically, speakers enter the speaker bureau with an annual speaking cap of $50,000. Brand teams, with mandatory Medical consultation, must review and approve any Annual Cap Reclassification request, which may increase the annual honorarium cap no higher than $150,000 for a speaker, prior to submitting the request through CE to Legal and Compliance for final approval.

Only speakers may be paid in connection with speaker programs; attendees may not be compensated in any manner. Speakers may also be reimbursed for reasonable expenses associated with speaking at the program, such as out-of-pocket lodging, transportation, or parking costs. Pfizer’s HCP Payment Disclosure Policy applies to all speaker and consulting fees, travel expenses, meals, and other items of value provided in connection with speaker programs.
**Speaker Training**

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

Depending on factors including the needs of the brand team, a speaker may complete training either online via the Speaker Resource Center, via WebEx, or live in-person. In limited instances, offline training may be conducted by a Field Medical Director (FMD) for speakers who cannot complete training through other available means. For more information on speaker training, see Training resources available on the Speaker Programs tab in OpSource.

**Program Execution**

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

**Promotional Opportunities at Third-Party Meetings and Conventions**

Pfizer brand teams are often provided the opportunity to promote Pfizer products by paying for promotional opportunities at third-party meetings and conventions. Common promotional opportunities include, but are not limited to:

- Symposia Programs/Product Theaters;
- Exhibit/Booth Display Space;
- Advertisement Space in Conference Brochure;
- Online Acknowledgement;
- Supporter’s Board Acknowledgement;
- Meeting Registrations; and
- Delegate Bag Inserts.
Financial support in exchange for these opportunities can occur at a variety of venues and programs, but the key principle is that Pfizer is paying for the space or opportunity to promote its products (or in some cases to promote Pfizer) and must not pay more than fair market value for the opportunity.

There are several factors to consider when making a determination about fair market value with respect to promotional opportunities. Examples include the following:

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

In addition, Pfizer should be sure that other companies providing financial support in exchange for promotional opportunities are charged the same amount for the same type of opportunity. Often, the event brochure lists the levels of support opportunities available and describes the space and services that are available at each level. This type of brochure should accompany the request for financial support whenever possible because it helps to validate the fair market value of the opportunity. Follow the procedures outlined in the Funding Requests for Not-for-Profit Organizations SOP to facilitate funding for promotional opportunities at third-party meetings and conventions. All promotional materials used at a marketing program, such as exhibit panels, professional advertising, or consumer materials, must be approved by the appropriate product RC.

**Symposia Programs**

Pfizer defines symposia as Pfizer-initiated and/or controlled live events held in conjunction with a congress or convention. (Note that external organizations may use the term “symposia” for other types of events; however, the preceding definition is used for purposes of Pfizer policy.) The content is typically customized for the event and delivered by a Pfizer-paid faculty speaker and is subject to RC approval. Attendees are not paid and are generally not asked to provide formal feedback.

Symposia may be open-door, at which any congress/convention participant may attend, or closed-door, invitation-only events, at which attendance is controlled. Open-door symposia take place at
third-party events, such as congresses or conventions, with logistical support provided by Symposia Specialists on the Convention Housing & Logistics team, and in partnership with the Global Congress Center of Excellence (CoE) group within Global Commercial Operations (GCO). Closed-door symposia may coincide with, but typically do not take place at, third-party events such as congresses or conventions, with logistical support provided by the Customer Engagement team.

There are three types of symposia:

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

### Initiating Symposia Programs

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

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

### Content Development

The content of a symposium, which includes any promotional materials that will be presented or handed out at the event, must be RC-approved. The Project Owner and the vendor are responsible for
ensuring the symposium faculty follow Pfizer’s content requirements and processes. For symposia managed with the support of the Global Congress CoE, Convention Housing & Logistics team, the Symposia Specialists are responsible for ensuring that all speakers have received compliance training.

**Invitations, Logistics, and Meals**

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

**Exhibit/Display & Other Advertising Opportunities**

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

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

External Websites and Other Digital Activities

Like other forms of promotion, the FDA regulates Pfizer’s use of the Internet to promote its products in the United States. This includes PfizerPro and product websites, as well as social media, banner, and other Internet advertisements. For more information, see White Guide Chapter 2: Advertising and Promotional Materials. Detailed information on the requirements of Internet promotion, including on social media platforms, such as YouTube and Facebook, can be found under the Advertising & Promotion Guidelines tab on OpSource.

Customer Engagement Programs (CEPs)

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

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

Complying with CP #902: Management of Safety Information for CEPs Policy and CP #902a: Management of Safety Information for CEPs Procedure ensures that Pfizer meets its legal and regulatory obligations for the timely reporting of safety information from CEPs. A full description of
the types of programs considered to be CEPs can be found in CP #902a: Management of Safety Information for CEPs Procedure. CEP Program Owners are accountable for ensuring that the design, review, approval, and conduct of the CEP comply with CP #902: Management of Safety Information for CEPs Policy and CP #902a: Management of Safety Information for CEPs Procedure. See the CEP Resource Center at http://CEP.Pfizer.com for tools and resource information.

Co-pay Relief Programs

Pfizer is committed to encouraging patients to talk to their doctors about available treatment options and to helping patients better afford Pfizer medications. An example of this commitment is the distribution of co-pay coupons, co-pay cards, savings cards, and other similar offerings to consumers relating to Pfizer medications, all of which are subject to RC approval.

Even though such programs are designed to benefit patients, if not carefully developed and implemented, they may raise a number of significant legal risks (such as federal and state kickback laws, consumer protection laws, the “Best Price” Medicaid Drug Rebate Statute, state contract law, and state pharmacy laws). Co-pay, rebate, and other similar programs offered by U.S. teams (including brand teams and non-brand teams, such as the U.S. Trade Group) must therefore be structured and implemented in accordance with the Policy on Free Trial Vouchers, Co-Pay Relief and Similar Consumer Programs, New Limitations Regarding Free Trial Voucher Programs, and the Massachusetts Update on Loosened Co-pay, Coupon and Free Trial Voucher restrictions, dated August 8, 2012, along with related documents that can be found on the Co-Pay Relief Programs page on OpSource.

Quality Programs

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

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

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

Quality programs improve patient care by providing customers with information about, for example, quality accreditation standards, HCPs’ patient interaction skills, and management of medical conditions. A listing of current Pfizer quality programs can be found at CRC.Pfizer.com.

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

Pfizer’s quality programs may never be offered to:

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

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

Commercial E-mail

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

All commercial e-mail must include the following:

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

• The sender’s physical postal address. The Direct Marketing Association requires that the address be a street address.

There is an exception from these requirements for transactional e-mails (such as an e-mail that confirms a purchase or provides an account balance). A transactional e-mail may contain advertising as long as the primary purpose of the e-mail is transactional, not promotional.

The Act prohibits false or misleading information in the “From” and “Subject” lines of commercial e-mail and transactional e-mail. The “Subject” line should accurately reflect the content of the e-mail and the “From” line should accurately indicate who is responsible for sending the e-mail. This requirement raises some difficult questions with respect to referral e-mails, such as in a promotion where people may authorize the sending of an e-mail to their friends and colleagues but the actual party sending the e-mail is the sponsor of the promotion. Consult with your team attorney if your program involves referral e-mails.

The Act also prohibits falsifying header information, harvesting e-mail addresses, opening multiple e-mail accounts using false information and using open relays to transmit commercial e-mail. It pre-empts state commercial e-mail laws but does not pre-empt state fraud and trespass laws that can be applied to commercial e-mail. This means advertisers no longer need to include “ADV:” in the subject line, as some states had once required, but states can still sue advertisers for fraudulent commercial e-mail.

Colleagues who are responsible for sending commercial e-mail should coordinate with Enterprise Multi-Channel Marketing (eMCM) and their team attorney to ensure compliance with all applicable laws and regulations.

FOR MORE INFORMATION

• For speaker programs, consult the Customer Engagement (CE) team, and for conventions/congresses/symposia consult the Global Congress CoE Leads.
• Speaker Programs tab in OpSource
• Orange Guide Chapter 9: Speaker Programs for HCPs
• Orange Guide Chapter 16: Consumer and Employee Interactions
• Policy on Free Trial Vouchers, Co-Pay Relief, and Similar Consumer Programs
• Co-Pay Relief Programs page on OpSource
• New Limitations Regarding Free Trial Voucher Programs
• Massachusetts Update on Loosened Co-pay, Coupon, and Free Trial Voucher restrictions
• HCP Consulting guidelines and resources available on the ENGAGE and HCP Engagements tabs on OpSource
• CEP Resource Center at Customer Engagement Programs home page
• White Guide Chapter 2: Advertising and Promotional Materials
• White Guide Chapter 5: HCP and Government Official Consulting Engagements
• White Guide Chapter 7: Support of External Organizations
• White Guide Chapter 12: Promotional Interactions with Consumers
• White Guide Chapter 15: State Laws: HCP and State Employee Restrictions
• White Guide Chapter 18: Meals, Educational Items, and HCP Payment Disclosure
• Refer any other questions to your team’s Regulatory colleague or team attorney
Chapter 5: HCP AND GOVERNMENT OFFICIAL CONSULTING ENGAGEMENTS

CONTENTS

HCP and Government Official Consulting Engagements

Introduction .................................................................................................................................................................... 3

Key Points to Ensure Compliance ........................................................................................................................ 6

Consulting Engagement Controls Overview ................................................................................................................ 7

Requirements for a Bona Fide Consulting Arrangement ................................................................................................................ 8

Legitimate Need for Services ........................................................................................................................................ 9

Consultant Qualifications ........................................................................................................................................ 10

Consultant Screening Requirements .................................................................................................................... 10

Export Controlled Technology ................................................................................................................................ 11

Fair Market Value Compensation ........................................................................................................................... 12

Output / Deliverables ............................................................................................................................................... 13

Written Agreement ................................................................................................................................................ 13

Meeting Venue .................................................................................................................................................... 15

Reimbursement of Expenses ...................................................................................................................................... 15

Types of Consulting Arrangements ............................................................................................................................ 15

Advisory Board Meeting ....................................................................................................................................... 15

Live Speaker Training Meeting .............................................................................................................................. 16

Focus Groups and Market Research .......................................................................................................................... 17

Preceptorships and Mentorships .......................................................................................................................... 17
Retaining Government Employees as Speakers or Consultants ................................................................. 18
Non-U.S. HCPs and Government Officials .............................................................................................. 18
U.S. State and Federal Government Officials .......................................................................................... 19
  Retaining Government Employees in Connection with Their Official Duties .............................. 20
  Retaining Government Employees Outside of Their Official Duties ........................................ 20
FOR MORE INFORMATION ..................................................................................................................... 22
Chapter 5: HCP AND GOVERNMENT OFFICIAL CONSULTING ENGAGEMENTS

Introduction

Pfizer enters into consulting engagements with Health Care Professionals (HCPs) for a range of services including business counseling, Pfizer colleague training, external HCP education and training, clinical program design, post-launch regulatory compliance assistance, and marketing program development, among others. For U.S.-based Business Units, Corporate Affairs, and Medical colleagues, the HCP Engagements SOP is applicable to most HCP and non-U.S. Government Official (GO) consulting engagements. However, that SOP does not apply to Marketing and Sales speaker programs, clinical services, and other activities subject to other policies (see the Scope section of the SOP for more information). HCP engagements in support of Pfizer's Research and Development (R&D) activities are generally subject to the policies and procedures set forth in the Pfizer Worldwide Research & Development (R&D) SOP #201: R&D GPIHP and External Funding Controls, rather than the HCP Engagements SOP. While all of Pfizer's HCP engagement policies reflect the same core principles, the specific requirements and controls detailed in this Chapter relate to engagements covered by the HCP Engagements SOP, which is applicable to the U.S.-based colleagues noted above.

Pfizer may provide compensation to HCP consultants at fair market value (FMV), and may reimburse reasonable expenses associated with consulting activities. Because these interactions potentially implicate federal and state anti-kickback laws and other U.S. and international anti-corruption laws, it is important for Pfizer colleagues to establish that a proposed consulting relationship is bona fide prior to engaging the consultant. An HCP consulting arrangement is permissible as long as:

- There is a legitimate business need for the services;
- The consultant(s) is selected based on his or her expertise and knowledge and not to gain access or to influence prescribing habits;
- The number of consultants and duration of the engagement are appropriate to the business need;

Rev. 01/16
• A written contract is executed that specifies the nature of the services and the basis of payment for those services;
• The term of the agreement is for at least one year (unless a shorter term is approved by a Legal colleague);
• The services are provided as outlined in the written contract; and
• Any compensation does not exceed fair market value.

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

In sum, your objective in entering into a consulting arrangement with an HCP must never be to:

• Establish or improve a relationship with the HCP;
• Gain or improve access to the HCP;
• Reward past prescribing;
• Induce future prescribing; or
• Influence formulary decision making.

The Corporate Policy (CP) #207: Global Policy on Interactions with Healthcare Professionals (GPIHP), governs relationships with HCPs, including interactions with physicians, nurses, pharmacists, and others who administer, prescribe, purchase, or recommend prescription medicines. The process for fair market value analysis of HCP payments is described in the HCP Engagements SOP and outlined in detail in the HCP Services: U.S. and International Fair Market Value SOP. The process for conducting meetings and consultancy engagements with non-US individuals is outlined in My Anti-Corruption Policy and Procedures (MAPP). You should consult these SOPs, as applicable, to identify the specific steps that are necessary to plan and execute a compliant consulting engagement. The OpSource website also contains job aids, guidelines, and other useful documents to help ensure a compliant consulting arrangement.

Rev. 01/16

Page 4 of 22
The Pfizer Customer Engagement North America (CE NA) team within Global Commercial Operations (GCO) is generally responsible for managing the logistics for meetings that involve HCP consultants.

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

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

- Further a legitimate business need that has been adequately documented.
- Involve HCPs/GOs who are:
  - Selected based on documented expertise and knowledge which meets that business need;
  - Not selected to gain access or influence prescribing or recommendation of a product, nor to promote off-label use (or make other impermissible claims);
  - Cleared through the Restricted Party Screening process (even if the engagement is occurring solely within the United States);
    - For HCPs/GOs processed through the ENGAGE system, automated Restricted Party Screening occurs in ENGAGE.
    - HCPs/GOs not processed through ENGAGE must be submitted to the Global Trade Controls Center of Excellence (GTC CoE), Restricted Party Screening Function for such screening by completing and sending the appropriate form to (rps@pfizer.com), at least one week in advance of any planned execution of an HCP/GO consultant agreement. The form is available on GTC.Pfizer.com.
  - Not on any applicable internal Pfizer exclusion lists, or any lists of HCPs/GOs subject to state disciplinary actions, state licensing suspension or revocation, FDA Warning Letters, Data Monitoring Committee membership, or any international equivalent to the foregoing.
- Be memorialized in a written contract that:
  - Specifies the nature and scope of the services and the amount and basis of payment for those services; and
  - Has a term of agreement for at least one year (unless Legal approves a shorter term).
Key Points to Ensure Compliance

- Not involve a payment in excess of fair market value; and
- Not include either of the following, unless required licenses or other authorizations have been obtained and written approval received from the responsible team attorney or GTC CoE Legal Division colleague:
  - Activities in a Restricted Country or individuals, organizations, or governmental entities from a Restricted Country; or
  - The exchange of Technology that is controlled for export from the United States (see CP #206: Compliance with Global Trade Control Laws Policy, CP Section #206E: Technology Transfers and Deemed Exports, and GTC.Pfizer.com).

Additionally, Pfizer colleagues must ensure that:

- The output/work product of a consulting engagement is collected and retained, and it is documented how such output/work product was used to aid the business; and
- The output/work product is consistent with the Business Rationale Form (BRF), consultant assessment form, and consulting agreement.

The GCO CE North America team oversees organization of meetings involving HCP consultants. For additional guidance on engaging an HCP or GO, consult the ENGAGE and HCP Engagements tabs on OpSource.

Consulting Engagement Controls Overview

Pfizer developed, implemented, and maintained controls to manage HCP consulting engagements. After Pfizer entered into a Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) in 2009, it further enhanced these controls. With a few additional and enhanced measures these controls continue to remain in force following the expiration of the CIA, including:

- **Annual Consultant Needs Assessment**: On an annual basis, Business Unit (BU) Compliance Counsel, Global Product Counsel and their respective brand teams will develop Annual Consultant Needs Assessments (ACNAs) relating to each product in accordance with each
brand's operating plan. Each ACNA must identify the estimated number of, expenses associated with, and the business rationale for, various HCP consultant engagements and activities intended to occur during the year in connection with government-reimbursed products.

- **Business Rationale Requirements:** Prior to each engagement, Pfizer must ensure that a Business Rationale Form (BRF) is completed describing the justification for retention of a consultant by Pfizer. The BRF must identify the business need for the services of the consultant and must provide specific details including qualifications of the consultant(s) to be engaged, the scope of services to be provided, and the expected work product/information to be generated from the engagement. The relevant team attorney will review the BRF for consistency with Pfizer policy and with the relevant ACNA and will document explanations for any variance from the ACNA.

- **Contract Requirements:** Pfizer must execute written agreements with the consultants it engages. The agreement must describe the scope of work to be performed as well as the consultant fees to be paid. Fees must be based on a centrally managed pre-set rate structure that is based on fair market value. The agreement must also describe the compliance obligations of the consultant, including consent to and cooperation with Pfizer's public disclosure of payment to the HCP. Finally, consultants must be required to disclose their consultant relationship with Pfizer to, and to adhere to the disclosure requirements of, any healthcare institution, medical committee, or other medical or scientific organization with which the consultants are affiliated.

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

**Requirements for a Bona Fide Consulting Arrangement**

The following section provides an overview of the key compliance requirements pertaining to the process for engaging HCP consultants as outlined in the [HCP Engagements SOP](#).
**Legitimate Need for Services**

Because of the inherent kickback risk that HCP consulting arrangements pose, Pfizer colleagues must complete a BRF to demonstrate that a legitimate need exists for a proposed consultant service. This involves:

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

The relevant team attorney must review each BRF associated with any proposed consulting engagements prior to the retention of consultants. The attorney will review BRFs for consistency with Pfizer policy and with the relevant Annual Consultant Needs Assessment (ACNA) and will document any variance from the ACNA.

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**Legitimate Need**

**Q.** A Marketing team would like to organize a series of four advisory board meetings with various specialties to gain a better understanding how its pain medication is used in different clinical settings. The team would like to engage 20 HCPs for each meeting and intends to use the information to improve and tailor the promotional message for each specialty. Is this an acceptable initiative?

**A.** Maybe. It is permissible to engage consultants to gain a better understanding of how a promotional strategy or campaign may be received by HCPs. However, it is important that such initiatives involve the minimum number of HCPs necessary to meet the business objectives of the team. Here, it is not clear whether it is necessary to hold four separate advisory board meetings involving a total number of 80 HCPs. Depending on the nature of the information sought, it may indeed be necessary and appropriate, but it is also possible that a smaller number of meetings and consultants would be able to provide the same information. The Marketing team must provide specific details in the Business Rationale Form explaining why this approach is necessary.
Consultant Qualifications

It is essential that Pfizer colleagues explain how the qualifications of a proposed consultant meet the identified business need. You are prohibited from selecting an HCP because he or she is a “high prescriber” or because you are seeking to influence his or her prescribing or recommendation of Pfizer products. Though a consultant’s experience with a particular class of drugs may be taken into consideration in determining whether he or she is qualified to provide the requested services, prescribing habits may not be the basis for selection. The following must be addressed in the Business Rationale Form:

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

Project Managers should work with a Pfizer Medical colleague to define the required qualifications and specifications for consultant selection.

Consultant Screening Requirements

Pfizer colleagues must submit a request to screen prospective consultants before proceeding with any engagement, and are required to certify that these screenings have been conducted.

- **Restricted Party Screening**: As discussed in [CP #206: Compliance with Global Trade Control Laws Policy](#) and [CP Section #206A: Restricted Party Screening](#), when HCPs/GOs are subjected to Restricted Party Screening, they are compared to over 70 Restricted Party Lists maintained by various governmental entities around the world. Individuals are placed on such lists for a variety of reasons, including participation in criminal activity and support for such activity. Pfizer is prohibited from any interactions with these Restricted Parties, even if the activity in question is occurring solely within the United States.
  - HCPs/GOs processed through ENGAGE are automatically subjected to Restricted Party Screening.
  - For HCPs/GOs not processed through ENGAGE, a request for Restricted Party Screening must be submitted to the **Global Trade Controls Center of Excellence (GTC CoE)**, **Restricted Party Screening (RPS) Function** ([rps@pfizer.com](mailto:rps@pfizer.com)), at least one week...
in advance of any planned execution of an HCP/GO consultant agreement. RPS requests should include a completed RPS template, which can be found on the GTC CoE website (see gtc.pfizer.com). An HCP/GO consultant agreement may only be signed after the GTC CoE indicates that an HCP/GO is not a Restricted Party.

- **State Discipline and FDA Warning Letter Screening**: Pfizer actively screens its HCP speakers and consultants for disciplinary actions by state medical boards, FDA warning letters, and other misconduct. Individuals appearing on a Restricted Party list may not be engaged as consultants or speakers for Pfizer. (In rare cases, exceptions may be granted by the BU Chief Counsel or BU Compliance Counsel.)

- **DMC Member List**: Per Clinical and Medical Controlled Document (CMCD) CT22-GSOP: Independent Oversight Committees, current members of an active Data Monitoring Committee (DMC) for a Pfizer trial may not be engaged in certain financial relationships with Pfizer, including as paid consultants, advisors, or speakers for Pfizer. (In rare cases, and in accordance with CMCD CT22-GSOP: Independent Oversight Committees, exceptions may be granted by attorneys who support R&D and the Chief Medical Officer. For additional information regarding permissible activities of DMC members, please consult CMCD CT22-GSOP: Independent Oversight Committees and White Guide Chapter 9: Clinical Research and Investigator-Initiated Research)

- **Minnesota-Licensed Prescribers**: Per Pfizer policy, Minnesota-licensed prescribers may only be engaged as consultants in connection with (1) R&D, clinical, or development-related projects, (2) Outcomes Research or medical publication-related projects, and (3) speaking and speaker training. (In rare cases, exceptions may be granted by the relevant BU Chief Counsel or BU Compliance Counsel.) For more information on Minnesota law, see White Guide Chapter 15: State Laws: HCP and State Employee Restrictions.

**Export Controlled Technology**

If there will be any exchange of Technology that is controlled for export under U.S. laws, Pfizer colleagues must determine if the interaction will involve the export or disclosure of such Controlled Technology, to someone who is not a U.S. Person (U.S. Citizen, U.S. Lawful Permanent Resident/“Green Card” Holder, Asylum Seeker, or Refugee).
As discussed in CP #206: Compliance with Global Trade Control Laws Policy and CP Section #206E: Technology Transfers and Deemed Exports, a License or other Authorization may be required to discuss or disclose certain Technology. Technology Transfers can occur through a variety of methods, including: (i) physical shipment of a document; (ii) electronic transmission of a file containing the Technology; (iii) oral or visual disclosure, whether in-person or not; or (iv) through practice or application under the guidance of persons with knowledge of the technology. Understanding the controls on a particular Technology may be difficult. If you need assistance in determining (i) if Technology is Controlled Technology; (ii) the controls applicable to a specific Technology; or (iii) when a License or other Authorization is required, please consult with a colleague from the GTC CoE (gtc@pfizer.com).

**Fair Market Value Compensation**

Pfizer may only provide compensation that does not exceed fair market value for consultant services and in a manner that does not account for the volume or value of business that may be generated by the consultant for Pfizer. Generally speaking, colleagues should determine appropriate fees by utilizing the ENGAGE system (or U.S. FMV calculator) for U.S. consultants and the FMV tab of the Country Profiles for non-U.S. HCPs and/or GOs. The FMV rate must then be reflected in the written agreement. Pfizer must pay all U.S.-based consultants directly for their consulting services (this does not apply to blinded market research).

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**Zero Fee Engagements**

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

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

Q. Do the HCP Engagements SOP and the requirements in this Chapter apply to interactions and payments to patients or U.S.-based non-healthcare professionals?

A. No. But colleagues must understand that the definition of “HCP” in the HCP Engagements SOP is very broad, and includes categories of individuals who may influence prescribing behavior without being prescribers themselves. For a list of specialties and categories considered to be HCPs for purposes of these requirements, consult the HCP Services: U.S. and International Fair Market Value SOP. Further, these requirements apply to interactions with any non-U.S. Government Officials.

Output / Deliverables

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

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

Written Agreement

Consultants must execute a written consulting agreement with Pfizer prior to the services being provided. The written agreement must:

- Include a detailed description of the services that the consultant will provide including the project deliverables or other appropriate milestones;
- Specify the fee and that payment is contingent on full participation in a meeting and/or completion of any written work product or other deliverables;
- State why the consultant was selected (i.e., why his/her expertise is needed);
• Indicate that the consulting fee was not determined in a manner which accounts for the past, present, or future volume or value of business generated by the consultant for Pfizer;
• Specify that only reasonable, documented expenses may be reimbursed;
• Describe the compliance obligations of the consultant;
• Contain the consultant’s consent to and agreement to cooperate with Pfizer’s disclosure of payments and other items of value provided in connection with the engagement, in accordance with Pfizer’s HCP Payment Disclosure Policy and applicable law;
• Require the consultant to disclose his/her relationship with Pfizer and to adhere to the disclosure requirements of any healthcare institution, medical committee, or other medical or scientific organization with which the consultant is affiliated;
• Contain the consultant’s representation that he/she has not been, and is not, subject to government discipline or criminal sanction unknown to Pfizer; and
• Include the Standard Anti-Corruption Contract Provisions for Consultancy or Services Arrangements, set forth in MAPP Appendix 8, if a non-U.S. HCP or GO is being engaged.

HCP Consultant Engagements with Employer Institutions

Q. An HCP that I wish to engage as a consultant has advised me that her employer-Institution requires that her consulting fees be paid to the Institution, not her. Is this OK?

A. Yes. In these cases, the Consulting Agreement should generally be between Pfizer and the Institution (or other employer entity) directly, with the HCP identified in the contract as the Institution employee performing the services. Although Pfizer contracts with and provides payment to the Institution rather than the HCP individually, all of the consulting arrangement compliance principles outlined in this Chapter apply. If the consultant is a U.S.-licensed prescriber, the data Pfizer reports to the government will identify the Institution receiving the payment and the individual HCP associated with the payment. Finally if you are engaging a non-U.S. HCP/Institution, MAPP/FCPA due diligence requirements will apply. Contact ENGAGE2@pfizer.com and/or FCPAQuestions@pfizer.com if you have questions about a particular arrangement.
Meeting Venue

The venue for any consultant meeting, including a speaker training, must be conducive to the business purpose of the meeting, commercially reasonable, and not susceptible to characterization by third parties as “resort-like” or “lavish.” Pfizer colleagues should generally utilize the CE NA team to organize meetings involving HCP consultants.

Reimbursement of Expenses

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

Types of Consulting Arrangements

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

Advisory Board Meeting

Advisory board meetings pose risk because they can involve larger numbers of HCPs and potentially entail discussion of off-label information about Pfizer products. (If off-label information is presented at an advisory board meeting, it must bear a direct relationship to the purpose of the meeting. For additional information, see White Guide Chapter 8: Non-Promotional and Media Activities.) The primary purpose of an advisory board meeting must be to gain expert feedback or advice on commercial or clinical/medical topics, and not to provide a forum for product promotion. Pfizer colleagues should ensure that advisory board participants clearly understand that they are being retained to provide a service and not merely to passively receive promotional presentations. An advisory board meeting cannot be designed to:

- Influence the invited consultants or to change their prescribing preferences;
- Provide physicians with an opportunity to meet and mingle with their peers; or
- Have physicians merely listen to information about Pfizer products.
Input from Sales Colleagues

Q. A brand team is planning an advisory board meeting to solicit feedback and learn about a disease state related to a pending new indication for the product. Can the Brand team seek assistance from Sales to identify possible advisory board consultants?

A. Yes. Sales can be a valuable resource in assisting brand teams with the identification of HCP experts. Sales may suggest possible consultants based on specific criteria provided by the brand team that would meet the needs for the advisory board. Sales Colleagues, however, may not be involved with any communications with HCPs regarding the proposed advisory board, e.g., offer an invitation to participate.

If the meeting involves an international HCP or GO, Pfizer colleagues must also complete the necessary FCPA due diligence in compliance with My Anti-Corruption Policy and Procedures (MAPP).

**Live Speaker Training Meeting**

Prior to conducting any speaking engagements, all Pfizer promotional speakers are required to complete training on (1) the brand’s core product training slide kit; and (2) Pfizer’s compliance requirements. Depending on the circumstances of the speaker program initiative, a speaker may complete training either online via the Speaker Resource Exchange, WebEx, or live in-person. Speaker training activities are treated as consulting arrangements.

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

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

Typically, market research initiatives are conducted in a manner which “blinds” Pfizer and the HCPs from knowing each other’s identities. In order to prevent Pfizer from learning the identity of individual market research respondents and to protect respondent-identifiable information, the final set of respondents are generally a randomly selected or screened subset of a larger sampling universe, and outside vendors are typically utilized to conduct the research. Such “double-blind” market research does not constitute a consultant engagement and is specifically excluded from the scope of the HCP Engagements SOP. Conversely, however, if either or both parties are unblinded as to the other’s identity, the HCP participants must be engaged in accordance with the policies and procedures set forth in this Chapter and that SOP.

To ensure compliance with Pfizer policies and procedures governing the conduct of market research, Pfizer colleagues should generally execute any market research activities through the Business Analytics & Insights (BAI) team within Strategy, Portfolio, and Commercial Operations (SPCO). All market research activities must be conducted in accordance with the CASRO Code of Standards and Ethics for Survey Research. Further, no detailing or other dissemination of promotional information is permitted, except for the purpose of legitimately testing a particular promotional message or strategy.

Preceptorships and Mentorships

A preceptorship is a training program for Pfizer colleagues, usually provided and hosted/managed by university or teaching hospitals, which addresses a therapeutic area or the clinical use of a Pfizer product(s) in professional practice. Occasionally, a preceptorship may also be conducted by one or more HCPs directly engaged by Pfizer at a Pfizer-organized/managed training event. All of the consulting arrangement compliance principles outlined in this Chapter apply to preceptorship programs regardless of whether Pfizer engages with and pays an institution or an individual HCP.
Preceptorships should not be confused with mentorship programs, which are one-on-one observational teaching sessions where a Pfizer colleague (usually a Sales Representative) observes or “shadows” an HCP (usually a physician) engaged in his or her daily office or institutional practice. No compensation of any kind may be provided to an HCP mentor. Mentorships are not considered consultantships subject to the HCP engagement process; however, a letter agreement describing the purpose of the mentorship and setting forth patient privacy and confidentiality obligations must be executed. For additional information regarding mentorships, please consult the Mentorship Guidelines and Forms available on PfieldNet. Preceptorship institutions and HCP mentors must be selected based on their expertise and qualifications. These programs may not be used as selling opportunities, or offered to influence the prescribing practices of a particular physician. For information on the privacy considerations of these activities, see White Guide Chapter 11: Privacy: Protecting Personal Information.

Retaining Government Employees as Speakers or Consultants

Non-U.S. HCPs and Government Officials

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

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

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

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

U.S. State and Federal Government Officials

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

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

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

Retaining Government Employees in Connection with Their Official Duties

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

Retaining Government Employees Outside of Their Official Duties

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

- Employee is advising on matters about which he/she is a subject matter expert and is not being engaged because of his/her official position, but rather based on that expertise;
- Employee is not advising in relation to a matter pending before his/her government agency;
- Employee is taking personal time to participate rather than participating during employer/government time (in which case he/she must be acting in an official capacity); and
- Employee is not conveying information that draws on ideas or official data that is not public information.
The rules on the acceptance of a fee in such circumstances are interpreted differently by different agencies. The individual agency that employs the individual must therefore determine whether or not the federal employee can accept a fee from Pfizer. If Pfizer engages a federal employee outside of his/her official duties, the federal employee may not use his or her official title or position to identify himself or herself in connection with the services, including teaching, speaking, or writing on behalf of Pfizer or in conjunction with Pfizer colleagues. An employee’s title or position may, however, be included as part of his or her general biographical details when teaching, speaking, or writing. The employee’s title or position may also be used in connection with the publication of an article in a scientific or professional journal; however, a disclaimer must be printed acknowledging that the views expressed in the article do not necessarily represent those of the employee’s agency or the United States.

**Promotional Speakers**

Q. Can a VA employee be a speaker for Pfizer?

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

**National Institutes of Health**

Q. Can National Institutes of Health (NIH) employees work for Pfizer as consultants, if they have their employer’s permission? May we offer them payment for speaking at a Pfizer event?

A. The NIH, as well as most other government agencies, has special conflict of interest rules. Part-time and full-time NIH employees are prohibited from working or consulting for industry, with or without compensation, unless they have been granted prior written approval. Therefore, Pfizer may not directly retain NIH employees as consultants in their personal capacity without written approval from an authorized representative of NIH, and may not compensate NIH employees for teaching, speaking, writing, or editing.
FOR MORE INFORMATION

- **ENGAGE**
- **OpSource**
  - HCP Engagements SOP
  - HCP Services: U.S. and International Fair Market Value SOP
- **Policy Source**
  - CP #206: Compliance with Global Trade Control Laws Policy
  - CP Section #206A: Restricted Party Screening
  - CP Section #206E: Technology Transfers and Deemed Exports
  - CP #207: Global Policy on Interactions with Healthcare Professionals (GPIHP)
  - CP #301: Travel, Entertainment and Other Business-Related Expenses Procedure
  - CP #304: Global Meetings and Conferences Policy and Procedure
- **Corporate Compliance**
  - My Anti-Corruption Policy and Procedures (MAPP)
  - Orange Guide Chapter 9: Speaker Programs for HCPs
- **White Guide Chapter 4: Marketing Programs**
- **White Guide Chapter 8: Non-Promotional and Media Activities**
- **White Guide Chapter 9: Clinical Research and Investigator-Initiated Research (IIR)**
- **White Guide Chapter 11: Privacy: Protecting Personal Information**
- **White Guide Chapter 15: State Laws: HCP and State Employee Restrictions**
- **White Guide Chapter 18: Meals, Educational Items and HCP Payment Disclosure**
- **CMCD CT 22: Use of Data Monitoring Committees and Conduct of Interim Analysis**
- **Pfizer Worldwide R&D SOP #201: R&D GPIHP and External Funding Controls**
- **E-mail Contacts**
  - Refer FCPA questions to FCPAQuestions@pfizer.com
  - Refer Global Trade Controls, Restricted Party Screening, and Restricted Country questions to gtc@pfizer.com
  - Refer any other questions to ENGAGE2@pfizer.com or your team attorney

Rev. 01/16
Chapter 6: GOVERNMENT HEALTHCARE PROGRAMS

CONTENTS

Government Healthcare Programs

Introduction .................................................................................................................................................................... 3

Key Points to Ensure Compliance ........................................................................................................................ 4

Medicare ........................................................................................................................................................................ 4

Medicare Part D ..................................................................................................................................................... 5

Pharmacy and Therapeutic (P&T) Committee Members ................................................................................... 7

Medication Therapy Management Programs ............................................................................................ 8

Patient Assistance Programs ...................................................................................................................... 9

Medicaid ....................................................................................................................................................................... 10

Medicaid Drug Rebate Program ......................................................................................................................... 10

Medicaid Risk Areas ............................................................................................................................................. 12

Inaccurate Price Reporting and Concealing Best Price ............................................................................. 12

Health Insurance Exchanges ........................................................................................................................................ 12

Section 340B Pricing Program ............................................................................................................................ 13

Federal Supply Schedule ........................................................................................................................................ 14

Federal Ceiling Price ..................................................................................................................................................... 14

Department of Veterans Affairs and the Department of Defense .................................................................... 15

State Pharmaceutical Assistance Programs ........................................................................................................ 15

340B AIDS Drug Assistance Programs ........................................................................................................ 16

Rev. 01/16

Page 1 of 17
Chapter 6: GOVERNMENT HEALTHCARE PROGRAMS

Introduction

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

Pharmaceutical manufacturers additionally provide preferred prescription drug pricing to federal customers generally via the Federal Supply Schedule and to specific federal purchasers, including the Department of Veterans Affairs (VA) and the Department of Defense (DoD), as required by statute. Companies also provide discounts under the Public Health Services 340B Outpatient Drug Discount Program, as well as through certain state-supported programs, including State Pharmaceutical Assistance Programs and AIDS Drug Assistance Programs.

Paying or providing benefits to healthcare providers or beneficiaries to prescribe or utilize products ultimately reimbursed by federal healthcare programs potentially implicates the federal Anti-Kickback Statute and state all-payer laws. Similarly, failure to provide the government with preferential pricing in certain situations may expose a manufacturer to liability under various federal and state laws. It is critical that Pfizer remain vigilant of – and responsive to – all federal and state laws that may be implicated while doing business with the government.

This Chapter summarizes key Pfizer policies regarding government healthcare programs. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination.

Rev. 01/16

Page 3 of 17
**Key Points to Ensure Compliance**

- Pfizer must not link or reference the terms of a commercial rebate agreement with a Medicare Part D agreement or leverage a commercial arrangement to secure a Medicare Part D agreement.

- Pfizer colleagues must not provide P&T Committee members with “special treatment.” In addition, Pfizer colleagues must take special care not to link any financial transaction (other than disclosed rebate or discount arrangements) to formulary decisions or formulary placement of a Pfizer product.

- Pfizer may not provide any substantial assistance in the structuring of a Part D sponsor’s “Medication Therapy Management Program” (MTMP). In addition, Pfizer may not provide any substantial resources to, or work with, a Plan D sponsor for the purpose of helping such a customer fulfill its MTMP obligations.

- Generally, if Pfizer provides anything of monetary value to its customers as part of price negotiations, it must be reflected in Pfizer’s reported discounts to Medicaid. Under no circumstances may Pfizer conceal information to avoid paying higher Medicaid rebates.

**Medicare**

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

The original Medicare program had two parts: Part A (Hospital Insurance) and Part B (Supplemental Medical Insurance). **Medicare Part A** helps defray the costs of inpatient care received in a hospital, skilled nursing facility, or hospice. **Medicare Part B** helps pay for medically-necessary healthcare professional services and other outpatient care not covered under Part A. Part B also covers some preventive services such as screening exams and lab tests to detect, prevent, or manage a medical condition. Under the original Medicare program, the government reimburses the provider (e.g., a

*Rev. 01/16*
doctor or an institution) for certain drugs used in certain settings as part of payment for the patient’s overall care. Medicare beneficiaries may also enroll in the Medicare Advantage (MA) Program, otherwise known as Medicare Part C. MA Plans are managed care Medicare plans that generally provide a wider range of services than those covered under the original Medicare program.

In addition, with the changes introduced by the MMA, individuals covered under Medicare are also eligible for outpatient prescription drug coverage under Medicare Part D. Operationally, beneficiaries may obtain prescription drug coverage through Part D stand-alone Prescription Drug Plans (also called PDPs) or through Medicare Advantage-Prescription Drug Plans (also called MA-PD plans) under Part C. Part D enrollees incur cost-sharing obligations (including deductibles and co-payments), although many low income individuals are eligible for subsidies.

**Medicare Part D**

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

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

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

- A pharmaceutical manufacturer and a Managed Care Customer have a commercial agreement that provides the Managed Care Customer with an average 10% rebate on all products. The parties enter into negotiations on new commercial and Part D agreements. In exchange for the Managed Care Customer placing 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 is the swap and may be considered an improper reward to the Managed Care Customer for providing the pharmaceutical company with access to the Managed Care Customer's Part D plan. In the government's eyes, this could be a problem, because Medicare beneficiaries would have been cheated out of an additional 2.5% rebate.

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

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

**Contract Negotiations**

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

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

**Pharmacy and Therapeutic (P&T) Committee Members**

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

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

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

Medication Therapy Management Programs

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

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

Q. May Pfizer provide approved patient care materials in order to help satisfy a Pfizer customer’s MTMP obligations?

A. No. Pfizer may not provide Pfizer materials (including Pfizer quality programs and quality care pyramids) with the intent that a customer use them to satisfy its MTMP requirements. Pfizer may not assist in the structuring of MTMPs or encourage the use of Pfizer materials in MTMPs. For additional information regarding MTMPs, consult the Organized Customer Legal team.

Patient Assistance Programs

A Patient Assistance Program (PAP) is a program that helps qualified (typically low income or indigent) patients obtain medications at lower or, in some circumstances, zero cost. Pfizer Inc and the Pfizer Patient Assistance Foundation™ jointly formed Pfizer RxPathways®, the family of Pfizer’s PAPs, to create options for people who may not be able to afford needed prescription medicine. These programs generally provide savings on Pfizer medicines or provide free Pfizer medicines for people with limited incomes who qualify. The Pfizer RxPathways website, http://www.pfizerrxpathways.com, provides information on Pfizer’s PAPs. Pfizer may also provide general reimbursement information about its products through Pfizer reimbursement assistance programs.

Over time, and increasingly since the creation of Medicare Part D, the government has become concerned that pharmaceutical manufacturer assistance could run afoul of the federal Anti-Kickback Statute or other laws. For example, the Office of Inspector General (OIG), the enforcement arm of the Department of Human Services (HHS), identified that the Anti-Kickback Statute might be implicated if manufacturers, via PAPs, subsidize cost-sharing obligations for covered Part D drugs. Specifically, the OIG stated that this type of program presents the typical fraud and abuse risks 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 beneficiaries’ incentives to use less expensive and equally effective drugs.

At bottom, however, the government has continued to permit PAPs where Medicare Part D beneficiaries are concerned, in certain properly structured scenarios. For example, PAPs that operate “outside of Medicare Part D” minimize risk. In such circumstances, a Part D enrollee chooses to obtain medication without using the Part D insurance and therefore, does not file any claims for payment with
the Part D Plan. Pfizer PAPs operate outside of Medicare Part D, meaning the PAP is not available to patients that wish to file a claim with a Part D plan for the Pfizer medication at issue. For additional information on Pfizer PAPs and Medicare Part D risks, consult White Guide Chapter 10: Patient Assistance Programs.

Medicaid

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

Medicaid Drug Rebate Program

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

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

- 23.1% of the Average Manufacturer Price (AMP) for such unit; or
- If greater, the difference between the AMP and the manufacturer's Best Price for such unit.
The Patient Protection and Affordable Care Act (PPACA) additionally revised the statutory minimum rebates for pediatric, clotting, and generic drug products.

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

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

The following transactions are excluded from the Best Price calculation:

- Sales at “nominal prices” (defined as prices less than 10% of AMP) if made to “covered entities” under Section 340B of the Public Health Service Act (see discussion below), intermediate care facilities for the mentally handicapped, and certain state-owned or operated nursing facilities;
- Prices paid by Medicare Part D Plans;
- Prices charged to the Indian Health Service, the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and entities entitled to discounts which include federally-qualified and migrant health centers and certain high-indigent care hospitals;
- Prices charged under the Federal Supply Schedule of the United States General Services Administration and qualifying single award contract price of any federal agency;
- Prices negotiated from drug manufacturers for covered drugs under a qualifying discount card program; and
- Any prices used under a qualified state pharmaceutical assistance program.
CMS uses AMP and Best Price data to calculate the **Rebate Per Unit (RPU)** (also called **Unit Rebate Amount (URA) values**). The RPU is the amount that is owed by the pharmaceutical manufacturer for each unit of its product reimbursed by state Medicaid agencies to dispensing pharmacies. For more information on Pfizer’s Medicaid Best Price determinations and AMP and rebate calculations, consult the Organized Customer Legal team.

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

**Medicaid Risk Areas**

**Inaccurate Price Reporting and Concealing Best Price**

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

**Health Insurance Exchanges**

On March 23, 2010, President Obama signed the **Patient Protection and Affordable Care Act (ACA)**, into law. The ACA seeks to expand coverage, control healthcare costs, and improve healthcare delivery in part by (1) requiring most U.S. citizens to have health insurance; (2) creating state-based health insurance exchanges where individuals can purchase coverage; and (3) providing premium and cost-sharing credits to individuals/families with income between 133-400% of the federal poverty level who purchase insurance on the exchanges.
The state-based exchanges created by the ACA, called Health Insurance Exchanges (HIEs or Exchanges) are intended to be a marketplace where individuals can compare health insurance benefit programs and costs and buy insurance. The ACA requires that health insurance plans provide a minimum package of services in 10 categories called “essential health benefits” (EHB), including prescription drug coverage. Individuals who purchase insurance through an Exchange may be eligible for premium credits and cost-sharing subsidies depending on their income. The premium credits offset an individual’s premium payments so that they do not exceed a certain percentage of their income (e.g., an individual whose income is 133-150% of the Federal Poverty Limit may receive credits so that their premium payments won’t exceed 4% of their income). Cost-sharing subsidies are intended to reduce the amounts individuals will have to pay for out-of-pocket costs.

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

Section 340B Pricing Program

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

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

Section 340B pricing discounts are calculated using the Medicaid rebate formula and notably are excluded from Best Price calculations. These discounts are deducted from the manufacturer’s selling
price, rather than paid as a rebate. To determine these discounts, each quarter Pfizer calculates the **Section 340B Ceiling Price** (the statutorily defined maximum price that can be charged to Covered Entities) for every covered drug marketed by Pfizer using the same pricing data submitted to CMS for the Medicaid Rebate Program. For additional information on Section 340B and Pfizer’s pricing policy, consult the Organized Customer Legal team.

**Federal Supply Schedule**

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

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

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

**Federal Ceiling Price**

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

Manufacturers must report their non-FAMP on a quarterly basis. As with Best Price, in calculating the non-FAMP, a manufacturer must take into consideration any eligible cash discount or similar price reduction to eligible customers during the reporting period. “Nominal” prices and prices paid by the federal government are categorically excluded from non-FAMP calculations. The government also requires an additional discount if the Federal Ceiling Price increases faster than inflation.

Department of Veterans Affairs and the Department of Defense

In addition to purchasing prescription drugs from FSS or from the manufacturer at the Federal Ceiling Price, the VA and the DoD may also negotiate independent contracts with pharmaceutical manufacturers, including “Blanket Purchase Agreements.” Through Blanket Purchase Agreements, the VA and DoD negotiate with drug manufacturers for additional discounts. Typically, these involve market share agreements whereby the VA or DoD guarantee a volume purchase in exchange for discounts below the FSS or Federal Ceiling Prices. Blanket Purchase Agreements are negotiated on behalf of the VA by the VA National Acquisition Center in Chicago and on behalf of the DoD by the Defense Supply Center in Philadelphia.

The VA and DoD may also negotiate lower prices through competitively bid national contracts. Generally the VA or the DoD will seek competitive bids from manufacturers for products that are in a therapeutically equivalent class and will enter into an agreement with those manufacturers whose products provide the best value based on efficacy, safety, and price. In exchange for deeper discounts, the manufacturers’ products are placed on the VA’s national formulary or listed on the DoD’s Military Treatment Facility or Mail Order Pharmacy formularies of its managed healthcare program known as TRICARE.

State Pharmaceutical Assistance Programs

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

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

**340B AIDS Drug Assistance Programs**

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

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

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

**FOR MORE INFORMATION**

- [Orange Guide Chapter 7: P&T Committee Interactions](#)
- [White Guide Chapter 10: Patient Assistance Programs](#)
- [Green Guide: Governance for External Medical Activities](#)
- [http://www.pfizerrxpathways.com](http://www.pfizerrxpathways.com)
• Refer any other questions to your team attorney or the Organized Customer Legal team.
Chapter 7: SUPPORT OF EXTERNAL ORGANIZATIONS

CONTENTS

Support of External Organizations

Introduction .................................................................................................................................................................... 3

Key Points to Ensure Compliance ......................................................................................................................... 5

Medical Education Grants ............................................................................................................................................. 8

Overview ............................................................................................................................................................... 8

Application Submission ........................................................................................................................................ 9

Application Review, Notification, and Payment ................................................................................................ 10

Pfizer May Not Influence Grant-Funded Activities ............................................................................................ 10

Promotional Opportunities at Medical Education Conferences ....................................................................... 11

Complimentary Exhibit or Display Space ........................................................................................................... 12

Sponsorships and Charitable Contributions: All Divisions ......................................................................................... 12

General ................................................................................................................................................................. 12

Sponsorships and Charitable Contributions: R&D ............................................................................................ 13

Sponsorships and Charitable Contributions: the U.S. Biopharmaceutical Business, Pfizer Medical, Corporate Affairs ........................................................................................................................................... 13

Sponsorships ........................................................................................................................................................ 14

Charitable Contributions ..................................................................................................................................... 17

Collaborations ............................................................................................................................................................. 22

Overview ................................................................................................................................................................. 22

Rev. 01/16
Collaborations – Tangible Benefit and Disclosure of Pfizer Involvement ........................................................ 23

Awards, Scholarships, and Fellowships ...................................................................................................................... 23

Overview .............................................................................................................................................................. 23

Non-Financial Support .................................................................................................................................................25

Personal Volunteering .........................................................................................................................................25

Regular Membership and Board Membership ..................................................................................................25

FOR MORE INFORMATION....................................................................................................................................... 26
Chapter 7: SUPPORT OF EXTERNAL ORGANIZATIONS

Introduction

Pfizer is often asked to provide funding or other support to external organizations, including for-profit and not-for-profit entities. Pfizer provides external funding through 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)** discloses 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. Beginning in 2015, CMS discloses calendar year data on June 30th of each year. Please refer to **White 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.
Key Points to Ensure Compliance

- Understand the Policies that Apply to Your Group

- Funding to not-for-profit organizations by colleagues within the U.S. Biopharmaceutical Business, 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**. For specific questions relating to funding by Corporate Affairs, e-mail **PolicyFRC@Pfizer.com**.

- Funding to external organizations by colleagues in R&D must follow **Pfizer Worldwide Research & Development (R&D) SOP #201: R&D GPIHP and External Funding Controls**

- 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 colleagues in the U.S. Biopharmaceutical Business, 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 BU Colleagues (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>
</tr>
</tbody>
</table>

Rev. 01/16
### Key Points to Ensure Compliance

<table>
<thead>
<tr>
<th>Type of Funding</th>
<th>Sales</th>
<th>Non-Sales BU Colleagues (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>Policy Focused Healthcare</td>
<td></td>
<td></td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Charitable Contribution</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Special Event</td>
<td></td>
<td></td>
<td>Yes</td>
<td></td>
<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></td>
<td></td>
<td></td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>Medical Education Grant</td>
<td></td>
<td></td>
<td></td>
<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), Oncology KAMs, HIT Specialists, and Vaccine Account Managers.

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**Rev. 01/16**

Page 6 of 27
Key Points to Ensure Compliance

- Field Commercial Colleagues, as defined in the Overview and Key Principles Chapter in 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.

- 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 non-research grant funding or donations unless approved in advance by the relevant Chief Counsel or Compliance Counsel.

- 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 off-label 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 United States (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 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 of the United States fund independent medical education programs occurring in the United States?
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.
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**

From time to time you may be asked to pay for or provide a meal at a medical education conference held by a third party organization where CME/CE credit is being offered. You may not under any circumstances fund a meal or any other type of expense associated with a third party's medical education conference or activity where credit is being offered.

On occasion, Pfizer may be 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 they 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: R&D**

Funding to external organizations by **Worldwide R&D (WRD)** colleagues must follow [Pfizer Worldwide R&D SOP #201: R&D GPIHP and External Funding Controls](#). Any charitable contributions initiated by WRD 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 colleagues should consult [Pfizer Worldwide R&D SOP #201: R&D GPIHP and External Funding Controls](#) for additional guidelines and requirements.

**Sponsorships and Charitable Contributions: the U.S. Biopharmaceutical Business, Pfizer Medical, Corporate Affairs**

The remainder of this section describes the policy that applies to the U.S. Biopharmaceutical Business, 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 Policy**”) 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 the General Manager and Medical Lead for each BU. Those activities are addressed in the External Funding Policy.

**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.
“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 Policy 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, and for purposes of this chart found in 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>
<thead>
<tr>
<th>Tangible Benefit Examples*</th>
<th>Fair Recognition Examples (Not Considered A Tangible Benefit)</th>
</tr>
</thead>
<tbody>
<tr>
<td>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).</td>
<td></td>
</tr>
<tr>
<td>Distribution of branded materials or dissemination of information on specific products.</td>
<td></td>
</tr>
<tr>
<td>Promotional placement of product logos on a podium or in literature aimed at HCPs or patients.</td>
<td></td>
</tr>
<tr>
<td>The opportunity to promote Pfizer products (e.g., via branded materials or a booth at an exhibition).</td>
<td></td>
</tr>
<tr>
<td>The opportunity to promote Pfizer’s programs or services (e.g., Pfizer RxPathways).</td>
<td></td>
</tr>
<tr>
<td>Providing or selecting a speaker (including for a policy topic).</td>
<td></td>
</tr>
<tr>
<td>The opportunity to promote Pfizer unbranded programs (such as smoking cessation which may have related branded or unbranded materials).</td>
<td></td>
</tr>
<tr>
<td>The 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.</td>
<td></td>
</tr>
<tr>
<td>Placement of a Pfizer corporate logo by itself on a podium, in literature, or on a purchased table at an event.</td>
<td></td>
</tr>
<tr>
<td>Honorable mentions and announcement of thanks, written or verbal.</td>
<td></td>
</tr>
<tr>
<td>Tickets to an event.</td>
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<tr>
<td>Recognition in conference brochure/program (such as listing as Gold Sponsor).</td>
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</table>

* Subject to meeting all relevant review committee approval requirements.
If a not-for-profit sponsorship opportunity satisfies the above key characteristics, U.S. Biopharmaceutical Business, Pfizer Medical, and Corporate Affairs colleagues may submit a funding request using the **Funding Request Form (FRF)** available at [https://aribaprime.pfizer.com/Sourcing/Main](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 BU colleague 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 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 [ED SOP2-01: Exhibits and Displays SOP](https://example.com) ("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](https://example.com) 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](mailto: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. Biopharmaceutical Business (except for Sales Colleagues), Corporate Affairs, and Pfizer Medical. For purposes of the SOP on Funding Requests for Not-for-Profit Organizations PCA includes Account Managers, as defined in the Orange Guide Chapter 1: Overview and Key Principles Chapter.
- **Approval Process:** Requests for non-healthcare charitable contributions may be submitted using the Funding Request Form at [https://aribaprame.pfizer.com/Sourcing/Main](https://aribaprame.pfizer.com/Sourcing/Main). All such requests are subject to review and approval by Legal.

Healthcare charitable contributions (non-policy focused) are charitable contributions to healthcare-related organizations or to 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 third-party not-for-profit 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 only.

• **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 third party not-for-profit 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 only.

• **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.

Colleagues in the U.S. Biopharmaceutical Business and Pfizer Medical 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.
### Key Characteristics: Sponsorships vs. Charitable Contributions

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Sponsorship</th>
<th>Charitable Contributions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Promotional in nature</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Payee must be a not-for-profit organization (501(c)(3) or similar designation)</td>
<td>Yes (except for Exhibit and Displays)</td>
<td>Yes (but only 501(c)(3) organizations are eligible)</td>
</tr>
<tr>
<td>Pfizer must receive a “tangible benefit”</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Payment can be made to an individual HCP or private practice group</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Tickets or invitations received as a result can be offered to Healthcare Professionals</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Agreement documenting terms and conditions of Pfizer funding</td>
<td>Yes (agreement must clearly indicate the “tangible benefit”)</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### Information on Pfizer’s External Funding Policy

**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://aribaprime.pfizer.com/Sourcing/Main](https://aribaprime.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. The OpSource site also includes a funding request “wizard” and other tools that can help you determine whether a proposed funding activity is permissible for you to undertake. 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 Policy 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 Policy 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 Policy.

### Sponsorship Request related to For-Profit Organizations

**Q.** Does the External Funding Policy 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 Policy and should not be processed using the Funding Request Form in Ariba-ACM (FRF). 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 Policy?

**A.** Sales Funded Exhibits and Displays are subject to a different SOP — [ED SOP2-03: Exhibits and Displays SOP](http://opsource.pfizer.com/Pages/FundingRequestsPolicies.aspx) available on OpSource under the Funding Request tab that is separate from the External Funding Policy. You should submit Exhibit and Display requests through Ariba ACM using the [Funding Request Form (FRF)](http://opsource.pfizer.com/Pages/FundingRequestsPolicies.aspx) 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 exhibit and display space), then the External Funding Policy should be followed.
Appropriate Pfizer Foundation Referrals

Q. Can a customer’s request for a charitable contribution be forwarded to the Pfizer Foundation for consideration?
A. No. The Pfizer Foundation is an independent, tax exempt organization established by Pfizer Inc. The Pfizer Foundation provides funding through targeted initiatives focused primarily on health care and science education such as the Pfizer Foundation Matching Gifts Program or the Pfizer Foundation Southern HIV/AIDS Prevention Initiative.

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. Biopharmaceutical Business, 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 specific and discrete shared policy or disease awareness objectives. Pfizer may provide funds, resources, or expertise to the collaboration. 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 external organization(s), however, retains ultimate control of the goals, activities, and messaging, subject to Pfizer’s limited right to review (via Review Committee, where applicable) for factual accuracy and to ensure compliance with relevant laws and regulations, industry codes, external standards, and internal Pfizer policies and procedures.

- **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:** Colleagues in the U.S. Biopharmaceutical Business, Pfizer Medical, and Corporate Affairs groups.
• **Approval Process:** All requests to participate in a collaboration must be submitted by appropriate colleagues by creating a Funding Request Project in Ariba-ACM. All such requests are subject to review and approval by Legal. Colleagues should discuss all pertinent facts about a collaboration with Legal prior to submitting the Funding Request Project for approval.

• 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 limited 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 independent grant (e.g., “Developed in collaboration 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 Affairs are permitted to fund awards, fellowships, and scholarships.
Awards are programs developed with an independent professional group to provide funds or other recognition to an individual demonstrating professional excellence or an outstanding commitment to public health or patient care. Fellowships are generally funds paid to U.S. 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 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.

- **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 recipients is completely independent of direct and indirect Pfizer influence, which includes direct selection of awardees as well as paying or 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; 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.

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 (CP) #203: Conflicts of Interest, and other applicable Pfizer policies that address conflicts of interest. 

Rev. 01/16

Page 25 of 27
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 Responsibilities leadership in accordance with Corporate Procedure (CP) #801a: Charitable Contributions Procedures for U.S. Colleagues – Contributions of Cash, Capital Assets and Other Non-Product Items Procedure.

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 SOP available in OpSource under the “Funding Requests”.
- SOP on Funding Requests for Not-for-Profit Organizations (applies to the U.S. Biopharmaceutical Business, 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, 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.
• For questions regarding awards, scholarships or fellowships, e-mail PolicyFRC@Pfizer.com.
• Please refer to White 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 8: NON-PROMOTIONAL AND MEDIA ACTIVITIES

CONTENTS

Non-Promotional and Media Activities

Introduction .................................................................................................................................................................... 3

Key Points to Ensure Compliance ........................................................................................................................ 4

Service-Based Relationships ......................................................................................................................................... 5

Bona Fide Consulting Engagements .................................................................................................................... 5

Speaker Programs ................................................................................................................................................ 6

Non-Promotional Communications ............................................................................................................................. 7

Scientific Exchange Generally ............................................................................................................................... 7

Third Party Scientific Meetings ............................................................................................................................ 9

Responding to Unsolicited Requests for Medical Information .................................................................................. 10

Specified Roles with Respect to Non-Promotional Communications ........................................................................ 11

Pfizer Medical Information Department ................................................................................................... 11

External Promotional Speakers ............................................................................................................................... 11

Field Medical Directors (formerly RMRS Colleagues) and Similar Field-Based Medical Colleagues .... 12

MOS Colleagues and Similar Field-Based Medical Colleagues ........................................................................ 12

Other Pfizer Medical Colleagues ................................................................................................................ 13

Press Releases and Other Media Communications ................................................................................................... 13

Disclosures of “Material” Developments ........................................................................................................... 14

Corporate Press Releases .................................................................................................................................... 15
"New Data" Press Releases ................................................................................................................................. 16
Public Disclosure of Clinical Trial Terminations ................................................................................................. 17
Promotional Press Releases ................................................................................................................................. 17
Product-Specific Press Kits and Other Media Materials ................................................................................... 18
Contact Information & Disclaimer ...................................................................................................................... 19
Non-Promotional External Speaking Engagements ............................................................................................ 20
Interviews and Other Requests for Information ................................................................................................. 21
FOR MORE INFORMATION ........................................................................................................................................ 21

Rev. 01/16
Chapter 8: NON-PROMOTIONAL AND MEDIA ACTIVITIES

Introduction

In the United States, the Food and Drug Administration (FDA) regulates all promotional statements that Pfizer makes about its products. The FDA does recognize, however, that certain activities and the provision of information about current research and scientific data can be non-promotional. Thus, manufacturers may distribute certain information, and make some communications, without being subject to FDA rules governing product promotion. Non-promotional activities can generally be characterized as either service-based relationships or non-promotional communications.

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

- Non-promotional activities can generally be characterized as either service-based relationships or non-promotional communications.

- Non-promotional communications are those which are not designed or intended to promote the use of a Pfizer product in order to impact prescribing. They must be: truthful, accurate, and not misleading; supported by the relevant scientific data (including any relevant safety data); narrowly tailored to the topic being discussed; and void of any promotional claims or promotional context.

- Within a service-based relationship, both on-label and unapproved uses and indications for an approved product may be presented or discussed with an HCP during his or her performance of a service for Pfizer so long as any off-label information is relevant and narrowly tailored to the specific bona fide purpose of the service arrangement. All applicable policies, procedures, and approval processes for engaging HCPs for services must be followed.

- Scientific exchange constitutes the communication of medical information in a non-promotional manner and may include off-label information. It is generally regarded by Pfizer as an infrequent activity in which authorized Medical colleagues engage.

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

- Pfizer policy only permits certain Pfizer Medical colleagues to respond to unsolicited requests for medical information about unapproved products or indications. All other colleagues must refer the request to Pfizer's Medical Information Department (1-800-438-1985).

- All press releases must be coordinated with and issued by Pfizer Global Media Relations (1-212-573-1226). A press release discussing an unapproved product or use or other information that may be considered off-label must be non-promotional in tone and must comply with the principles of scientific exchange. It may not state that an unapproved product (or an unapproved use of an approved product) is "safe" or "effective."

Rev. 01/16
Key Points to Ensure Compliance

- Material nonpublic information (i.e., information that might affect the Company’s stock price) must be communicated only in a press release, a filing with the U.S. Securities and Exchange Commission, and/or a webcast presentation to which the public has been invited in advance.

- All media inquiries must be directed to Pfizer Global Media Relations (1-212-573-1226) and all inquiries from investors and investment analysts must be directed to Pfizer Investor Relations (1-212-573-2668).

Service-Based Relationships

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

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

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

**Speaker Programs**

Although speaker programs involve a Pfizer service-based relationship with a speaker, speaker programs are promotional activities because they are intended to influence the prescribing of the HCPs who attend the programs. To ensure compliance, all speakers must be trained and contractually agree to abide by FDA regulations and Pfizer policies governing promotion. These policies require that all Pfizer speakers use RC-approved materials and provide information consistent with product labeling.

In strictly limited circumstances, Pfizer permits speakers to respond to unsolicited questions from the audience requesting specific information outside of product labeling. The speaker may briefly respond to the specific question but must note that the use/information under discussion is off-label and that he or she is answering the question based upon his or her own knowledge or experience. Remember that it is not permissible to engage a particular HCP as a speaker in order to influence his or her prescribing. For more information, see [White Guide Chapter 4: Marketing Programs](#) and [Orange Guide Chapter 9: Speaker Programs for HCPs](#).

**Bona Fide Consulting Engagement**

Q. Pfizer is planning to pursue a new indication for an oncology product. The clinical team lead for the product would like to engage a consultant to assist with clinical trial design, which would involve discussion of off-label uses for the product. Is this permissible?

A. Yes. In order to obtain services in connection with clinical trial strategy for a new indication, the clinical team would have to discuss off-label uses for the product. Of course the interaction must always be scientific and objective in tone and substance and follow appropriate Pfizer guidelines.
Non-Promotional Communications

The FDA regulates promotional statements – those designed or intended to promote the use of a Pfizer product in order to impact prescribing – regardless of whether the promotional statement is made by a Sales or Marketing colleague or someone from another function. All promotional statements must be consistent with a product’s approved labeling. In contrast, non-promotional communications are those that are not designed or intended to promote the use of a Pfizer product in order to impact prescribing.

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

- Responses to unsolicited medical requests from HCPs or other customers;
- Proactive communication of clinical or scientific information that is new and/or urgently important to particular HCPs/customers (“scientific exchange”); and
- Publications in peer-reviewed journals.

Each category has specific rules that govern its appropriate use.

Non-promotional communications must be:

- Truthful, accurate, and not misleading;
- Supported by the relevant scientific data, including any relevant safety data;
- Narrowly tailored to the topic being discussed; and
- Void of any promotional claims or promotional context.

Scientific Exchange Generally

In certain circumstances, the Company may proactively provide scientific information that is outside the scope of an approved product’s labeling under the principle of “scientific exchange.” Scientific exchange constitutes the proactive communication of medical information in a non-promotional manner. Whether a communication will be considered non-promotional depends on the content of the communication as well as the context in which the information is presented. For example:
In terms of content:

- Providing previously disclosed information that is no longer new or is already known within the medical community is more likely to be viewed as promotional, while providing new, important scientific information that is not widely known in the medical community is more likely to be viewed as non-promotional.
- Non-promotional communications must not be promotional in tone (i.e., they must be devoid of brand logos and colors, promotional slogans or other content promoting a Pfizer product). Claims about the safety or efficacy of an unapproved product or for an unapproved indication are likely to be considered promotional and are not permitted to be proactively delivered under the guise of scientific exchange.

In terms of context:

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

Scientific exchange is generally regarded by Pfizer as an infrequent activity in which authorized Medical colleagues engage, and is reserved for exceptional circumstances.

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

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

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

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

To ensure that responses to unsolicited questions seeking off-label information are considered non-promotional communications, Pfizer policy permits only certain Pfizer Medical colleagues to respond to

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Since no one factor is determinative, the totality of the circumstances must be taken into account when assessing whether a particular presentation or activity constitutes legitimate scientific exchange or other non-promotional communication not subject to promotional standards. For more information please consult your team attorney.
such requests for information. For these colleagues, the provision of off-label information in response to a question is appropriate so long as the question is unsolicited and the response is:

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

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

**Specified Roles with Respect to Non-Promotional Communications**

**Pfizer Medical Information Department**

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

**External Promotional Speakers**

HCPs retained as promotional speakers cannot initiate off-label discussions of our products to other HCPs at Pfizer speaker programs. If a promotional speaker is asked an unsolicited question regarding off-label information by an audience member, however, he or she may briefly respond to the specific question. Speakers must note that the use/information under discussion is off-label, and that he or she is answering the question based upon his or her own knowledge or experience. A promotional speaker retained by Pfizer is “speaking for Pfizer” when he or she presents, and failure to adhere to these guidelines exposes Pfizer (and the speaker) to the risk of prosecution and penalties.
Field Medical Directors (formerly RMRS Colleagues) and Similar Field-Based Medical Colleagues

The Regional Medical & Research Specialists (RMRS) role in the United States transitioned to the Field Medical Director (FMD) role in 2014. The FMD role has been purposefully designed to allow these Field Medical Colleagues to provide approved (through the Medical Review Committee process), non-promotional medical and scientific information to HCPs regarding the safe and appropriate use of Pfizer medicines for approved indications. FMDs may also provide support for Pfizer-sponsored research activities (e.g., facilitation of research site selection and study placement) and interact, where appropriate, with investigator-initiated research investigators. Please consult the Green Guide: Governance for External Medical Activities, for policy on responding to requests for off-label information and other non-promotional activities. The Green Guide is applicable to Field Medical Directors (FMD), Medical Outcomes Specialists (MOS), and other field-based Medical colleagues in the United States, as well as U.S. Business Unit (BU) Medical Affairs/Engagement colleagues when interacting with HCPs.

MOS Colleagues and Similar Field-Based Medical Colleagues

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

All unsolicited requests received by MOS for off-label data, including those seeking information on the general safety or efficacy of Pfizer products, must be referred to Pfizer’s Medical Information

Rev. 01/16
Department. The MOS group and other similar field-based medical groups must adhere to the Green Guide.

**Other Pfizer Medical Colleagues**

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

### Unsolicited Request for Medical Information

**Q.** A lead investigator on a Pfizer-sponsored study calls a Pfizer Medical colleague on a brand team seeking data on file relevant to an off-label use of the Pfizer product which is the subject of the study. Can the Medical colleague provide this information?

**A.** Yes. It is permissible to provide the requested information as long as the information provided is: (1) truthful, accurate, and not misleading; (2) supported by the relevant scientific data, including any safety data; (3) narrowly tailored to answer the question asked; and (4) void of any promotional claims.

### Press Releases and Other Media Communications

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

Because Pfizer is a publicly traded company, the investment community generally must be informed when there are “material” developments that could impact the company’s stock price. Press releases help Pfizer to meet this obligation. Our press releases must provide balanced, accurate, complete, and non-misleading information. Failure to do so can trigger lawsuits. For example, investors might seek damages based on a claim that they were not provided adequate information about events that negatively impacted the company’s stock price. Pfizer Global Media Relations includes disclaimer information at the end of these press releases when the releases include forward-looking information (see “Contact Information & Disclaimer” below).

Material nonpublic information may not be disclosed selectively – meaning it may not be disclosed in nonpublic conversations, meetings, or written materials or other means. Such information may be disclosed only for legitimate business reasons on a need-to-know basis internally to Pfizer colleagues or to engaged consultants who are bound by a legal obligation to maintain confidentiality. At the time of public disclosure, such information must be disclosed to the entire investment community in a press release, a filing with the U.S. Securities and Exchange Commission (SEC), and/or a webcast presentation to which the public has been invited in advance. Only information that has been previously disclosed publicly may be discussed in nonpublic settings, such as in meetings or calls with investors or investment analysts. For more information, see CP #604: Treatment of Material Nonpublic Information.

Corporate Governance, in consultation with investor relations/media (as well as, if appropriate, certain internal stakeholders) will make an assessment as to whether a press release is material (i.e., market moving). A determination will also be made regarding whether a blackout notice (which may restrict trading of Pfizer stock by certain colleagues) should be sent to, and/or preclearance procedures imposed upon, those colleagues “in the know” prior to public disclosure of the development. Individuals that are “in the know” should not trade in Pfizer stock prior to the determination of whether the information included in the press release is material and whether a blackout notice is required.

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

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

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

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

**Corporate Press Releases**

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

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

Q. Is it permissible to issue a press release to the investment community claiming that a new study demonstrates that a product (or a new use) that has not yet been FDA-approved is safe and effective?

A. No. Press releases that provide details about unapproved products or uses must be objectively factual and should avoid the use of promotional adjectives or conclusory comments about safety or efficacy (as the FDA has not yet made its determination about those issues). They should also describe such uses as “investigational.”

“New Data” Press Releases

Pfizer often issues a “new data” press release to disseminate results of a study that have not been previously made public. Press releases announcing new data must describe the size of the study, the study design, and the primary endpoints. If a team wishes to include results on secondary endpoints, all such endpoints should generally be included, to avoid the perception of “cherry picking.” Furthermore, if the “new data” release is a disclosure of pivotal primary results pursuant to Clinical and Medical Controlled Document (CMCD) CT20-POL: Public Disclosure of Pfizer Clinical Study Data and Authorship, the requirements of that SOP should be met, including secondary endpoints (as appropriate, and, if being issued pursuant to CMCD CT20-POL: Public Disclosure of Pfizer Clinical Study Data and Authorship (see below), in accordance with the requirements set forth in CMCD CT20-POL: Public Disclosure of Pfizer Clinical Study Data and Authorship), the statistical significance of the findings, adverse events or other safety information seen in the study, significant exclusion criteria, and whether the product which is the subject of the press release is or is not approved for the use described in the study. A new data press release must not omit material information about the study (which might include whether the study results are contradicted by other major findings). In addition, “new data” press releases should be carefully reviewed and considered if the press release seeks to portray positive aspects of a trial that failed to achieve its endpoint(s) with statistical significance. In short, the press release cannot present “cherry-picked” data.

CMCD CT20-POL: Public Disclosure of Pfizer Clinical Study Data and Authorship provides that, with certain exceptions, Pfizer must issue press releases (as soon as practicable after the availability of the results of the primary endpoints) to disclose results of the primary endpoints of Phase 3 (including Phase 3B) and certain Phase 4 studies, whether or not the results are considered material. For more
information, including information regarding the disclosure of secondary endpoints, see CMCD CT20-
POL: Public Disclosure of Pfizer Clinical Study Data and Authorship.

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

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

**Public Disclosure of Clinical Trial Terminations**

For Phase 3 discontinuations, Pfizer’s standing policy is to issue a press release upon internal endorsement of the recommendation. Pfizer generally does not issue press releases for discontinuation of clinical trials prior to Phase 3, unless deemed necessary given materiality considerations or advisable given Investor Relations considerations.

**Promotional Press Releases**

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

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

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

**Product-Specific Press Kits and Other Media Materials**

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

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

As with press kits, other media materials, such as audio/video news releases, are generally regarded as promotional and therefore must meet promotional standards and be RC approved. For more information on the review and approval process of product-specific press kits and other media materials, see White Guide Chapter 2: Advertising and Promotional Materials.

**Post-approval Communications**

Q. Do we need to submit for internal review a press release that highlights newly published clinical trial data for an approved Pfizer product? What about an unapproved product?

A. Yes. Any release that discusses data about an approved product must be approved by Legal, Medical, and Regulatory, as well as Pfizer Global Media Relations in consultation with Investor Relations and Corporate Governance. Approval is also required for releases on unapproved products.
Contact Information & Disclaimer

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

If the press release contains any forward-looking information, it should include a disclosure notice, approved by Corporate Governance, such as the following:

DISCLOSURE NOTICE: The information contained in this release is as of [insert date of the release]. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about [certain product candidates and certain potential additional indications for [insert names of applicable approved product(s) or investigational compound(s)] [to be customized to reflect contents of the release], including their potential benefits, that involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including, without limitation, the ability to meet anticipated clinical trial commencement and completion dates as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; whether and when new drug applications may be filed in any jurisdictions for [insert name of product(s) or compound(s)]; whether and when such applications may be approved by regulatory authorities, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of [name of product(s) or compound(s)]; and competitive developments] [to be customized to reflect contents of the release].

A further description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for [insert the latest year for which a 10-K has been filed] and in its subsequent reports on Form 10-Q, including in the sections thereof captioned “Risk Factors” and “Forward-Looking Information and Factors That May Affect Future Results,” as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and are available at [www.sec.gov] and [www.Pfizer.com].
The press release should also direct the audience to other sources where it may find additional information about the product’s potential risks. Of course, a press release’s disclosure language should be customized to the information included in the press release and reviewed by Corporate Governance prior to use.

**Non-Promotional External Speaking Engagements**

Pfizer colleagues may participate in external non-promotional speaking engagements and contribute to articles and publications relevant to their areas of expertise. As representatives of Pfizer, colleagues must, however, ensure that any company information disclosed in presentation materials, handouts, Q&A sessions, articles, etc., is truthful, accurate, complete, timely, and consistent with Pfizer’s publicly stated position on related issues. When invited to speak at a third-party sponsored meeting, seminar, workshop, conference, etc., or to author a document for publication, you must obtain the approval of your manager. Your manager must determine whether it is appropriate for you to participate and should consult Legal, if necessary. (If you are unclear whether the content of your proposed activity is likely to be perceived as promotional, you should consult your team attorney for further guidance).

Colleagues approved to participate in external speaking engagements are not required to obtain prior review and approval of their presentation materials (including pre-read materials, PowerPoint presentations, handouts, etc.) unless requested by the approving manager, but must be sure not to disclose any confidential information or material non-public information. If you have any uncertainty regarding what information may be considered confidential or material (or if the nature of the engagement involves discussion about Pfizer products) you should consult with your manager or Legal, as appropriate. You are responsible for assuring that any company information disclosed in those materials, or in the course of the event itself, is truthful, accurate, complete, timely, and consistent with Pfizer’s publicly stated position on related issues. If you are asserting any personal opinions in a talk or speaking engagement, you must clarify with the audience that the opinions expressed are yours and not necessarily those of Pfizer. If the press or media and/or analysts or investors are likely to be present at a third-party sponsored event, you must contact Pfizer Global Media Relations and Pfizer Investor Relations (as applicable) well in advance of the event to ensure effective preparation.
Interviews and Other Requests for Information

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

- If you receive any type of inquiry or request for information from the media (including verbal or telephone, written or electronic requests): direct the inquiry or request to Pfizer Global Media Relations (1-212-573-1226). Unless specifically directed by a member of Pfizer Global Media Relations, you may not answer any questions or supply any information directly to the media, or conduct interviews with the media. For more information, see Corporate Policy & Procedure (CP) #409: Relations with the News Media.
- If you receive any type of inquiry from investors or investment analysts: direct the inquiry to Pfizer Investor Relations (1-212-573-2668).
- If you receive any type of inquiry or request for information from any federal, state, or local government entity: promptly seek guidance from the Legal Division before responding.

FOR MORE INFORMATION

- Refer any questions to your Regulatory Affairs or Legal team colleague, Pfizer Global Media Relations & Digital Communications (1-212-573-1226), or Pfizer Investor Relations (1-212-573-2668)
- Green Guide: Governance for External Medical Activities
- Orange Guide Chapter 9: Speaker Programs for HCPs
- White Guide Chapter 2: Advertising and Promotional Materials
- White Guide Chapter 4: Marketing Programs
- White Guide Chapter 5: HCP and Government Official Consulting Engagements
- CMCD CT20-POL: Public Disclosure of Pfizer Clinical Study Data and Authorship
- Corporate Policy (CP) #407: Social Media Policy
- Corporate Policy & Procedure (CP) #409: Relations with the News Media
- Corporate Policy (CP) #604: Treatment of Material Nonpublic Information
- Medical Policy CT20CT 20-POL: Public Disclosure of Pfizer Clinical Study Data and Authorship
- Pfizer Twitter Guidelines
• **USMI SOP** – Requests for medical information should be directed to Global Medical Information at 1-800-438-1985
Chapter 9: CLINICAL RESEARCH AND INVESTIGATOR-INITIATED RESEARCH (IIR)

CONTENTS

Clinical Research and Investigator-Initiated Research (IIR)

Introduction .................................................................................................................................................................... 3
Key Points to Ensure Compliance ........................................................................................................................ 6
Healthcare Law Compliance Issues ............................................................................................................................... 7
Pfizer-Sponsored Clinical Studies ................................................................................................................................. 7
Regulatory and Ethical Framework ............................................................................................................................. 7
IND Requirements ........................................................................................................................................ 7
IDE Requirements ........................................................................................................................................ 8
Privacy Rules ................................................................................................................................................. 8
Good Clinical Practices ...................................................................................................................................... 8
Interactions with HCPs and Government Employees ......................................................................................... 9
Additional Requirements ..................................................................................................................................... 9
Scientific Validity and Value to Pfizer .................................................................................................................. 10
Selection of Investigators .................................................................................................................................... 10
Study Design, Conduct, and Monitoring .............................................................................................................. 12
Managing Study Conduct Quality Issues ........................................................................................................... 12
Compensating Investigators ................................................................................................................................... 13
Investigator Meetings ........................................................................................................................................... 15

Rev. 01/16
Financial Support ................................................................................................................................................. 15
Public Disclosure and Access to Study Data ...................................................................................................... 16
Compassionate Access ........................................................................................................................................ 18
Investigator-Initiated Research (IIR) Studies .............................................................................................................. 18
Receipt of Proposals ............................................................................................................................................ 18
Scientific Validity and Value to Pfizer .................................................................................................................. 19
Nature and Basis of Pfizer Support ....................................................................................................................... 20
Independence and Investigator Responsibilities .................................................................................................. 21
Regulatory and Ethical Framework ....................................................................................................................... 22
IND Requirements ............................................................................................................................................. 22
IRB/IEC Approvals ............................................................................................................................................ 22
Publication of IIR Study Results .......................................................................................................................... 22
FOR MORE INFORMATION ........................................................................................................................................ 23
Chapter 9: CLINICAL RESEARCH AND INVESTIGATOR-INITIATED RESEARCH (IIR)

Introduction

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

At times, Pfizer sponsors clinical trials as part of the development of medicinal products and devices. Sponsored clinical studies are designed, conducted, overseen, and analyzed by Pfizer or on behalf of Pfizer. Consequently, Pfizer is generally responsible for all of the regulatory obligations applicable in the geographies where these trials are conducted. Pfizer-sponsored studies may be intended to support a new product, a significant change in the labeling of a Pfizer product, a new indication, or a proposed advertising claim. The company may engage the services of Contract Research Organizations (CROs) or other service providers to assist in execution of some or all elements of clinical trial conduct including study design, start up, study management, data monitoring, analysis, and reporting.

Pfizer also provides support for research activities designed and sponsored by outside investigators or institutions, often referred to as Investigator-Initiated Research (IIR) studies. IIR projects can include preclinical studies and interventional or non-interventional clinical studies, and may or may not involve the use of a Pfizer product. Pfizer may choose to support such studies with funding, study medication, clinical trial data, pure drug substance, laboratory analyses, or a combination of one or more of these support types. Pfizer is not the regulatory sponsor of IIR studies and does not intend to rely on data.
from these IIR studies in any regulatory submissions. Pfizer employees should not be involved in the design, conduct, supervision, direct management, or monitoring of an IIR project. This would violate Clinical and Medical Controlled Document (CMCD) CT25-GSOP: Pfizer Non-Sponsored Research, because involvement of Pfizer employees in these studies could result in Pfizer becoming subject to liability for the study generally and/or for ensuring regulatory compliance of the study. If Pfizer intends to have regulatory responsibility for a clinical trial (e.g., Pfizer is the study sponsor), then the study is not an IIR and must follow all appropriate SOPs for Pfizer-sponsored studies.

Interventional studies, often called clinical trials, are carried out to determine the effects of a treatment. The study participants are assigned to a particular treatment strategy, decided in advance by a study protocol. The protocol defines specific diagnostic, therapeutic, and/or other types of interventions that study subjects will receive/undergo. The assignment of the intervention may or may not be random. Study subjects are followed and biomedical and/or health outcomes are assessed.

Clinical and Research Collaborations (CR Collaborations) are engagements under which Pfizer collaborates with a third party to perform a clinical study and/or research activities. Unlike IIRs under CMCD CT25-GSOP: Pfizer Non-Sponsored Research or a grant of pure substance only under CMCD CT15-GSOP: Request for Pfizer Compound, CR Collaborations can be initiated by Pfizer (e.g., Pfizer approaches an external party to propose a collaboration) or initiated by a third party (e.g., a third party approaches Pfizer to propose a collaboration).

CR Collaborations managed by the External Medical Communications Group are subject to the requirements of CMCD CT44-GSOP: Clinical and Research Collaborations. These engagements are defined as collaborations under which Pfizer provides financial and/or non-financial benefit to a third-party (e.g., intellectual property rights, data, pure compound, formulated drug, product, device, etc.) where the conduct of such study requires approval of, and/or consultation with, a regulatory authority (including approval via an IND or a CTA) and/or an IRB or EC, and one or more of the following criteria are met:

- Pfizer is involved in designing, conducting, monitoring, and/or supervising the research or clinical study; and/or
• Pfizer intends to submit the data generated by a third party in support of an application to a regulatory authority or to fulfill a regulatory commitment post approval; and/or
• Pfizer intends to use the data for internal research purposes.

Please note also that CR Collaborations are not subject to the requirements of CMCD CT25-GSOP: Pfizer Non-Sponsored Research. CT25-GSOP only applies to IIRs and Clinical Trial Data Access Requests (CTDs). Studies initiated as “Collaborative IIRs” as previously defined in CT25-GSOP are now subject to the requirements of CMCD CT44-GSOP: Clinical and Research Collaborations and are no longer subject to the requirements of CT25-GSOP.

For more information, please refer to CMCD CT44-GSOP: Clinical and Research Collaborations.

This Chapter is relevant to all Pfizer colleagues who have responsibility for Pfizer-sponsored clinical studies, IIRs, and CR Collaborations. Non-compliance with policies applicable to those activities puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination.
**Key Points to Ensure Compliance**

- The decision to engage an HCP as a clinical investigator or to provide support for an IIR or CR Collaboration study must be made by Pfizer colleagues in a Medical, Clinical, or R&D function (i.e., not Commercial).

- Funding or other support for medical research must never be provided to:
  - Establish or improve Pfizer’s relationship with an HCP or organization;
  - Gain or improve access to an HCP;
  - Reward past prescribing practices or influence or induce future prescribing practices; or
  - Reward a past formulary decision or influence an upcoming formulary decision.

- Research sponsored or supported by Pfizer must:
  - Have genuine scientific and/or clinical value;
  - Involve investigators or institutions selected on the basis of criteria relevant to the research;
  - Involve compensation that is “fair market value” for the services provided; and
  - Be conducted in compliance with recognized scientific and ethical standards, as well as applicable laws and regulations.

- The recipients of IIR support must be chosen on the basis of the merits of their research proposals and the scientific qualifications of the investigators. This same principle applies to engaging with collaborators for CR Collaborations.

- An asset or product’s IIR strategy is determined by the Medical Asset or Brand Leadership. Commercial colleagues may not attend strategy development meetings or otherwise influence or participate in the decision to fund an IIR study. Refer to [CMCD CT25-GSOP: Pfizer Non-Sponsored Research](#) for additional guidance on IIR strategy determination.

- Commercial colleagues may not attempt to influence a decision to engage the services of an HCP as a clinical investigator, to award an IIR to an HCP, or to collaborate in a CR Collaboration.

- Pfizer colleagues must follow all Pfizer policies and procedures in establishing and administering Pfizer-sponsored studies and in the support of IIR and CR Collaborations.
Healthcare Law Compliance Issues

Payments to HCPs may violate certain international, federal, and/or state anti-kickback statutes if such payments are offered or made to reward or influence the recipient’s prescribing or formulary practices or to establish, maintain, or improve Pfizer’s relationship with an HCP or formulary decision maker. In addition, both the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals and the Department of Health and Human Services Office of Inspector General (OIG) Compliance Program Guidance for Pharmaceutical Manufacturers forbid the use of “token” consulting arrangements. An example of a “token” consulting arrangement would be one involving payment to an investigator to encourage the use of a Pfizer product or to reward an investigator for previous use of a Pfizer product, rather than to address a genuine scientific issue or obtain meaningful clinical information.

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

Pfizer-Sponsored Clinical Studies

Regulatory and Ethical Framework

IND Requirements

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

In certain instances, Pfizer may choose to conduct some non-U.S. studies under an IND application to facilitate acceptance of the results of those studies by the FDA. Such non-U.S. studies would then be
subject to FDA regulations. In addition, all non-U.S. studies must comply with applicable local laws and regulations.

**IDE Requirements**

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

**Privacy Rules**

Global and U.S. data privacy rules require investigators to protect the confidentiality of any identifiable health information about a study participant that they obtain in connection with the study and to secure appropriate consents from study participants before disclosing such information to Pfizer. The *Privacy Rule of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)* also impacts the conduct of Pfizer-sponsored clinical studies. While HIPAA is not applicable to Pfizer in its role as study sponsor, it applies to most of Pfizer’s contracted U.S. investigators with respect to their use and disclosure of protected health information collected in studies. Pfizer personnel must always consider the confidential nature of study participant information that they review and ensure that appropriate safeguards are taken to protect such information in accordance with *Corporate Policy (CP) #404: Protecting the Privacy of Personal Information*. For a more detailed discussion of protected health information, please see *White Guide Chapter 11: Privacy: Protecting Personal Information*.

**Good Clinical Practices**

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

All interactions with HCPs in connection with Pfizer-sponsored studies must comply with *CP #207: Global Policy on Interactions with Healthcare Professionals (GPIHP)*. Pfizer is also committed to compliance with relevant industry standards, including *PhRMA’s Principles for Conduct of Clinical Trials and Communication of Clinical Trial Results*. In addition, all interactions with government officials or persons likely to interact with government officials in Pfizer-sponsored studies must comply with *My Anti-Corruption Policies and Procedures (MAPP)* and *International Anti-Bribery and Anti-Corruption Procedure*. See *White Guide Chapter 5: HCP and Government Official Consulting Engagements*, for additional information on interactions with government officials. In addition there are useful materials available at the WRD Anti-Corruption Resource Center ([http://acrc.pfizer.com/Pages/WRDACRC.aspx](http://acrc.pfizer.com/Pages/WRDACRC.aspx)) and on OpSource ([http://opsource.pfizer.com](http://opsource.pfizer.com)), such as the *U.S. Healthcare Professional Payment Disclosure, State Law and Physician Payment Sunshine Act Reporting SOP*.

Additional Requirements

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

In controlled studies, Pfizer policy also requires that the medical care provided to the control group is medically and ethically appropriate. Placebo-controlled studies are appropriate only in certain limited circumstances (e.g., when use of a placebo does not present undue risk to the health or well-being of the study participants), and in all cases the IRB/IEC must review and approve the appropriateness of the proposed treatment for the control group. Pfizer-sponsored clinical study teams should also address post-study care issues, including whether to provide the study drug to study participants after the study concludes and, if offered, which participants would qualify for this benefit. Applicable regulatory and ethical requirements and industry standards for Pfizer-sponsored clinical studies are reflected in the *CMCD Policies and SOPs on Clinical Trials*.
**Scientific Validity and Value to Pfizer**

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

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

**Selection of Investigators**

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

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

The roles and responsibilities of Pfizer clinical investigators in a Pfizer-sponsored study are documented in a Clinical Study Agreement between Pfizer and/or Pfizer’s CRO and the investigator or his or her institution. The Clinical Study Agreement also memorializes the investigator’s commitment to conduct the study in accordance with an approved protocol, comply with all regulatory obligations, report to
Pfizer any adverse experiences that occur over the course of the study, and secure study participant informed consent.

Pfizer policies and procedures relating to selection of investigators and financial disclosures are described in CMCD_CT08-GSOP: Clinical Site Management and Monitoring, and CMCD_CT23-GSOP: Financial Disclosure by Investigators.

**Conflict of Interest**

Q. May Pfizer engage an investigator to conduct a Pfizer-sponsored clinical study if the investigator owns stock in Pfizer or a subsidiary of the Company?

A. Yes. Ownership of Pfizer stock does not disqualify an investigator from participating in a Pfizer-sponsored clinical study. However, it is important to remember that, under FDA regulations, the investigator must disclose any significant (more than $50,000) equity interest in Pfizer during the time the investigator participates in the study and up to one year after the study's completion.

**Data Monitoring Committee Members**

Q. May a member of a Data Monitoring Committee (DMC) for a Pfizer-sponsored study be engaged as an investigator for another Pfizer study? May a DMC member be engaged for other services, such as consulting or speaking for Pfizer?

A. Members of a Data Monitoring Committee for Pfizer-sponsored studies relating to a particular product are not permitted to serve (concurrently or within the prior 12 months) as an investigator on a study relating to the same product. They are permitted, however, to serve as a DMC member for one product and simultaneously be an investigator for a different product. With strictly limited exceptions, individuals may not contract with Pfizer in any other capacity (e.g., on an advisory board, as a speaker, or as a consultant) or author a publication of the study results while serving as a DMC member for a Pfizer study. For further details, see CMCD_CT22-GSOP: Independent Oversight Committees, and White Guide Chapter 5: HCP and Government Official Consulting Engagements.
**Study Design, Conduct, and Monitoring**

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

**Managing Study Conduct Quality Issues**

It is the responsibility of all Pfizer colleagues and parties with whom Pfizer contracts to report promptly to the appropriate Pfizer Quality Assurance group any suspected significant quality issues associated with the conduct or management of Pfizer-sponsored studies. Examples of significant quality issues are those that involve the safety or rights of participants, or non-compliance with accepted ethical research norms that is likely to impact the integrity of the study data, such as significant departures from the study protocol or falsification of research records. It is Pfizer policy to investigate promptly any suspected quality issue related to a clinical study. Pfizer will take appropriate action to investigate the quality issue, remedy it, when possible, and prevent future recurrence. Pfizer’s requirements and procedures for reporting and handling suspected significant quality issues are described in CMCD QMS01-GSOP: Management of Significant Quality Events and Monitoring of Corrective and Preventive Actions.
Safety Information & Adverse Event Monitoring

Q. Are Pfizer study teams obligated to report safety information from Pfizer-sponsored studies? Can Pfizer choose what type of information it reports to regulatory authorities?

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

Compensating Investigators

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

Requirements relating to investigator compensation are set out in CMCD CT18-POL: Compensation to Investigators in Clinical Studies, and include the following:

- Compensation must be linked to specific services or associated activities (e.g., reimbursement of reasonable travel, lodging, and meal expenses associated with attendance at investigator meetings);
- The basis of compensation must be documented in a study budget that serves as an attachment to the Clinical Study Agreement;
• Compensation must be reasonable when compared to compensation for similar clinical studies sponsored by the pharmaceutical/biotechnology industry in the country where the study is conducted; and
• Study participants should be informed, as part of the informed consent process, that Pfizer is providing compensation to the investigator or institution for involvement in the study.

Under no circumstances may financial compensation to investigators in Pfizer-sponsored studies:

• Be tied to the outcome of the study;
• Include Pfizer stock or stock options;
• Include payments to physicians outside the study for referring potential study participants;
• Include special incentives such as enrollment bonuses, awards, or gift certificates designed to reward the achievement of participant enrollment goals within a specified time period; or
• Include any other type of additional incentives or rewards, except those prospectively identified in the Clinical Study Agreement or approved by the IRB or IEC. An acceptable basis for an incentive payment could be, for example, to recognize timely reporting of clinical data.

Investigator Compensation

Q. If enrollment is lagging in a sponsored study, can Pfizer offer investigators increased compensation to help expedite enrollment? For example, can we pay investigators an extra $700 per enrolled study participant?

A. While Pfizer may compensate investigators with fair market value payments for their participation in a clinical study, it would not be appropriate to offer investigators increased per-participant incentives to accelerate enrollment. Investigator compensation must be linked to bona fide services. If enrollment is difficult, Pfizer can make arrangements to cover the cost of additional advertising, staff time, or recruitment work by the investigator. It is important to remember that additional payments will need to be made to an investigator’s institution or clinical trial office, rather than to an individual investigator or his or her staff. If a study team has questions about whether a particular type of additional compensation is acceptable, the team should consult with the relevant attorney supporting the asset on the Clinical Development Legal team.
Investigator Meetings

Pfizer routinely invites investigators and key research staff to study-related meetings. Such meetings are usually held at the launch of a study and, as needed, intermittently as the study progresses. These investigator meetings provide information about the drug and study protocol, as well as opportunities for training and other activities designed to increase the consistency and quality of study conduct. Because investigator meetings are an expected component of clinical study participation, reimbursement for expenses associated with such meetings may be made in accordance with the terms of the Clinical Study Agreement. A separate agreement is not required. Reimbursement to investigators and staff for travel to investigator meetings and associated expenses must comply with CP #301: Travel, Entertainment and Other Business Related Expenses. The venue of investigator meetings should be conducive to the business purpose of the meeting, convenient for the participants, and not “resort-like” or “lavish.” International investigator meetings must comply with Pfizer’s MAPP. The Customer Engagement groups within Global Commercial Operations are typically responsible for organizing investigator meetings.

Financial Support

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

Some studies also include certain protocol-required Standard of Care (SOC) services. SOC services are medically necessary treatments, procedures, or tests that would be administered to the patient even if he/she had not enrolled in the study, consistent with good medical practice. Under certain circumstances, the costs of SOC services are not required to be covered by the study sponsor. However, Pfizer generally will not charge study participants for the costs of a Pfizer drug used in a Pfizer-sponsored study, even if the use of that drug is standard of care. For studies conducted in the United States, the determination of whether SOC costs may be charged to the study participant/insurer is governed by CMCD CT10-POL: Cost Coverage of Protocol Required Services in U.S. Clinical Studies.
For studies conducted outside the United States, this determination requires consultation with local Legal and Regulatory.

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

### Participant Compensation

**Q.** May Pfizer compensate research participants for their time and any reasonable expenses incurred during their participation in a sponsored clinical study? Can any payment be made contingent upon the completion of the study?

**A.** Pfizer is committed to compensating research participants fairly. Study participants should not have to bear unduly burdensome costs as a result of their participation in a Pfizer-sponsored study, but should also not be offered compensation that could be seen as excessive and, therefore, undermine the principle of voluntary informed consent. Pfizer may offer payment to research participants so long as the payment has been reviewed and approved by an IRB or IEC prior to the commencement of the clinical study. Payments must also be prorated (e.g., per visit), and must be based on the nature of the procedures, or the actual or anticipated expenses of participation, such as parking fees and travel and lodging expenses. While the entire payment may not be contingent upon completion of the study, Pfizer may reserve a small portion of the compensation as an incentive to complete the study, provided that the incentive is not excessive.

### Public Disclosure and Access to Study Data

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

Pfizer is committed to compliance with all federal and state requirements regarding access to clinical study information and results.

Pfizer also voluntarily complies with PhRMA’s Principles for Conduct of Clinical Trials and Communication of Clinical Trial Results and encourages the publication of the results of its sponsored studies by investigators, whether or not the results are favorable to the Pfizer product. Under those principles and Pfizer policy, study results must be reported in an objective, accurate, balanced, and complete manner and must discuss study strengths and limitations. Reports must also disclose Pfizer’s financial support. Pfizer reserves the right to review, prospectively, any proposed publication or other disclosure of the results of a Pfizer-sponsored study to prevent inadvertent disclosure of Pfizer proprietary information, and may request a delay in publication, if necessary, to protect intellectual property rights. In addition, all investigators who participated in the conduct of a single or multi-site clinical study are entitled to review relevant statistical tables, figures, and reports for the entire study at a designated Pfizer facility or other mutually-agreeable location.

Pfizer supports the authorship criteria established by the International Committee of Medical Journal Editors (ICMJE), which ensures that only those individuals who deserve authorship credit based on their contributions to a publication are identified as authors. Individuals who contribute to the publication in other roles, including technical writers, should be appropriately acknowledged, and sources of financial support for the study should be disclosed.

Pfizer’s policy on the public disclosure of information, access to data, and publications related to Pfizer-sponsored studies is outlined in CMCD CT20-POL: Public Disclosure of Pfizer Clinical Study Data and Authorship, CMCD CT28-GSOP, Public Disclosure of Pfizer-Sponsored Studies, and CMCD CT37-GSOP Development of Pfizer Publications. Authorship of publications, including the standards for acknowledgment as an “author” or “contributor,” is also discussed more fully in White Guide Chapter 17: Publications.

Rev. 01/16

Page 17 of 24
Compassionate Access

Pfizer is sometimes asked to provide an investigational product that has not yet received regulatory approval to treat a seriously ill patient who has exhausted approved treatment options and is ineligible to participate in any ongoing clinical study. Such requests should be submitted to Pfizer’s external online portal, PfizerCARES.com (for Pfizer Compassionate Access Request System). CMCD CT16-POL: Investigational/Unlicensed Product Use Outside of a Clinical Trial identifies the criteria that must be met for Pfizer to consider a “compassionate access” request. Compassionate access requests are decided on a fair and equitable basis generally within five days of submission. Generally, such a request will not be honored unless the investigational product (for which Pfizer intends to pursue marketing approval) is being investigated under an appropriate regulatory authorization and there is meaningful human clinical data to support the determination that the potential benefits to the patient outweigh the risks. Non-clinical factors, such as the identity of the patient or the requestor, must not play a determinative role in the consideration of a compassionate access request. The relevant study team is responsible for evaluating compassionate access requests and the clinical lead will make the final determination of whether or not to honor the request. See http://www.pfizer.com/research/compassionate_use for more information and to review Pfizer’s Compassionate Access policy, and email PfizerCARES@pfizer.com with any questions.

Investigator-Initiated Research (IIR) Studies

Through its IIR program, Pfizer supports research that advances medical and scientific knowledge about Pfizer products and disease areas of interest. Pfizer’s IIR program and the process used to review, approve, support, and follow-up on IIR proposals is outlined in CMCD CT25-GSOP: Pfizer Non-Sponsored Research.

Receipt of Proposals

Pfizer accepts proposals for IIR grants submitted by interested investigators and institutions through its online web portal. Investigators may propose clinical studies of approved and unapproved uses of marketed products, or unapproved Pfizer compounds and devices; in vitro or animal studies; observational studies; or other types of independent research on disease states. To ensure Pfizer receives all necessary information, Pfizer requires the investigator to submit requests through the IIR submission portal at www.pfizer.com/IIR.
Pfizer Medical (non-Commercial) teams may also choose to implement a competitive grant award program for research relating to a particular product, disease, or area of scientific inquiry. These programs typically have a defined set of research criteria and are limited to a certain timeframe. They are publicized broadly to a specific audience via professional journals or websites, and typically have an external independent advisory committee review and approve the program’s competitive grant recipients. While the IIR Office administers competitive grant award programs, the Independent Grants for Learning & Change group (IGLC) administers Dissemination & Implementation research grants which assess whether HCP interventions are effectively delivered within clinical and community practice settings.

Scientific Validity and Value to Pfizer

Multi-disciplinary Pfizer teams review IIR proposals for medical and scientific merit and study feasibility. The teams also consider the investigator's qualifications, including his or her experience, training, and capability to perform all sponsor responsibilities such as filing for any necessary regulatory approvals. The IIR investigator must agree to provide Pfizer with a copy of any final study results and any resulting publications for Pfizer's review. The team that approves the IIR study must document the scientific rationale for Pfizer support.

IIR studies are not intended to support a regulatory submission, and Pfizer does not receive any raw or participant-level data. If a Pfizer team wishes to receive, or reserve the right to receive, raw data from an IIR study for possible regulatory or future research use, even though Pfizer does not own the data, CMCD CT44-GSOP: Clinical and Research Collaborations must be followed. See CMCD CT25-GSOP: Pfizer Non-Sponsored Research, for additional details.
IIR Support

Q. Can Pfizer encourage an HCP to submit a proposal for an IIR grant involving an off-label use of a Pfizer product?

A. Research involving an off-label use of a Pfizer product would be eligible for IIR support only if the proposed research is likely to provide valuable scientific or clinical information, improve clinical care, lead to new or improved treatments, or otherwise benefit patients. A non-Commercial colleague may encourage an HCP to submit an IIR proposal, as long as the decision to support it is based on the scientific merits of the proposal and is not an attempt to influence the HCP’s prescribing behavior. Pfizer may only select IIR investigators based on their credentials and research capabilities. It is not appropriate for any Pfizer colleague to encourage the submission of an IIR proposal for non-scientific reasons. While Sales Colleagues may respond to an HCP’s questions about the process for IIR requests, Sales Colleagues should not proactively encourage or seek out IIR proposals for any reason. Sales Colleagues should consult Orange Guide Chapter 6: Clinical Research and Investigator Initiated Research, for further details.

IIR Support

Q. Could our clinical personnel help an IIR applicant with a proposed protocol?

A. Pfizer colleagues may offer limited support for protocol development, providing advice that only Pfizer is in a position to provide. Such support must not rise to the level of protocol authorship. It should be focused on issues affecting patient safety (dosage and co-administered medications) or appropriate use of resources (recommendation of appropriate statistical approaches and inclusion/exclusion criteria, based upon Pfizer experience). Investigators interested in learning more about Pfizer’s IIR Program or who wish to submit a request should be directed to www.pfizer.com/IIR.

Nature and Basis of Pfizer Support

An IIR grant may include free Pfizer product (including marketed or investigational products, finished goods, and/or pure substance), funding, both product and funding, or other types of support. However, requests for pure substance only are covered by a separate policy, CMCD CT15-GSOP: Request for Pfizer Compound. IIR grants are only provided to support specified, prospectively approved research projects. IIR grants may not be provided to support general research, educational or training programs, studies being conducted on behalf of Pfizer, or where services are being provided for
Pfizer’s benefit, such as development of software, technology, or methodologies to which Pfizer would be granted ownership, a license or other rights. IIR grants may not support studies that would involve new product registration, a change in Pfizer product labeling, or other regulatory approval efforts. See CMCD_CT25-GSOP: Pfizer Non-Sponsored Research and CMCD_CT44–GSOP: Clinical and Research Collaborations, for additional details.

Further, when considering IIRs for a given asset program, it should be understood that Pfizer does not own the data and therefore cannot use study results for promotion. Brand teams, however, may seek RC-approval for promotional use of a published IIR study reprint, if it meets the guidelines outlined in White Guide Chapter 2: Advertising and Promotional Materials.

IIR grants may not be provided to reward or influence the prescribing practices of the investigator or institution. IIR grants must not be based in any way on any preexisting or future business relationships with the investigator or institution or on any decisions the investigator or institution has made or may make in the future related to Pfizer or Pfizer products.

Funding for an IIR study must represent fair market value for the activities being funded, including appropriate institutional overhead. As part of Pfizer’s review of an IIR study proposal, the team must assess the reasonableness of the study budget. For IIR studies requesting funding, agreements must contain payment milestones, unless prohibited by local law.

Pfizer support can only be initiated once an IIR agreement has been fully executed and Pfizer has received all of the required documents outlined in the agreement.

Independence and Investigator Responsibilities

All IIR protocols must be developed by the outside investigator or institution and, as the sponsor, the principal investigator or institution must assume all legal and regulatory responsibilities. Pfizer may not design the study or write the protocol, nor, as the study supporter, may Pfizer be actively involved in the conduct or monitoring of the research. Pfizer may, however, track study progress, as well as review and comment on a draft protocol and provide suggested content (e.g., information relating to the Pfizer product or Pfizer safety reporting requirements). With respect to approved IIRs that were initiated as Collaborative IIRs, study teams must work closely with Clinical Development Legal to determine the appropriate level of involvement by Pfizer in the conduct of the study. Since August 1,
2014, for any clinical Collaborative IIR studies undertaken by a third-party researcher where Pfizer is collaborating on clinical study design, conduct, and data analysis, or where Pfizer intends to use and rely on the data, **CMCD_CT44-GSOP Clinical and Research Collaborations** applies, and these studies no longer follow **CMCD_CT25-GSOP Pfizer Non-Sponsored Research**.

**Regulatory and Ethical Framework**

**IND Requirements**

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

**IRB/IEC Approvals**

 Unless an exemption applies, all applicable investigator-initiated clinical studies must be reviewed and approved by a qualified [Institutional Review Board (IRB)](#) or [Independent Ethics Committee (IEC)](#) to ensure the protection of the rights and welfare of study participants.

Pfizer support of IIR studies is documented by an IIR agreement with language approved by Legal or, for Clinical Research Collaboration under **CMCD_CT44-GSOP Clinical and Research Collaborations**, Business Operations in WRD Development Operations.

**Publication of IIR Study Results**

Pfizer supports the exercise of academic freedom and encourages the investigator to publish the results of an IIR study, whether or not the results are favorable to a Pfizer product. As with sponsored studies, Pfizer may request an opportunity to review proposed publications or other public disclosures of the results in advance, to prevent inadvertent disclosure of Pfizer proprietary information. Pfizer may request a delay in publication, if necessary, to protect intellectual property rights. Pfizer also expects

Rev. 01/16
the investigator or institution to comply with recognized ethical standards concerning publications and authorship, including the disclosure of Pfizer support of the study in any publication of study results. For further information, see White Guide Chapter 17: Publications.

An IIR grant may include funding for publication costs, including manuscript preparation. This will be specifically documented in the IIR agreement and associated project budget. Pfizer must decide before the grant is awarded whether to include publication support in the IIR grant. Pfizer cannot make this decision after completion of the study, as it could create the appearance that Pfizer’s decision was based on whether the results of the project are favorable to a Pfizer product.

FOR MORE INFORMATION

- My Anti-Corruption Policy and Procedures (MAPP)
- Corporate Policy #207: Global Policy on Interactions With Healthcare Professionals (GPIHP)
- Corporate Procedure #215: International Anti-Bribery and Anti-Corruption Procedure
- Corporate Procedure #301: Travel, Entertainment and Other Business Related Expenses
- Corporate Policy #404: Protecting the Privacy of Personal Information
- PhRMA’s Principles for Conduct of Clinical Trials and Communication of Clinical Trial Results
- Consult the following Clinical and Medical Controlled Documents (CMCD) Policies and SOPs
  - CMCD AEM01-POL: Adverse Event Monitoring (AEM) System
  - CMCD CT08-GSOP: Clinical Site Management and Monitoring
  - CMCD CT10-POL: Cost Coverage of Protocol Required Services in U.S. Studies
  - CMCD CT15-GSOP: Request for Pfizer Compound
  - CMCD CT16-POL: Management of Compassionate Access Requests
  - CMCD CT18-POL: Compensation to Investigators
  - CMCD CT19-POL: Global Standards for Interventional Clinical Studies
  - CMCD CT20-POL: Public Disclosure of Pfizer Clinical Study Data and Authorship
  - CMCD CT22-GSOP: Independent Oversight Committees
  - CMCD CT23-GSOP: Financial Disclosure by Clinical Investigators
  - CMCD CT25-GSOP: Pfizer Non-Sponsored Research
  - CMCD CT28-GSOP: Public Disclosure of Pfizer-Sponsored Studies
  - CMCD CT 44-GSOP: Clinical and Research Collaborations
• **CMCD QMS01-GSOP: Management of Significant Quality Events and Monitoring of Corrective and Preventive Actions**

- Refer any other questions to your manager or Clinical Trial Attorney
- **Orange Guide Chapter 6: Clinical Research and Investigator Initiated Research**
- **White Guide Chapter 2: Advertising and Promotional Materials**
- **White Guide Chapter 5: HCP and Government Official Consulting Engagements**
- **White Guide Chapter 11: Privacy: Protecting Personal Information**
- **White Guide Chapter 17: Publications**
Chapter 10: PATIENT ASSISTANCE PROGRAMS

CONTENTS

Patient Assistance Programs

Introduction ........................................................................................................................................................................2

Key Points to Ensure Compliance ................................................................................................................................3

Patient Assistance Program Compliance Requirements ......................................................................................... 3

Pfizer RxPathways General Overview ......................................................................................................................... 4

Summary of Pfizer RxPathways (PRxP) Services ........................................................................................................4

Pfizer RxPathways Institutional Patient Assistance .................................................................................................. 8

Other Assistance Programs .......................................................................................................................................... 8

Brand Specific “Patient Hub“ Programs ................................................................................................................... 8

Co-Promoted Products ........................................................................................................................................ 9

Industry-Sponsored Service ......................................................................................................................................... 9

Pfizer RxPathways Eligibility and Enrollment ............................................................................................................. 9

Eligibility Requirements – Savings on Medicines through Pfizer RxPathways ......................................................... 9

Eligibility Requirements – Free Medicines through Pfizer RxPathways Patient Assistance .................................... 9

Eligibility Requirements – Pfizer RxPathways Co-pay Assistance ........................................................................ 10

A special note about Medicare Part D patients .................................................................................................. 11

Guidance for Marketing: Including PRxP References in Marketing Materials ..................................................... 13

Guidance for Field Commercial Colleagues – Talking About Pfizer RxPathways™ ........................................... 13

Donation of Pfizer Products to Support PAPs ........................................................................................................ 14

FOR MORE INFORMATION ........................................................................................................................................ 15

Rev. 01/16

Page 1 of 15
Chapter 10: PATIENT ASSISTANCE PROGRAMS

Introduction

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.

Pfizer and the Pfizer Patient Assistance Foundation™ offer prescription assistance to patients through Pfizer RxPathways® (PRxP). PRxP helps eligible patients get access to their Pfizer medicines by offering a range of support services, including insurance counseling and other reimbursement support services, co-pay assistance, providing Pfizer medicines for free or at a savings, and more.

This Chapter summarizes certain key Pfizer policies regarding Patient Assistance Programs. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary actions up to and including termination.
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 Commercial Colleagues must follow the requirements described in this Chapter when discussing PAPs with customers.
• Internal questions about Pfizer PAPs should be e-mailed to the Pfizer RxPathways team at PfizerRxPathways@pfizer.com.
• Patients and healthcare professionals should visit www.PfizerRxPathways.com to learn more, or contact a customer service representative for Pfizer RxPathways at 1-866-706-2400 or

A PAP:
  o May not make assistance determinations with regard to any provider, practitioner, supplier, or insurance plan used by the applicant;
  o Should assess applicants on a first-come, first-served basis;
  o Should not exhibit any characteristics of a marketing program or in any way promote Pfizer products; and
  o 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 more than 25 years, Pfizer has offered an array of prescription assistance programs to help eligible patients get access to their Pfizer medicines. Today, this assistance is provided through Pfizer RxPathways, which helps eligible patients obtain access to their Pfizer medicines by helping patients get connected to the appropriate Pfizer assistance offerings, including insurance counseling for select Pfizer medicines to help patients understand the coverage offered through their insurance plans, co-pay cards for those with private/commercial insurance, and information on alternate sources of help, like independent co-pay foundations, referrals to other industry resources that may help if it is determined that a patient is not taking a Pfizer medicine, providing Pfizer medicines for free or at a savings, and more. Pfizer RxPathways is a joint program of Pfizer Inc and the Pfizer Patient Assistance Foundation.

**Summary of Pfizer RxPathways (PRxP) Services**

When calling the PRxP toll free number (1-866-706-2400) or by visiting the PRxP website (www.PfizerRxPathways.com), patients or their advocates will provide some basic information about the patient (e.g., household income, name, address, etc.) and the Pfizer medicine prescribed so they can be directed to the appropriate PRxP services for which they may be eligible. These services include:
### Patient Type

<table>
<thead>
<tr>
<th>Patient Type</th>
<th>Assistance Offered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uninsured patients</td>
<td>Uninsured patients who need help accessing their Pfizer medicines may be eligible for the following:</td>
</tr>
<tr>
<td></td>
<td><strong>1. Free Medicines:</strong> Pfizer RxPathways offers Pfizer medicines for free to uninsured patients. To be eligible, uninsured patients must live in the United States, US Virgin Islands, or Puerto Rico and must not have prescription coverage. Patients seeking Pfizer medicines for free must meet income guidelines and receive treatment from a licensed health care provider on an outpatient basis.</td>
</tr>
<tr>
<td></td>
<td><strong>2. Alternate Funding Assistance:</strong> Pfizer also provides alternate funding assistance based on medicine type:</td>
</tr>
<tr>
<td></td>
<td>o <strong>For primary care medicines:</strong> Pfizer will refer uninsured patients to <a href="http://www.healthcare.gov">www.healthcare.gov</a> to explore insurance options that may now be available to them. Patients are encouraged to investigate these options, but are not required to apply before enrolling in Pfizer RxPathways.</td>
</tr>
<tr>
<td></td>
<td>o <strong>For oncology and specialty medicines:</strong> Pfizer will help determine if new or renewal patients are eligible for Medicaid or low-income subsidies for Medicare Part D. If they appear to be eligible, case managers will help guide patients through the application process for the insurance options available to them.</td>
</tr>
<tr>
<td></td>
<td><strong>3. Savings:</strong> Pfizer offers savings on Pfizer medicines through the Pfizer RxPathways Savings Card, which helps patients without prescription coverage get savings on Pfizer medicines through participating pharmacies. Savings from the Pfizer RxPathways Savings Card can vary from 35 to 50 percent, depending on the product and patient’s income level. This savings card is an option for patients whose household income exceeds the eligibility requirements for receiving free medicines through Pfizer RxPathways or for patients who need assistance with Pfizer branded medicines no longer offered through the program.</td>
</tr>
</tbody>
</table>
### Underinsured patients

Pfizer understands that people with prescription coverage may still have difficulty affording their medicines. Here’s how Pfizer may be able to help eligible patients:

1. **Co-Pay Help:** For patients with private/commercial insurance, Pfizer RxPathways offers co-pay assistance. Eligible underinsured patients with prescription coverage who need help getting their Pfizer medicines can either apply for co-pay assistance through Pfizer RxPathways for certain medicines or be directed to other Pfizer co-pay programs that may be able to help.

2. **Alternate Funding:** Patients who participate in federal or state health programs, such as Medicare or Medicaid, may not be eligible for co-pay help. These patients can call Pfizer RxPathways to learn more about alternate funding options for their prescription medicine. For oncology/specialty medicines, Pfizer RxPathways case managers will assist patients with researching alternate funding, such as co-pay foundations, and help with the application process.

3. **Free Medicines:** If co-pay help and alternate funding are not available, eligible underinsured patients may be able to get their medicines for free through Pfizer RxPathways. To be eligible, underinsured patients must live in the United States, US Virgin Islands, or Puerto Rico, meet income guidelines and have insurance, but not be able to afford their medicines due to financial hardship.
<table>
<thead>
<tr>
<th>Patient Type</th>
<th>Assistance Offered</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insured patients</td>
<td>For insured patients, Pfizer RxPathways offers insurance counseling and other reimbursement support services. Specifically, these services help patients with insurance understand and navigate their coverage and reimbursement options for certain Pfizer oncology and specialty medicines.</td>
</tr>
<tr>
<td></td>
<td><strong>1. Benefits Verification:</strong> Pfizer RxPathways counselors are available to help patients and their health care professionals understand coverage and reimbursement options. This includes benefit verification, in which the counselor will review a patient’s benefits to see how they are covered for the medicine they need, and explain coverage options and policies.</td>
</tr>
<tr>
<td></td>
<td><strong>2. Prior Authorization Information:</strong> Pfizer RxPathways counselors are available to help patients investigate prior authorization requirements and explain the process.</td>
</tr>
<tr>
<td></td>
<td><strong>3. Appeals Process Information:</strong> If a claim is underpaid or denied, Pfizer RxPathways provides patients with information on the appeals process.</td>
</tr>
<tr>
<td></td>
<td><strong>4. Specialty Pharmacy Referral:</strong> Select Pfizer medicines are available through select specialty pharmacies. A Pfizer RxPathways counselor can help patients connect to the specialty pharmacy appropriate for their insurance plan. The specialty pharmacy will then conduct a benefits verification to determine coverage options and the process to receive the medicines.</td>
</tr>
</tbody>
</table>
Generally, however, Pfizer cannot represent individual patients or fund representation for them regarding a particular claim.

**Pfizer RxPathways Institutional Patient Assistance**

Pfizer RxPathways also partners with nearly 400 health clinics, hospitals and central fill pharmacies for patients in need through our institutional patient assistance program (IPAP). 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**

While assistance is available on many Pfizer medicines through Pfizer RxPathways, some Pfizer medicines are supported by other programs described below:

**Brand Specific “Patient Hub” Programs**

Some Pfizer brands offer brand-specific “Patient Hub” programs that offer a variety of services for patients, including patient assistance and 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 Patient Support program, and the Pfizer XelSource Program. While the patient assistance and reimbursement support services offered through these patient hub programs are managed by Pfizer RxPathways operations, hub programs have separate 800 #s and websites. If patients prescribed one of these brands contact Pfizer RxPathways, they will be warm 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 RxPathways Eligibility and Enrollment

Eligibility Requirements – Savings on Medicines through Pfizer RxPathways

Savings on Pfizer medicines are available to uninsured patients only. To enroll, patients need to call the Pfizer RxPathways toll-free number at 1-866-706-2400 and 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 RxPathways savings 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 35% to 50% off of the retail price of the medicine.

Eligibility Requirements – Free Medicines through Pfizer RxPathways Patient Assistance

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 Pfizer RxPathways. In general, to qualify for free medicines through Pfizer RxPathways, 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);
- Have a valid prescription for the desired Pfizer product;
- Live in the US, Puerto Rico or the US Virgin Islands; and
- Be treated by a healthcare professional licensed to practice in the US 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 who meet eligibility requirements will 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.

Underinsured patients who meet eligibility requirements 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. Similar to the uninsured, their medicine will be shipped to their doctor’s office in most cases, or for some products, directly to their home address.

**Eligibility Requirements – Pfizer RxPathways Co-pay Assistance**

For certain products, underinsured patients who have commercial/private insurance may qualify for a Pfizer RxPathways co-pay assistance 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

Rev. 01/16
to the pharmacist. This co-pay card is separate from brand-specific co-pay cards. To be eligible, patients must complete an application and meet income eligibility requirements. Patients enrolled in public insurance programs such as Medicare Part D or Medicaid, are not eligible for co-pay assistance and can apply for free medicines through the Pfizer RxPathways Patient Assistance program (see above).

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. Pfizer RxPathways lists Lyrica as being covered. Should you tell him to have his patients apply to Pfizer RxPathways?

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 PRxP 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. The 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 Pfizer RxPathways?

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 Pfizer RxPathways. Patients should call Pfizer RxPathways at 1-866-706-2400 or visit http://www.PfizerRxPathways.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 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 PROMOs a set of unbranded PRxP materials that can be used by Field Force Colleagues for purposes of discussing the PRxP programs.
- 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 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 Commercial Colleagues – Talking About Pfizer RxPathways

Pfizer Field Commercial Colleagues may engage in limited proactive discussions regarding PRxP subject to the following requirements:

Rev. 01/16
• 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 PRxP programs with healthcare professionals, messaging must remain broad, consisting of basic information about PRxP programs, application processes, and eligibility criteria.
• The call-to-action should still remain, “visit [http://www.PfizerRxPathways.com](http://www.PfizerRxPathways.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 PRxP is designed to help eligible patients in need get access to Pfizer medicines for free or at a savings. Reimbursement support services for people with insurance are also offered for some Pfizer oncology and specialty medicines.</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 PRxP as a way to fill gaps in coverage (e.g., donut hole).</td>
</tr>
</tbody>
</table>

**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.
Chapter 11: PRIVACY: PROTECTING PERSONAL INFORMATION

CONTENTS

Privacy: Protecting Personal Information

Introduction .................................................................................................................................................................... 3

Key Points to Ensure Compliance ......................................................................................................................... 5

The Legal Landscape ..................................................................................................................................................... 7

Health Insurance Portability and Accountability Act of 1996 (HIPAA) ............................................................... 7

Pfizer is Not a Covered Entity under HIPAA ................................................................................................ 7

Pfizer is Generally Not a Business Associate under HIPAA ........................................................................ 7

HIPAA is Still Relevant for Pfizer ................................................................................................................. 8

State Medical Information Privacy Laws ............................................................................................................. 8

Federal and State Information Security Laws ..................................................................................................... 8

Federal and State Breach Notification Laws ....................................................................................................... 9

Laws Protecting the Personal Information of Children ...................................................................................... 9

Requirements for Transparency, Notice, and Consent ..................................................................................... 10

Pfizer’s Policies Relating to Privacy and Personal Information ................................................................................. 10

Notice and Consent ............................................................................................................................................. 11

Aggregated or Anonymized Data ...................................................................................................................... 11

Avoiding Exposure to Protected Health Information ....................................................................................... 12

Vendor Obligations ............................................................................................................................................. 12

Activities That May Result in the Use and Disclosure of Personal Information .................................................... 12
Marketing Initiatives and Other Communications ................................................................. 13
Pfizer-Sponsored Third Party Communications .................................................................... 13
Digital Marketing Initiatives ................................................................................................... 14
Pfizer’s Patient Programs ......................................................................................................... 14
Working with HCPs .................................................................................................................. 15
Mentorships and Preceptorships ............................................................................................ 16
Consumer Health Fairs or Screenings ..................................................................................... 17
Patient Information and Clinical Trials ................................................................................... 18
Other Privacy Issues ................................................................................................................ 19
Healthcare Professional Prescriber Data ............................................................................... 19
Handling Healthcare Professionals’ and Other Customers’ Personal Information ............... 20
Pfizer Policy on Your Responsibility for Safeguarding Personal Information ...................... 20
FOR MORE INFORMATION................................................................................................. 21
Chapter 11: PRIVACY: PROTECTING PERSONAL INFORMATION

Introduction

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.

Personal information or PI includes any information that alone or in combination with other data can be used to identify a person such as name, address, phone number, or e-mail address. Sensitive Personal Information is a subset of Personal Information and includes information relating to 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” or “PHI” of a “Covered Entity” under HIPAA); geolocation data; financial information; national identifiers, such as social security numbers, as well as information about an individual's race, ethnicity, religion, or sexual orientation.

There are many U.S. federal and state laws applicable to Pfizer's use of Personal Information and Sensitive Personal Information. Moreover, many other countries around the world impose even more stringent limitations on the use, access, or transfer of Personal Information and Sensitive Personal Information. The European Union is widely regarded as having imposed among some of the most stringent privacy protections for individuals in the world. Other countries with comprehensive, rigorous privacy regimes include Argentina, Australia, Canada, Colombia, Israel, Japan, Mexico, Peru, Singapore, South Korea, and Uruguay.

Although this Chapter is focused largely on certain U.S. privacy topics, it is important to consider whether any sales and marketing activities conducted in the United States can have privacy implications for complying with the laws of other countries. Consult your team attorney or the Global Privacy Office (GPO) if a proposed activity presents potential privacy implications for individuals outside of the United States or involves the transmission of Personal Information collected outside of the United States to the United States. It is important to note that merely accessing Personal...
Information about an individual in another country via your computer or a database could be considered a transmission of 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 that person to use that information for limited purposes, hold that information in confidence, and 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 safeguard all Personal Information it receives and maintains, regardless of the form, format, location, or use. For additional information, see Corporate Policy (CP) #404: Protecting the Privacy of Personal Information.

This Chapter highlights certain key Pfizer policies regarding the protection of Personal Information. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination.
Key Points to Ensure Compliance

- Pfizer’s [CP # 404: Protecting the Privacy of Personal Information](#), requires all Pfizer colleagues and contractors to protect Personal Information collected by or on behalf of Pfizer. Before your team collects Personal Information (directly or via any third party service providers), your team attorney must be consulted and approve the collection and use of the data.

- Access to Personal Information should be minimized and access to Sensitive Personal Information should be limited to individuals who “need to know” the information in order to perform their job duties.

- Sensitive Personal Information should only be received where it is necessary for an authorized business purpose. If Pfizer or its business partner or service provider will be receiving Sensitive Personal Information, consult with your team attorney. Pfizer colleagues and contractors must ensure that such information is received in compliance with applicable law and, if applicable, that a proper patient authorization has been obtained by the entity that is collecting and/or disclosing the information.

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

- All Pfizer-sponsored third-party communications to patients, healthcare professionals (HCPs), and other customers must be approved by the appropriate Pfizer Review Committee (RC), which will consider issues of privacy and consent as part of its review process.

- Do not sign a document that is called a “Business Associate Agreement” or otherwise relates to “Business Associate” status without receiving explicit written approval to do so by your team attorney or the Global Privacy Office (GPO).

- When using Personal Information to identify and communicate with current and potential Pfizer customers (HCPs or consumers) it is important to work with Enterprise Multi-Channel Marketing (eMCM) to ensure compliance with applicable legal requirements and Pfizer policies and procedures.
Key Points to Ensure Compliance

- When setting up a mentorship or preceptorship, Pfizer colleagues must inform physicians serving as mentors or preceptors that they are required to obtain their patients’ written authorization before Pfizer colleagues may be allowed to observe any consultation, examination, and/or treatment of any patient.

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

- Pfizer colleagues should not engage health fair attendees in specific discussions regarding a patient’s health.

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

- Safeguard the confidentiality of prescriber data as you would any other Personal Information. As a general rule, prescriber data should be used only for internal business purposes and not in dealings with Pfizer’s customers, including the HCPs themselves.

- Do not share an HCP’s prescriber data with anyone outside of Pfizer other than properly contracted and on-boarded vendors who are assisting with your initiative. Check with your team attorney before sharing HCP prescriber data with anyone outside of Pfizer.

- Any suspected breach of security of Personal Information or Sensitive Personal Information must be immediately reported. Lost or stolen computers or other devices containing Pfizer data must be reported to the user’s local Service Desk/Help Desk (the worldwide list of contact telephone numbers is available online at http://ITSupport.pfizer.com). Any other incidents of potential unauthorized access to Pfizer data must be reported to the Global Security Operations Center at 1-212-733-7900 or GSOCwatchroom@pfizer.com. You should also notify your team attorney.
The Legal Landscape

**Health Insurance Portability and Accountability Act of 1996 (HIPAA)**

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

**Pfizer is Not a Covered Entity under HIPAA**

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

**Pfizer is Generally Not a Business Associate under HIPAA**

In addition to protecting PHI in the hands of a Covered Entity, HIPAA also protects PHI created, received, maintained, or transmitted by a Covered Entity’s “Business Associate.” A Business Associate is a person or entity that creates, receives, maintains, or transmits PHI for certain functions, activities, or services it conducts for or on behalf of a Covered Entity. Under HIPAA, Covered Entities are obligated to enter into a written contract called a **Business Associate Agreement** with a Business Associate before any PHI is disclosed to the Business Associate. A Business Associate Agreement requires a Business Associate to comply with a variety of requirements under HIPAA, including safeguarding PHI, limiting its use and disclosure in connection with the functions performed or services it provides, and requiring notifications of breaches of PHI. In the vast majority of situations, Pfizer does not perform work on behalf of an HCP or other Covered Entity and does not function as a Business Associate. **No Pfizer colleague or contractor may enter into a Business Associate Agreement without the express written consent of the team attorney or the GPO.**

Rev. 01/16
For more information about Business Associate Agreements, see the section on Working with HCPs within this Chapter.

**HIPAA is Still Relevant for Pfizer**

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

**State Medical Information Privacy Laws**

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

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

**Federal and State Information Security Laws**

Section 5 of the FTC Act prohibits “unfair and deceptive” trade practices. This federal law has been interpreted to require companies to provide reasonable information security for Personal Information. Significant fines have been levied against companies that have suffered information security breaches and were found not to have adequate information security controls in place.
In addition, some states mandate special security protections for specific classes of data. For example, Massachusetts has implemented information security requirements applicable to certain types of Personal Information (e.g., social security number, driver’s license number, and financial account information) about Massachusetts residents. These requirements include encryption of portable devices, e-mail, and back-up tapes that contain such classes of Personal Information. Since information related to Massachusetts residents is intermingled with data relating to residents of other states, this law has effectively raised the bar for information security requirements beyond its borders.

**Federal and State Breach Notification Laws**

HITECH added new breach notification requirements under HIPAA for Covered Entities and Business Associates related to “unsecured” health information. The HIPAA Breach Notification Regulations require that affected individuals, HHS, and in some cases, the media, are notified of a breach when PHI is acquired, accessed, used, or disclosed in a manner not permitted by the HIPAA Privacy Regulations that compromises the security or privacy of the PHI.

In addition to the federal requirements, nearly every U.S. state has its own breach notification law. The state breach notification laws require that, under certain circumstances, the individuals whose data has been compromised be notified of the breach and/or that government officials be notified. These laws do not contain consistent requirements. Consequently, managing even a relatively small breach (e.g., a lost laptop containing Personal Information) can be complex, time-consuming and costly. Some notification periods under these breach notification laws are very short. Therefore, it is critical that any suspected breach be reported immediately to Pfizer’s Global Security Operations Center (GSOC) (1-212-733-7900 or GSOWatchroom@pfizer.com). You should also notify your team attorney. Lost or stolen computers or other devices containing Pfizer data must be reported to your local Service Desk/Help Desk (the worldwide list of contact telephone numbers is available online at http://ITSupport pfizer.com).

**Laws Protecting the Personal Information of Children**

The federal Children’s Online Privacy Protection Act (COPPA) prohibits the collection, use or disclosure of a broad range of Personal Information collected online from children younger than 13 without the verifiable consent of a parent or guardian and is enforced by the U.S. Federal Trade Commission.
Commission (FTC). Most Pfizer programs and services do not target children. If your program does intend to target children, please work with your team attorney.

Requirements for Transparency, Notice, and Consent

There is a strong trend toward transparency, notice, and opt-out consent with respect to collection and use of Personal Information, device identifiers, and IP addresses. The FTC has brought enforcement actions against businesses that tracked online activities of consumers without clear notice. Furthermore, the FTC has made clear that it is a critical best practice for businesses to provide clear, simple notice of any unexpected privacy practices before data is collected.

Concerns about transparency, notice, and consent are particularly acute in the online space. For example, the FTC issued a report on Self-Regulatory Principles for Online Behavioral Advertising in February 2009. Behavioral advertising involves the tracking of a consumer's activities on the Internet and then using that information to target advertising. Concerns relating to online tracking and targeting are shared internationally. For example, the EU amended its e-Privacy Directive to require affirmative consent prior to dropping an Internet "cookie" for a wide range of tracking purposes.

As privacy laws are constantly evolving, Pfizer colleagues and contractors should consult with their team attorney before engaging in any activity that may impact an individual's privacy, whether that individual is an HCP, patient, or other consumer.

Pfizer's Policies Relating to Privacy and Personal Information

Pfizer respects the privacy of individuals, including patients, caregivers, and HCPs. Pfizer policy is to safeguard all Personal Information it receives and maintains, regardless of the form, format, location, or use.

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

**Notice and Consent**

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

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

To be compliant with law and Pfizer policy, it is critical that the appropriate disclosures and consents (and in some cases contracts) be in place prior to accessing, collecting, or using Personal Information. Before your team collects any Personal Information or designs any program which could result in Personal Information being directly or inadvertently disclosed to Pfizer, you must first consult your team attorney to ensure that any required notice and consent have been provided and/or obtained.

**Aggregated or Anonymized Data**

It is sometimes permissible for Pfizer to obtain previously personally identifiable information from an HCP or health plan administrator without an individual’s consent if the information has been **aggregated or anonymized**. “**Aggregated**” data is information about multiple individuals that is compiled and does not allow for the identification of any one participant. “**Anonymized**” data is data that cannot be identified as belonging to any specific individual and usually involves removing certain key identifiers (including the individual’s name, many elements of the individual’s address, telephone number, date of birth, patient ID, and social security number), which either alone or in combination,
could link the information with a specific individual. The standard for “anonymizing” data varies between countries. Therefore, always consult your team attorney before assuming information has been properly “anonymized.”

**Avoiding Exposure to Protected Health Information**

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

**Vendor Obligations**

All Pfizer vendors who will have access to Personal Information of or on behalf of Pfizer must follow our policy of safeguarding Personal Information. To this end, Pfizer has a **Privacy and Information Security Addendum**, which includes **Third Party Security Requirements** that may be included as part of contracts with such vendors following consultation with Procurement and/or the Global Privacy Office. Please note that in addition to the contractual requirements, any vendors that will have access to or process Personal Information on behalf of Pfizer may be required to complete and pass appropriate Pfizer vendor vetting processes managed by BT Audit and Assessment. For more information about Pfizer’s **Vendor Compliance Assessment Service (VCAS)** please visit: [http://ecf.pfizer.com/sites/BTQCAandA/default.aspx](http://ecf.pfizer.com/sites/BTQCAandA/default.aspx).

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

When using Personal Information to communicate with current or potential Pfizer customers (HCPs or consumers) it is important to work with **Enterprise Multichannel Marketing (eMCM)** to ensure compliance with applicable legal requirements as well as Pfizer policies and procedures.
Marketing Initiatives and Other Communications

Pfizer-Sponsored Third Party Communications

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

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

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

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

Pfizer must appropriately secure Personal Information collected and transmitted via the Internet. Additionally, laws and other guidance restrict the use of Personal Information in order to target online marketing.

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

Pfizer’s Patient Programs

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

Pfizer has a standardized Privacy and Consent Policy for all U.S.-based consumer activities that involve the collection of consumers’ Personal Information by any channel, including hard copy or online forms, business reply cards, or telephone/fax. To obtain the Privacy and Consent Policy and related requirements, see the Privacy and Consent Policy section under the Patient & Physician Marketing Group tab in OpSource. These activities include, but are not limited to, disease management program enrollment forms, coupons and rebate offers, and sweepstakes offers. The guidelines apply only when the consumer provides Personal Information, such as name and address or e-mail address. Whenever a Pfizer program requires a consumer to provide such information, the program must also include a simple, timely mechanism (e.g., a toll-free telephone number or a mailing address) that allows participating individuals to promptly discontinue or “opt-out” of the program. In addition, all programs must contain appropriate privacy language. This Privacy and Consent Policy must also be communicated to, and followed by, any vendors preparing materials on behalf of Pfizer. Therefore, it is important that Pfizer teams considering programs that would collect Personal Information consult the eMCM team to determine whether appropriate authorizations and guidelines are in place. In addition,
it is important to work through eMCM vendors and systems to ensure compliance with “Do Not Contact” lists and appropriate management of data.

**Working with HCPs**

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

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

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

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

A copy of the Privacy Pledge and Patient Health Information Confidentiality Agreement can be downloaded from [PfieldNet](https://pfieldnet.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?

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 are able to sign the Pfizer Privacy Pledge or Patient Health Information Confidentiality Agreement using the templates found on PfieldNet. Providing a copy of one of these documents with your signature is usually enough to satisfy the HCP’s concerns about patient privacy. If the HCP continues to insist on a Business Associate Agreement, please promptly contact your team attorney for assistance.

Signing Customer Confidentiality Agreements

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 the version the HCP wants me to sign?

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

Mentorships and Preceptorships

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

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

When setting up a mentorship or preceptorship, Pfizer colleagues must ensure that physicians serving as mentors or preceptors know they must obtain their patient’s written authorization before Pfizer colleagues may be allowed to observe any consultation, examination, and/or treatment. You may offer...
Pfizer’s [sample Patient Authorization Form](available on PfieldNet) to an HCP; however, they are not required to use it. This form includes language and provisions required by HIPAA and may not be altered. The requesting HCP should maintain the signed authorization form as part of the patient’s record and provide a copy of the form to the patient. You should not retain a copy of a signed Patient Authorization Form.

For more information on these activities, see [White Guide Chapter 5: HCP and Government Official Consulting Engagements](available on PfieldNet) and the Mentorship Guidelines and Forms which is available on PfieldNet under the “Compliance” tab.

### Patient Consents Regarding Mentorships and Preceptorships

**Q.** Does a patient have to sign an authorization form before a Pfizer Sales colleague can observe an examination or treatment as part of a mentorship or preceptorship, or is oral permission sufficient?

**A.** It is the HCP’s responsibility to secure appropriate patient authorization in a mentorship or preceptorship. Pfizer has developed a form for the HCP to use in the event there is no existing authorization. Under HIPAA, a patient must authorize in writing the disclosure of his or her PHI. Oral permission is not acceptable under Pfizer guidelines. It is also important to remember that once proper authorization is obtained from the patient, the Pfizer colleague participating in the mentorship or preceptorship must identify himself or herself as an employee or contractor of Pfizer, as the case may be. A name badge identifying the colleague as a Pfizer employee must be worn at all times when interacting with a patient.

### Chart Reviews

**Q.** Is it permissible to conduct chart reviews as part of our collaborative studies/programs with customers?

**A.** No. Colleagues should never conduct a chart review.

### Consumer Health Fairs or Screenings

Consumer health fairs and screenings may raise patient privacy concerns because Personal Information is often obtained in the presence of Sales Colleagues or other Pfizer colleagues at the health fair. Pfizer colleagues should not engage health fair attendees in discussions regarding a specific patient’s health.

*Rev. 01/16*

*Page 17 of 21*
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, is not providing medical advice, and should redirect the patient to an HCP at the fair or state that the patient should discuss the matter with his or her physician.

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

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

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. Colleagues are not permitted to practice medicine or provide clinical advice to patients in the course of their work for Pfizer.

**Patient Assistance Programs and Protected Health Information**

Q. May Pfizer receive Protected Health Information from health plans for the purposes of Pfizer’s Patient Assistance Programs?

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

**Patient Information and Clinical Trials**

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

In accordance with Clinical and Medical Controlled Document (CMCD) CTo8: Clinical Site Management and Monitoring, clinical study team members must always protect the confidential nature of the Personal Information that they review. If Personal Information is copied or referred to in monitoring reports, appropriate written authorizations must generally be obtained from patients. Although Pfizer...
is not directly covered by HIPAA, it is subject to other laws which protect the confidentiality of subjects’ Personal Information. Pfizer is committed to protecting the privacy and security of the Personal Information generated in clinical trials, including with respect to the electronic transmission of clinical trial data. Pfizer has established technical, physical, and administrative security measures, which include integrity controls and encryption (where appropriate), to guard against unauthorized access to Personal Information that it electronically transmits or receives.

**Use of Data from Clinical Studies**

Q. May Pfizer use records from its sponsored clinical studies for marketing purposes?

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

**Other Privacy Issues**

*Healthcare Professional Prescriber Data*

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

Pfizer respects the confidentiality of this data and shall abide by the wishes of any HCP who asks that his or her prescriber data not be made available to Pfizer Sales Colleagues. Pfizer also has designated the Leader of Commercial Information Management (CIM) in U.S. Commercial Operations as the
internal contact to respond to inquiries regarding Pfizer’s policy on the use of prescriber data. Given that this area of law is quickly evolving, Pfizer colleagues must consult with their team attorney or the GPO before engaging in an activity that involves the use or disclosure of prescriber data for marketing or promotional purposes.

Handling Healthcare Professionals’ and Other Customers’ Personal Information

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

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

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

Pfizer Policy on Your Responsibility for Safeguarding Personal Information

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

- CP #403: Acceptable Use of Information Systems;
• **CP #404:** Protecting the Privacy of Personal Information; and
• **CP #405:** Records and Information Management Policy and Procedure.

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

• Encrypting your computer and using only encrypted USB flash drives;
• Properly destroying media or paper containing Personal Information;
• Promptly reporting lost or stolen Pfizer equipment, Personal Information, and other potential data incidents to Pfizer’s **Global Security Operations Center (GSOC)** (1-212-733-7900 or 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); and
• Never using unencrypted e-mail to transfer Personal Information outside of the Pfizer network.

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

**FOR MORE INFORMATION**

• **Corporate Policy (CP) #403:** Acceptable Use of Information Systems
• **Corporate Policy (CP) #404:** Protecting the Privacy of Personal Information
• **Corporate Policy (CP) #405:** Records and Information Management Policy and Procedure
• **Handling Sensitive Information (HSI) Guidelines - Procedures for Handling PI and SPI for Colleagues and Contractors**
• **Clinical and Medical Controlled Document (CMCD) CTo8: Clinical Site Management and Monitoring**
• Refer any questions to the Enterprise Multi-Channel Marketing team, your team attorney or the Global Privacy Office (privacy.officer@pfizer.com).
# Chapter 12: PROMOTIONAL INTERACTIONS WITH CONSUMERS

## CONTENTS

<table>
<thead>
<tr>
<th>Topic</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Promotional Interactions with Consumers</td>
<td></td>
</tr>
<tr>
<td>Introduction</td>
<td>2</td>
</tr>
<tr>
<td>Key Points to Ensure Compliance</td>
<td>3</td>
</tr>
<tr>
<td>Meals and Items of Value to Consumers</td>
<td>4</td>
</tr>
<tr>
<td>Exhibits and Displays</td>
<td>4</td>
</tr>
<tr>
<td>Consumer Speaker Programs</td>
<td>5</td>
</tr>
<tr>
<td>Health Fairs and Public Screenings</td>
<td>6</td>
</tr>
<tr>
<td>Screenings Offered to Employees of a Single Employer</td>
<td>6</td>
</tr>
<tr>
<td>Screenings Offered to the Public at Large</td>
<td>7</td>
</tr>
<tr>
<td>Additional Guidelines for All Screenings</td>
<td>7</td>
</tr>
<tr>
<td>Product Support Programs</td>
<td>9</td>
</tr>
<tr>
<td>Disease Management Programs</td>
<td>9</td>
</tr>
<tr>
<td>Unbranded Communications</td>
<td>9</td>
</tr>
<tr>
<td>Branded Communications</td>
<td>10</td>
</tr>
<tr>
<td>Medication Compliance Programs</td>
<td>11</td>
</tr>
<tr>
<td>Sweepstakes and Prizes</td>
<td>12</td>
</tr>
<tr>
<td>Employees as Consumers</td>
<td>13</td>
</tr>
<tr>
<td>FOR MORE INFORMATION</td>
<td>13</td>
</tr>
</tbody>
</table>

*Rev. 01/16*
Chapter 12: PROMOTIONAL INTERACTIONS WITH CONSUMERS

Introduction

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

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

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

- Pfizer colleagues may provide occasional meals of minimal value to consumers ($40 or less per person, including tax and tip). Meals may never, however, be provided to solicit business or in a manner that might suggest that the recipient is being bribed or improperly influenced.

- As with speaker programs for HCPs, Pfizer is responsible for the conduct of speakers and the content of presentations at speaker programs for consumers. The program and speaker must follow all applicable EZSpeak requirements. The content of a consumer program should be appropriate for a “lay” audience consistent with Pfizer Principles for Clear Health Communication.

- Pfizer Sales Colleagues may promote Pfizer products at health screenings as long as the exhibit and display booth is physically separate and apart from the screening area.

- If you are present during any patient/consumer interactions at a health fair or screening, you must clearly identify yourself as a Pfizer employee and may not offer any medical opinions, advice, or consultation, even if you have a license to practice medicine or are any type of healthcare professional.

- The Managed Care Review Committee (MCRC) or Organized Customer Legal team must approve all disease management program arrangements with managed care organizations. Such arrangements must be documented in a service agreement that sets forth the basis for payment, as well as the program materials.

- Employees of customer organizations may also be considered consumers. Pfizer interactions with such employees (such as at a health fair) must conform to the same principles applicable to consumer interactions.

- As outlined in White Guide Chapter 4: Marketing Programs, Customer Engagement Programs must be designed, reviewed, approved, and conducted in compliance with Corporate Policy (CP) #902: Management of Safety Information for Customer Engagement Programs (CEPs) Policy and Corporate Procedure (CP) #902a: Management of Safety Information for Customer Engagement Programs (CEPs) Procedure.
Meals and Items of Value to Consumers

Pfizer may provide occasional gifts or meals of minimal value ($40 or less per person, including tax and tip) to consumers. Some examples of such items include providing a modest snack or refreshment (e.g., fruit, granola bars, bottled water) to consumers that visit a Pfizer exhibit or display, or providing a modest meal to attendees at a Pfizer consumer speaker program. However, gifts and meals may never be provided to solicit business or in a manner that might suggest that the recipient is being bribed or improperly influenced.

Exhibits and Displays

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

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

Providing Food to Consumers at a Display

Q. I have a display table at a community health fair next week. Can I provide food at my table? What about covering the cost of sandwiches for all the health fair attendees?

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, and drinks. It would not be appropriate for you to cover the costs of sandwiches or other food items for all attendees since you are permitted to provide food only to those consumers with whom you interact. Remember, even when you have more extensive interactions with consumers (e.g., at a speaker program) the cost of food, beverage, tax, and tip should never exceed $40 per attendee.
Consumer Speaker Programs

A speaker program for consumer audiences is a promotional activity controlled by Pfizer at which an HCP presents a Pfizer RC-approved slide deck intended for consumers. As with a speaker program for an HCP audience, Pfizer is responsible for the conduct of the speaker and the content of the presentation to consumers. Pfizer colleagues must adhere to Pfizer policies regarding consumer presentations and follow EZSpeak procedures to set up the speaker program. Prior to engaging in any speaking engagements, speakers are required to complete training on (1) Pfizer Promotional Speaker Compliance Guidelines (annually); and (2) the brand’s core product training or topic training slide kit, as applicable.

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

Accordingly, slide decks for consumer programs should be designed and executed with the following principles in mind:

- Use easy to follow layouts and simple pictures;
- Write information at an appropriate reading level;
- Replace complicated medical or technical words with plain language;
- Use pictures and diagrams that clarify written concepts;
- Focus materials on behavior rather than on medical facts; and
- Make information culturally sensitive and personally appropriate.

Consumer programs should be broadly advertised such that each program will likely result in an audience of at least three consumers. The chosen venue for the program must be conducive to providing educational information, and Pfizer may not offer entertainment or recreation. A modest meal of $40 or less in value per person (including food, beverages, tax, and tip) may be provided. Of course, an HCP hired to speak at the program must not provide specific medical advice to a consumer attendee, nor may the speaker use the Pfizer program as an opportunity to promote his or her medical services or practice, or to recruit new patients. For more information on speaker programs to consumer
audiences, see Orange Guide Chapter 16: Consumer and Employee Interactions, and for more information on speaker programs generally, see White Guide Chapter 4: Marketing Programs.

Health Fairs and Public Screenings

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

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

Screenings Offered to Employees of a Single Employer

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

These screenings may not be offered for employees of healthcare providers or payers of healthcare items and services, including hospitals, medical practice groups, or managed care organizations (MCOs) that seek reimbursement from the federal government. The screening must be limited to current employees and their beneficiaries only and must expressly exclude retirees who are beneficiaries under the employer’s retiree health plan. Also, the screening cannot be organized or designed in any way to generate referrals for any particular customer.

Pfizer Sales Colleagues may promote Pfizer products at the screenings as long as the exhibit and display booth is physically separate and apart from the screening area. Further, no financial return-on-investment (ROI) analysis can be tied to the screening event.
Screenings Offered to the Public at Large

Screenings offered to the public at large may be organized by a third-party or Pfizer directly. If an IRS 501(c) (3) healthcare-related charitable organization requests Pfizer support for a screening, the request must be submitted directly by the organization to Pfizer’s office of Independent Grants for Learning & Change (IGLC), formerly Medical Education Group (MEG), via the charitable contribution website at www.pfizer.com/healthcarecharitables. See White Guide Chapter 7: Support of External Organizations, for additional information about healthcare-related charitable contributions.

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

Sales Colleagues can promote Pfizer products at these screenings with an exhibit and display as long as the exhibit and display booth is physically separate and apart from the screening area. Again, however, no financial ROI analysis can be tied to the screening event. Screenings offered to the public must be advertised and open to the community at large. This means the screening should have a broad, community audience and should not be targeted to members of any particular group. It does not mean that an entire city must be invited or that the event must be advertised in a city newspaper. The public screening must, however, be advertised in a broad manner and not merely at a particular hospital or in particular medical offices. All advertising and publicity materials must be approved by the relevant product Review Committee (RC) or the PCA RC.

Additional Guidelines for All Screenings

All consumer health fairs and screenings implicate privacy issues when they involve obtaining personal information from individuals. If an individual’s affiliation with Pfizer and Pfizer’s sponsorship of the screening are disclosed and apparent, a consumer’s participation in the event is deemed to be his/her consent to share this personal information with a Pfizer representative.
Pfizer’s ability to use de-identified data obtained at consumer health fairs or public screenings is strictly limited by the terms specified on Pfizer’s **Patient Authorization and Release form**, which the screening vendor must require that all screening participants sign. You may obtain a copy of the form under the [Compliance tab on PfieldNet](#). Aggregated de-identified data can be provided to an employer and/or managed care customer only if the screening participant has signed a Patient Authorization and Release form which specifically authorizes that the data can be provided to the employer and/or managed care plan managing the Rx drug benefit. For more information on the topic of patient consent, see *White Guide Chapter 11: Privacy: Protecting Personal Information*.

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

### Managed Care Customer Health Screening

Q. A Managed Care Organization (MCO) would like Pfizer to conduct a disease screening for employees of an employer to which the MCO provides pharmacy benefit services. The MCO would also like Pfizer to provide it with the de-identified, aggregate data from the screening. Can Pfizer organize the screening and provide the data?

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

Q. Is there a list of approved vendors that can be used to conduct health screenings?

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

HCP Screener

Q. Can a doctor or nurse from a healthcare provider/payer, such as a hospital or private practice, conduct the screening free of charge if Pfizer pays for screening materials?

A. No, the screening must always be conducted by a vendor that is not a healthcare provider/payer, even where no payment is being made to the screener.

Product Support Programs

Disease Management Programs

Pfizer or an MCO may at times mail Pfizer RC-approved disease management, patient education materials or other types of branded materials to healthcare providers and/or patients, subject to certain reimbursement and authorization requirements under Health Insurance Portability and Accountability Act of 1996, as amended, including by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH) (collectively referred to as HIPAA).

Unbranded Communications

Unless prior authorizations are obtained from members, Pfizer is limited to providing unbranded health information to an MCO’s members, if protected health information will be used by the MCO in making the communication.
Branded Communications

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

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

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

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

From time to time, Pfizer may want to pay for a medication compliance program to be provided by or through a customer (e.g., an MCO or a pharmacy). These programs typically involve sending scheduled mailings to patients to remind them to fill or refill a current prescription used to treat a chronic condition. Such programs are appropriate promotional activities, and Pfizer can provide payment on a fair market value basis for the cost of each mailing or contact. The proposed mailings must conspicuously disclose Pfizer’s support. These programs may be implemented without seeking patient authorizations if Pfizer and the MCO comply with the terms of the updated requirements of the marketing “refill reminder exception” under the HIPAA Privacy Regulations. The type of compensation permitted under the refill reminder exception depends on whether compensation is provided directly by Pfizer to either the MCO or business associate for the relevant communications.

If Pfizer pays an MCO directly, Pfizer may reimburse the MCO only for reasonable direct or indirect costs related to the labor, materials, supply, and capital and overhead costs of making the communications. If Pfizer pays an MCO’s business associate, Pfizer may compensate the business associate up to the fair market value of the services provided.

Please note that the following activities are not permitted under the refill reminder exception:

- Communications regarding new formulations of a currently-prescribed drug or biologic;
- Communications about a drug that may be used in conjunction with a currently prescribed drug or biologic, also known as an adjunctive drug; and
- Communications encouraging an individual to switch from a currently prescribed drug or biologic.

As noted in the preceding section, for arrangements that do not comply with the requirements of the refill reminder exception, the MCO must obtain patient authorizations before disseminating the communications.

The team RC must approve any medication compliance program, each of which must also be documented in a service agreement that sets forth the basis for payment, as well as the program materials. If the customer is an MCO, the MRCR or Organized Customer Legal team must review and approve the proposed arrangement. Since the use of confidential patient medical information to

Rev. 01/16

Page 11 of 14
communicate with patients has privacy implications even if patient identifiable information is not disclosed, please consult the section on Pfizer-Sponsored Third-Party Communications in *White Guide Chapter 11: Privacy: Protecting Personal Information*.

**Sweepstakes and Prizes**

Sweepstakes and skill contests are governed by a variety of federal and state laws, including state lottery and sweepstakes laws, state prize notification statutes, state registration statutes, the Federal Sweepstakes Law, and the *Deceptive Mail Prevention and Enforcement Act (DMPEA)*. The conduct of sweepstakes and contests is further subject to the CAN-SPAM Act of 2003 and, if directed to children, the Children’s Online Privacy Protection Act (see *White Guide Chapter 11: Privacy: Protecting Personal Information*). Non-compliance with these laws may subject sweepstakes and contest sponsors to individual and class action lawsuits, as well as fines and injunctions.

Colleagues that are considering designing a sweepstakes program should also be mindful of a number of other issues, including:

- The contest rules may be considered Pfizer’s contract with entrants, so it is vital to make sure the rules are very clear and contain all required elements (e.g., “no purchase necessary;” “decision of judges are final;” “void where prohibited;” eligibility requirements; criteria for winning; method of winner selection and notification);
- In a sweepstakes, “consideration” or “substantial effort” (such as a purchase, payment of a fee, or significant expenditure of time) cannot be required in order for the entrant to participate. If consideration is required, then the contest is a lottery (which involves a prize, consideration, and chance), and lotteries are illegal unless sanctioned by the government;
- If a sweepstakes requires a method of entry that might constitute consideration (e.g., it requires a significant expenditure of time or effort) the sponsor must also provide an alternate method of entry that does not require consideration; and
- Customer-only sweepstakes are acceptable provided that the sponsor ensures that the customer status was obtained prior to the start of the sweepstakes (i.e., sponsors should not induce anyone to become a customer in order to enter the sweepstakes).
- Not all sweepstakes are permitted in all areas, and some states have sweepstakes registration requirements.
Pfizer should generally contract with third-party sweepstakes vendors to ensure compliance with the matrix of legal requirements and other considerations. All sweepstakes programs, including rules, prizes, and advertising, must be reviewed and approved by the relevant team RC before they may be implemented. Teams must consult with their team attorney if considering a sweepstakes or contest.

**Employees as Consumers**

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

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

Also note that discussions with employees, as consumers, must comply with FDA regulations. For more information on interactions with employer representatives (such as benefit managers and medical/non-medical personnel who play a role in administering health benefits for an employer), see **White Guide Chapter 13: Promotional Interactions with Employer Groups**.

**FOR MORE INFORMATION**

- Guidance for the Implementation of the Updated PhRMA DTC Principles
- Pfizer Principles for Clear Health Communication
- CEP Resource Center at [http://cep.pfizer.com](http://cep.pfizer.com)
- Corporate Policy (CP) #902: Management of Safety Information for Customer Engagement Programs (CEPs) Policy
- Corporate Procedure (CP) #902a: Management of Safety Information for Customer Engagement Programs (CEPs) Procedure
- Orange Guide Chapter 16: Consumer and Employee Interactions
- White Guide Chapter 2: Advertising and Promotional Materials
- White Guide Chapter 4: Marketing Programs

Rev. 01/16

Page 13 of 14
• [White Guide Chapter 7: Support of External Organizations]
• [White Guide Chapter 11: Privacy: Protecting Personal Information]
• [White Guide Chapter 13: Promotional Interactions with Employer Groups]
• Refer any other questions to Regulatory or your team attorney
Chapter 13: PROMOTIONAL INTERACTIONS WITH EMPLOYER GROUPS

CONTENTS

Promotional Interactions with Employer Groups

Introduction ....................................................................................................................................................................2

Key Points to Ensure Compliance .........................................................................................................................3

Coordinate with Director, Employers (DE) ............................................................................................................3

Treat Employer Representatives (Decision Makers) as HCPs ...........................................................................3

Tailor Discussion to Individual Employer Representative ..................................................................................4

Benefit Managers .................................................................................................................................................4

State/Municipal Employees ................................................................................................................................5

Unions ....................................................................................................................................................................5

Brokers and Consultants .......................................................................................................................................5

FOR MORE INFORMATION ................................................................................................................................6
Chapter 13: PROMOTIONAL INTERACTIONS WITH EMPLOYER GROUPS

Introduction

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

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

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

Coordinate with Director, Employers (DE)

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

Treat Employer Representatives (Decision Makers) as HCPs

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

Employers and Employees

Q. May Pfizer employees treat employer representatives (decision makers) and employees in the same manner?

A. No. Pfizer colleagues must treat employer representatives as HCPs. Employees should be treated as consumers. When interacting with employer representatives, however, Pfizer colleagues must tailor any product discussion carefully to the representative’s background, especially if the employer representative does not have a medical background.

Tailor Discussion to Individual Employer Representative

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

Benefit Managers

Benefit managers may want to discuss the coverage offerings and access availability for Pfizer products. As with HCPs at medical groups or hospitals, Pfizer colleagues may engage in discussions about coverage and access, provided that their statements are truthful, accurate, and not misleading, and that Pfizer colleagues only use materials approved for that purpose, such as approved access grids.

Rev. 01/16

Page 4 of 6
Pfizer colleagues may not direct employers to a specific PBM/HMO, or encourage an employer to switch to a different PBM/HMO. Pfizer colleagues may not discuss confidential information between Pfizer and a PBM/HMO, including whether or not Pfizer has a rebate agreement with a particular PBM/HMO or any of the contractual terms with any employer, even if the employer is a customer of the PBM/HMO in question.

**State/Municipal Employees**

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

**Unions**

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

**Brokers and Consultants**

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

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

FOR MORE INFORMATION

- Contact a member of the Director, Employers team or an attorney from the Organized Customer Legal Team
- [White Guide Chapter 3: Promotional Interactions with HCPs](#)
- [White Guide Chapter 12: Promotional Interactions with Consumers](#)
- [White Guide Chapter 16: Federal Employee Interactions and Lobbying](#)
- [The Orange Guide](#)
Chapter 14: STARTERS

CONTENTS

Starters

Introduction .................................................................................................................................................................. 2

Key Points to Ensure Compliance ....................................................................................................................... 3

Starter Allocation ......................................................................................................................................................... 4

Starter Packaging ......................................................................................................................................................... 5

Key Points: Basic Rules Regarding Handling of Starter Packaging ................................................................. 6

Inclusion of Materials with Starters ............................................................................................................................. 7

Distribution of Starters to Approved Recipients ........................................................................................................ 7

Hospitals, VA, and DoD Institutions ..................................................................................................................... 10

Starters May Not Be Distributed for Research, Charitable Activities, or To Defray Patients’ Pharmacy Expenses ........................................................................................................................... 11

Managing Starters ...................................................................................................................................................... 12

Starter Storage Requirements ................................................................................................................................ 12

Accurately Document Receipt and Delivery of Starters .................................................................................. 12

Key Points: Documenting the Receipt and Delivery of Starters ..................................................................... 13

Completion of eSAFs and SAFs .......................................................................................................................... 13

Reconciling Starter Inventory ................................................................................................................................ 14

Reminder on Expired Starters ............................................................................................................................ 15

Free Trial Vouchers: An Alternative to Starter Distribution ........................................................................... 15

Key Points for Developing a Voucher Program and Distributing Vouchers ................................................... 16

FOR MORE INFORMATION ...................................................................................................................................... 16

Rev. 01/16

Page 1 of 17
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.
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 personally witness the signature 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 not be used except 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 the Samples COE and the responsible District Manager. Significant losses and thefts must be reported by the Samples COE 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 implies or states that he or she is using a Pfizer product for an off-label use, providing starters to that HCP for the off-label use may be considered off-label promotion and can 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

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. Leaving a starter with an HCP implicitly delivers a message that the product is appropriate for its labeled use(s).

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 (“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 may “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 he or she can or cannot do with respect to a particular product’s starter packaging, he or she should consult his or her manager, the Samples COE, 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, or 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 are distributed in a starter kit (or independent of the starters), they must be reviewed and approved for such use by the applicable 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 though 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, the Samples COE, 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 witness the signature on all starter requests.

If a Sales Colleague suspects that an HCP is charging the government or patients for starters, the colleague must immediately stop providing starters to that HCP and discuss the situation with his or her manager, the Samples COE, or relevant team attorney.

Pharmaceutical companies must maintain records tracking the movement of all starters from the time they leave the distribution facility to the time they are delivered to the healthcare provider. Significant losses, including inventories with unacceptably large negative variances and all thefts of starters, must be reported by the Samples COE to the FDA within five business days. It is essential, therefore, that Sales Colleagues notify the Samples COE of all thefts and starter losses immediately upon becoming aware of them. Some states also have reporting obligations that are more stringent than federal law. Record falsification and diversion of starters must also be reported to the FDA.
The Pfizer Samples COE 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, and may cause both a Sales Colleague and Pfizer to be liable for substantial penalties.

### On-label Use of Starter

**Q.** If a specific dosage of a starter package of a product is not used on-label by a particular specialty because they never see the appropriate type of patient, but there is a dosage that can be used on-label by the same specialty, is there any limitation on what Sales Colleagues can distribute to them?

**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.

**Q.** If physicians can prescribe drugs for both on-label and off-label uses, can a Sales Colleague leave starters with a physician who wishes to use them in the treatment of a patient for an off-label purpose?

**A.** No. When a Sales Colleague distributes starters, he or she is engaging in product promotion. Leaving a starter with an HCP implicitly delivers a message that the product is effective and safe for its labeled uses. When an HCP implies or states that he or she is using a Pfizer product for an off-label use, providing starters to that HCP may be considered off-label promotion and may subject Pfizer to prosecution under the False Claims Act. 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).
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. Failure to bring such a request to Pfizer’s attention, or knowingly giving any starter away for personal use, is a violation of the Duty to Act and a violation of Pfizer policy and the law.

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 institution (this may include the pharmacist in charge of handling starters for the hospital).

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 the Samples COE by calling Standard Register at 1-800-313-8263 and following the caller-directed prompts.
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 the Samples COE 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 Clinical Research and Investigator-Initiated Research Chapter in this Guide.) HCPs seeking to assist their patients in mitigating their medication costs can 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 or 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 the Samples COE for further evaluation and reporting to the FDA.

**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 dropping starters at an institution that requires the starters 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 the Samples COE 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 underlying causes of the malfunction are 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, and information provided as part of the CSC Help Center assigned ticket, to StarterCompliance@pfizer.com.

*Rev. 01/16*
If a paper SAF is used as permitted above, Sales Colleagues must enter the 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**

<table>
<thead>
<tr>
<th>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?</th>
</tr>
</thead>
<tbody>
<tr>
<td>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. (However, 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.)</td>
</tr>
</tbody>
</table>

**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 the Samples COE for further guidance.

In addition, all starter losses and thefts should be reported to the Samples COE 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 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**

Q. Can a Sales Colleague pay for bins or space in starter closets in physicians’ offices?

A. No. Paying for space in starter closets could violate anti-kickback laws.

**Free Trial Vouchers: An Alternative to Starter Distribution**

Some product teams use free trial voucher programs as a substitute for, or alternative to, the physical distribution of starters.

In a voucher program, 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

Rev. 01/16
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, New Limitations Regarding Free Trial Voucher Programs Advisory, 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.

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 the Samples COE, 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 Clinical Research and Investigator-Initiated Research Chapter.
• For more information on distributing starters in government institutions, see the Federal Employee Interactions and Lobbying Chapter.
Chapter 15: STATE LAWS: HCP AND STATE EMPLOYEE RESTRICTIONS

CONTENTS

State Laws: HCP and State Employee Restrictions

Introduction ................................................................................................................................................................... 4

Summary of Key State HCP-related Healthcare Compliance Laws ................................................................. 5

Summary of Key State Employee Gift Laws .............................................................................................................. 11

California ....................................................................................................................................................................... 13


Definition of Healthcare Professional ................................................................................................................. 13

How the Law Impacts Pfizer Colleague Activities ............................................................................................. 13

Colorado ....................................................................................................................................................................... 14

The Law: Restrictions on Gifts to State Employees .......................................................................................... 14

Definition of Healthcare Professional State Employee under the law ............................................................. 14

How the Law Impacts Pfizer Colleague Activities ............................................................................................. 15

Connecticut .................................................................................................................................................................. 16

The Law: Connecticut Compliance Program Law & Senate Bill 257 .............................................................. 16

How the Law Impacts Pfizer Colleague Activities ............................................................................................. 16

District of Columbia ..................................................................................................................................................... 16

The Law: Prescription Drug Marketing Costs Disclosure Law ........................................................................ 16

Definition of Healthcare Professional ................................................................................................................. 17

How the Law Impacts Pfizer Colleague Activities ............................................................................................. 18

Rev. 01/16

Page 1 of 36
The Law: SafeRx Amendment Act of 2008

Gifts to D.C. Medication Advisory Committee Prohibited

How the Law Impacts Pfizer Colleague Activities

Louisiana

The Law: Code of Governmental Ethics

Definition of "Public Servant"

How the Law Impacts Pfizer Colleague Activities

Massachusetts

The Law: Pharmaceutical and Medical Device Manufacturer Conduct Law (Massachusetts Marketing Code of Conduct)

Definition of Healthcare Professional

How the Law Impacts Pfizer Colleague Activities

Meals

Other Prohibited Items of Value and Activities

Disclosure

Non-patient Identified Prescriber Data

Minnesota

The Law: Gift Restriction Law

Educational Items

Meals

Consulting Engagements with MN HCPs

Definition of Practitioner

How the Law Impacts Pfizer Colleague Activities

Nevada

The Law: Nevada Marketing Code of Conduct
New York ...................................................................................................................................................................... 30

   The Law: Restrictions on Gifts to State and Local Officers and Employees .......................................................... 30
   Definition of Officer or Employee ......................................................................................................................... 30
   How the Law Impacts Pfizer Colleague Activities ............................................................................................. 30

Vermont ........................................................................................................................................................................ 31

   The Law: The Prescribed Products Law .................................................................................................................. 31
   Definition of Healthcare Provider ....................................................................................................................... 31
   How the Law Impacts Pfizer Colleague Activities ............................................................................................. 32
   Meals .................................................................................................................................................................... 32
   Gift Ban ................................................................................................................................................................. 33
   Marketing Research ............................................................................................................................................ 33
   Disclosure of Expenditures to Vermont HCPs ................................................................................................... 34
   The Law: Vermont Price Disclosure Law ............................................................................................................ 35

West Virginia ................................................................................................................................................................ 36

   The Law: Advertising Expense Reporting Law .................................................................................................. 36

FOR MORE INFORMATION ........................................................................................................................................... 36
Chapter 15: STATE LAWS: HCP AND STATE EMPLOYEE RESTRICTIONS

Introduction

States are increasingly enacting laws and regulations that impact our business and restrict our activities, including your interactions with HCPs and state employees. Many of these state laws are more restrictive than federal law and the generally applicable Pfizer policies set forth elsewhere in this Guide.

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.

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>
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<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.</td>
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<tr>
<td></td>
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<td>Monitor expenditures per HCP and coordinate with your colleagues to ensure compliance with Pfizer’s annual limit of $3,500 per California HCP.</td>
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</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) 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.                      |
### District of Columbia

- 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 consecutive days are exempt from this requirement.
- 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.

<table>
<thead>
<tr>
<th>Key Points to Ensure Compliance</th>
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<tbody>
<tr>
<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.</td>
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<tr>
<td>Accurately and completely record all HCP expenditures.</td>
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<tr>
<td>Do not provide any gift or meal to any member of the Medication Advisory Committee, no matter how nominal the value.</td>
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<tr>
<td>State</td>
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<td>Massachusetts</td>
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## State Laws: HCP and State Employee Restrictions

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<tbody>
<tr>
<td>Minnesota</td>
<td>Gifts to practitioners are prohibited.</td>
<td>Do not invite MN practitioners to any speaker programs that provide meals (even if the program is outside of MN).</td>
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<tr>
<td></td>
<td>Pfizer policy prohibits HCP meals to MN practitioners, including nominal meals and snacks.</td>
<td>Unless an exception applies, do not provide MN practitioners meals or snacks.</td>
</tr>
<tr>
<td></td>
<td>Pfizer policy prohibits providing text books, journal subscriptions, online subscription services (e.g., Epocrates), and anatomical models, to MN practitioners.</td>
<td>Do not provide MN practitioners text books, journal subscriptions, online subscription services (e.g., Epocrates, including trial memberships), or anatomical models.</td>
</tr>
<tr>
<td></td>
<td>Pfizer policy also prohibits engaging MN practitioners as paid consultants, except for the following type of projects:</td>
<td>Do not engage MN HCPs as commercial consultants.</td>
</tr>
<tr>
<td></td>
<td>• R&amp;D, clinical, or development-related projects</td>
<td>Accurately and completely record all practitioner expenditures.</td>
</tr>
<tr>
<td></td>
<td>• Outcomes Research or medical publication-related projects</td>
<td>If you are unsure of whether an HCP has a MN license, you can check the HCP License List on the “State Healthcare Law Compliance” tab on <a href="http://OpSource.Pfizer.com">http://OpSource.Pfizer.com</a>. Also, Veeva CRM flags most (but not all) HCPs with MN licenses.</td>
</tr>
<tr>
<td></td>
<td>• Speaking and Speaker training</td>
<td>You must make a good faith effort to determine whether an HCP is licensed in Minnesota.</td>
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<tr>
<td></td>
<td>Pfizer must report permissible non-gift expenditures that exceed $100/year.</td>
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**Rev. 01/16**

*Page 8 of 36*
<table>
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<tr>
<th>State</th>
<th>Important Provisions of the State Law</th>
<th>Key Points to Ensure Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nevada</td>
<td>Nevada Marketing Code of Conduct requires companies to adopt a marketing code of conduct – the PhRMA Code is acceptable.</td>
<td>No specific guidance, other than to follow all Pfizer policies and procedures.</td>
</tr>
</tbody>
</table>
### Vermont

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.

**Key Points to Ensure Compliance**

- 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 Pfizer.com).
- If you are unsure of whether an HCP has a VT license, you can check the HCP License List which is available on the “State Healthcare Law Compliance” tab on OpSource.Pfizer.com or under the Compliance tab on PfizerNet. 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.
### 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><strong>West Virginia</strong></td>
<td>West Virginia no longer requires disclosure of HCP or advertising expenditures.</td>
<td>N/A</td>
</tr>
</tbody>
</table>
| **Colorado**   | State employees may not receive anything of value worth more than $59 from a company (as a whole, not by employee) **per year.** | Accurately and completely record all expenditures on state employees.  
Monitor spending per state employee and coordinate with your colleagues to ensure we are not spending beyond the $59 annual limit. |
| **Louisiana**  | 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. | Before considering engaging a state employee to perform a compensated service, consult with your manager.  
Before providing a meal or refreshments to state employees, coordinate with your colleagues to ensure the employee is not receiving value greater than $60 during the event. |
### New York

State and local employees are prohibited from receiving gifts. However, state and local employees may receive food items of nominal value as long as they are not part of a meal.

### Key Points to Ensure Compliance

- **Understand the laws and policies of the states in which you work and the states where the HCPs with whom you interact hold licenses.** Always remember that several state laws may apply regardless of where an interaction occurs.

- **Before providing a meal or educational item to an HCP, know where the HCP is licensed and follow any applicable state restrictions.** For example, regardless of where the interaction takes place, significant restrictions apply to HCPs with active VT, MA, 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 with a retail value equal to or greater than $25.
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 with retail value of less than $25.

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.

**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:

• Meals provided in connection with an educational presentation (e.g., speaker program) that is widely attended by non-state employees;
• 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;
• 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 & Senate Bill 257

- 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 (Senate Bill 257) now requires manufacturers to disclose payments and transfers of value provided to an Advanced Practice Registered Nurse (APRN). Definition of Advanced Practice Registered Nurse below.

For purposes of the Connecticut disclosure law, an advanced practice registered nurse is defined as:

- An APRN who practices “not in collaboration with a physician” (i.e., an APRN who practices independently); and
- Who appears in the Connecticut Department of Public Health annual APRN list.

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;
- Compensation for bona fide clinical trial activities; and
- Scholarships and expenses for attending educational, scientific, or policy conferences if attendee is selected by the sponsoring organization.
- Payments to D.C.-licensed HCPs for participating in blinded market research, if: 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 health care 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: SafeRx Amendment Act of 2008

The SafeRx Amendment Act of 2008 ("SafeRx") 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, in October 2015, the law was amended to include a provision exempting individuals who engage in “pharmaceutical detailing” less than 30 consecutive days from the requirement to obtain licensure. SafeRx also prohibits offering a gift or remuneration of any kind to a member of the D.C. Medication Advisory Committee (DCMAC).

Gifts to D.C. Medication Advisory Committee Prohibited

Because of the SafeRx gift prohibition, colleagues must not give the following to any DCMAC member (even if the item is RC-approved or would be acceptable for non-DCMAC members):

- 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, stethoscopes, 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 at http://doh.dc.gov/sites/default/files/dc/sites/doh/publication/attachments/Pharmacy_Pharmaaceutical_Detailer_FAQs.pdf (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](District of Columbia Board of Pharmacy). 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 1-800-328-2615 or program@cmrinstitute.org to determine if you already received renewal credit.

The District of Columbia can impose significant penalties on Pfizer 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 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 significantly 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 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. Examples 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.).
HCP does 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 are considered Covered Recipients for MA disclosure, as described below.)

**How the Law Impacts Pfizer Colleague Activities**

All colleagues (regardless of division, business unit, or role) who engage in activities with Massachusetts-licensed HCPs, regardless of where the HCP practices or where the interaction occurs, should be aware that Massachusetts laws restrict Pfizer’s ability to provide meals and other items of value to Massachusetts HCPs. In addition, certain expenditures have to be reported, so all colleagues must ensure that their records on these expenditures are accurate and complete.

You must make a good faith effort to determine whether an HCP is licensed in Massachusetts. To help you determine whether an HCP holds a MA license, you should check the [HCP License List](http://hcplookup.pfizer.com/HCPDataStewardshipApplication/) available on Opsource under the State Healthcare Law Compliance tab. Sales Colleagues can also access this information on PfieldNet under the Compliance Tab or by looking up the HCP Veeva CRM. Note that Veeva CRM flags most (but not all) MA HCPs. The HCP Lookup Tool is also available at the following link: [http://hcplookup.pfizer.com/HCPDataStewardshipApplication/](http://hcplookup.pfizer.com/HCPDataStewardshipApplication/).

**Meals**

The Massachusetts Marketing Code of Conduct is more restrictive than the PhRMA Code with respect to the provision of meals to HCPs. Recently, Massachusetts legislation loosened some of these restrictions on meals. 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.
- Sales representatives 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.

Meals are prohibited in all other settings that are not specifically identified in the guidance above.

**Other Prohibited Items of Value and Activities**

Generally, educational items may be provided to Massachusetts-licensed HCPs as long as they are RC-approved.

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) – formerly known as MEG) 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.

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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 PfieldNet for a list of MA HCPs or Veeva CRM for assistance, as noted above.
- The meal and gift restrictions apply even when a MA-licensed HCP is located in another state.
Disclosure

Pfizer must track and report annually all expenditures made to MA Covered Recipients for sales and marketing activities in excess of $50 (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 prohibited from receiving meals (because they are not included in the definition of HCP), they are subject to the disclosure requirements since they are considered Covered Recipients, so certain payments to pharmacists must be disclosed. The only expenditures that do not need to be disclosed are 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.

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;
- 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. All meals must, however, comply with all Pfizer policies on providing meals to HCPs, including the policy that meals should be modest and not exceed $135 in value.

Companies are required to submit annual reports to the Minnesota Board of Pharmacy of non-gift payments to practitioners, such as consulting fees, speaking honoraria, and related expenses, if the payments total $100 or more per year per practitioner.

**Consulting Engagements with MN HCPs**

Pfizer policy prohibits engaging MN-licensed practitioners as consultants except with respect to the following types of projects:

- R&D, clinical, or development related projects;
- Outcomes Research;
- Medical publications; and
- 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, optometrists, 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 List available on [Opsource](#) under the State Healthcare Law Compliance tab. Sales Colleagues can also access this information on [PfieldNet](#) under the Compliance Tab or by looking up the HCP on their Veeva CRM tablet or iPad. Note that Veeva CRM flags most (but not all) MN HCPs. The HCP Lookup Tool is also available at the following link: [http://hcplookup.pfizer.com/HCPDataStewardshipApplication/](http://hcplookup.pfizer.com/HCPDataStewardshipApplication/).

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 educational items.
- 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 PfieldNet or Opsource for a list of Minnesota HCPs, as noted above.
- The meal and gift restrictions apply even when a Minnesota HCP is located in another state.

Nevada

The Law: Nevada Marketing Code of Conduct

The Nevada Marketing Code of Conduct requires all manufacturers and wholesalers who sell or market a drug in Nevada to:

- Adopt a written marketing code of conduct (the current PhRMA Code is acceptable);
- Adopt a training program to provide regular training to appropriate employees on the marketing code of conduct;
- Conduct annual audits to monitor compliance with the marketing code of conduct;
- Adopt policies and procedures for investigating instances of noncompliance with the marketing code of conduct;
- Identify a compliance officer responsible for the marketing code of conduct; and
- Submit certain information annually to the Nevada State Board of Pharmacy (including the marketing code of conduct, description of the training program; description of the investigation policies; contact information for the Compliance Officer; and certification of the company’s annual audit and compliance with its marketing code of conduct).
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 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.
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.

**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 List available on Opsource under the State Healthcare Law Compliance tab. Sales Colleagues can also access this information on PfieldNet under the Compliance Tab or by looking up the HCP in their Veeva CRM tablet or iPad. Note that Veeva CRM flags most (but not all) VT HCPs. The HCP Lookup Tool is also available at the following link: [http://hcplookup.pfizer.com/HCPDataStewardshipApplication/](http://hcplookup.pfizer.com/HCPDataStewardshipApplication/).

**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**

In June 2011, the Attorney General in the state of Vermont updated its Guide to the Prescribed Products Gift Ban and Disclosure Law by adding new restrictions in connection with VT-licensed HCPs’ participation in paid 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 PfieldNet or Opsource 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), must be disclosed, regardless of the amount.

This includes tracking and disclosing the distribution of samples, coupons, and vouchers. Vermont’s law defines “sample” as a unit of a prescription drug, biological product, or medical device that is not intended to be sold and is intended to promote the sale of the drug, product, or device, including starter packs and coupons or vouchers that allow any individual to receive a prescribed product for free or at a discounted price.

Items exempt from disclosure are:

- Refreshments and other snacks provided at a booth at a convention/congress;
- Rebates and discounts;
- Royalties and licensing fees for patent rights;
- Labels on prescribed products;
• Reasonable expenses related to an interview by a manufacturer in connection with a bona fide employment opportunity; and
• Prescribed products distributed free of charge or at a discounted price pursuant to a Pfizer Patient Assistance Program.

**The Law: Vermont Price Disclosure Law**

The Vermont Price Disclosure Law requires that, when marketing directly to Vermont 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>
</tbody>
</table>
E-mails or electronic communications.

<table>
<thead>
<tr>
<th>Promotional Activity</th>
<th>Action Required</th>
</tr>
</thead>
<tbody>
<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.

**West Virginia**

*The Law: Advertising Expense Reporting Law*

On March 24, 2015, West Virginia repealed the state’s Prescription Drug Advertising Expense Reporting requirement. As such, disclosure reports are no longer required at the state level in West Virginia. However, all colleagues must continue to record expenditures and transfers of value to West Virginia prescribers.

**FOR MORE INFORMATION**

- Refer any questions to the team attorney with responsibility for the relevant state.
Chapter 16: FEDERAL EMPLOYEE INTERACTIONS AND LOBBYING

CONTENTS

Federal Employee Interactions and Lobbying

Introduction .................................................................................................................................................................... 3
Federal Employee Interactions...................................................................................................................................... 3
  Key Points to Ensure Compliance ....................................................................................................................... 5
Promotional Activities ................................................................................................................................................... 7
  Impact of Formulary Status on Ability to Promote ............................................................................................. 7
  Promotional Materials ........................................................................................................................................... 7
  Starters ................................................................................................................................................................... 7
  Gifts to Federal Employees (HCPs at IHS, DOD, and VA Facilities)................................................................... 8
  Meals in Connection with Promotional Presentations ....................................................................................... 8
  Meals in Connection with Speaker Programs ..................................................................................................... 9
  Educational Items ................................................................................................................................................ 11
Non-Promotional Activities ......................................................................................................................................... 12
  Selecting HCPs Employed by the Government as Speakers ............................................................................ 12
  Supporting Independent Medical Education ..................................................................................................... 13
Lobbying ....................................................................................................................................................................... 13
  Federal Lobbying ................................................................................................................................................. 13
  Key Points to Ensure Compliance ....................................................................................................................... 14
Who Is a “Lobbyist?” ............................................................................................................................................... 15

Rev. 01/16

Page 1 of 24
Chapter 16: 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.

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 Part 1 ("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.

- 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 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 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 can be offered to federally-employed HCPs (except for VA employees and volunteers) 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.

- 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 the Sunshine Act. Additionally, always check the State Laws: HCP and State Employee Restrictions Chapter in this guide, for additional guidance.
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 submit 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. 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. 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 should not be left for VA DoD HCPs at the government institution in which they work. However, “free goods” may 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 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. 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 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 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 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 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 the Meals, Educational Items, and HCP Payment Disclosure Chapter in this guide.

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, or government agency); 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 on alternating Tuesdays and bring a modest lunch, such as a sandwich and soda?

**A.** No. VA Rules prohibit you from providing a meal to VA employees, even if the office staff gives approval for you to do so.

### 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 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 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 above, 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. 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 for Clinical and Medical Controlled Document (CMCD) MEG01-POL: U.S. Medical Education Grants Policy and CMCD 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 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 in this guide.
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,” your time spent supporting the lobbying efforts of others within the Company is still reportable under federal law.

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 the 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 programs;
• Requesting a meeting with a congressional or agency official or his or her staff, if the request does not include an attempt to influence the official; and
• Responding to a request by an official for reports, information, statistics, subpoenas, or similar documents.

Pfizer’s grassroots advocacy program works to inform and educate colleagues on public policy issues, and provide colleagues the opportunity to engage in policy debates by making their voices heard in Washington, D.C. and state capitols across the country. There may be other activities developed by a State Action Team (formerly called State Resource Team) or the Regional Council that involve interaction with government officials or public employees and would be subject to the Pfizer policies in this Chapter.

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

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<thead>
<tr>
<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 political and lobbying activities related to Pfizer business.</td>
</tr>
<tr>
<td>Report your political and lobbying activities as required.</td>
<td>Experiment or try something new without checking with your GRD or team attorney.</td>
</tr>
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</table>

### 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.**

Rev. 01/16
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 contacts 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 in this guide. 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 Affairs 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 Medicated 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.**

**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 PAC 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 [https://governmentrelations.pfizer.com/home.aspx](https://governmentrelations.pfizer.com/home.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](http://ecf.pfizer.com/sites/eSOPPortal/Lists/Index/MEG.aspx) for CMCD MEG01-POL: U.S. Medical Education Grants Policy and CMCD MEG01-GSOP: Processing of U.S. Medical Education Grants SOP.
- For more information about the Pfizer PAC, visit [https://governmentrelations.pfizer.com](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 17: PUBLICATIONS

CONTENTS

Publications

Introduction ....................................................................................................................................................................2

Key Points to Ensure Compliance ......................................................................................................................... 3

Publication Planning ..................................................................................................................................................... 4

Authorship and Disclosures ........................................................................................................................................... 5

Compendia ..................................................................................................................................................................... 7

Payments to Authors and Contracts ............................................................................................................................. 7

Supplements ................................................................................................................................................................. 8

Publication of IIR Study Results .................................................................................................................................... 8

FOR MORE INFORMATION ......................................................................................................................................... 9
Chapter 17: PUBLICATIONS

Introduction

As part of our commitment to publishing the results of Company-sponsored clinical research studies, Pfizer supports the timely publication of manuscripts associated with these studies. Pfizer also supports other types of publications, such as abstracts, congress presentations, and review articles.

This Chapter summarizes policies and procedures for managing Pfizer-supported publications, including author selection, informing external authors of Pfizer’s publication policies, payments to authors (where applicable), contracts with authors, manuscript development, and disclosure of Pfizer support.

Publications subject to the requirements of this Chapter include:

- Submissions to peer-reviewed medical and scientific journals, such as primary and secondary manuscripts, review articles, and letters to the editor;
- Submissions to scientific congresses, such as abstracts, posters, and presentations;
- Book chapters; and
- Publications that mention a Pfizer product or are in support of a Pfizer product, including those associated with Pfizer-sponsored clinical trials
- Note that pre-clinical studies are separately addressed by the Non-Clinical Publication Approval System, available at: http://ncpas.pfizer.com/ncpas/?_dmfClientId=1232081148445%2526__dmfTzoff=300.

Pfizer colleagues, external authors, and the parties with which Pfizer contracts (e.g., publications agencies) who are involved with Pfizer-supported publications must understand Pfizer’s publications policies. Non-compliance with these policies puts the Company at risk and can subject Pfizer colleagues to disciplinary action up to and including termination.
**Key Points to Ensure Compliance**

- **Publications are not marketing tools.** While they may eventually be used in a promotional context, the planning and development of a publication must be true to the data and independent of commercial strategy or messaging.

- All members of a Publications Subcommittee must understand their roles and responsibilities and the applicable Pfizer policies.

- Marketing and Sales Colleagues must not participate in or otherwise influence or attempt to influence the publication planning process or content of publications.

- The selection of authors must be consistent with the **International Committee of Medical Journal Editors (ICMJE)** authorship criteria and all applicable disclosure obligations. Authorship credit requires: (1) Substantial contributions to conception or design of the study, acquisition of data, or analysis and interpretation of data; and (2) Drafting the publication or revising it critically with respect to important intellectual content; and (3) Final approval of the version to be published; and (4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

- Pfizer colleagues may be listed as authors if they satisfy the ICMJE criteria for authorship. General supervision of a research group that is conducting or supervising a project is not sufficient for authorship.

- In those rare circumstances where HCPs or healthcare institutions are paid to author or produce publications, Pfizer must ensure that those payments are consistent with a **fair market value (FMV)** determination and other applicable requirements of Pfizer policy, including Corporate Policy #207: Global Policy on Interactions with Healthcare Professionals (GPIHP) and My Anti-Corruption Policies and Procedures (MAPP). Pfizer does not compensate authors who are investigators in a Pfizer-sponsored clinical study for work associated with the preparation of the primary abstract, congress presentation, or manuscript regarding the study.
Pfizer publications are not marketing tools. While a publication may eventually be used in a promotional context, the planning and development of a publication must be true to the data and independent of commercial strategy or messaging. Pfizer publications fulfill the Company’s commitment to the truthful, accurate, and objective disclosure of data from Pfizer-sponsored clinical studies in a timely manner, and support the safe and effective use of Pfizer medicines. Specific timelines apply to publication of primary manuscripts disclosing the results of Pfizer-sponsored interventional clinical studies. Pfizer colleagues must ensure that any engagement of HCPs or healthcare institutions (HCIs) to author or produce publications does not give rise to inappropriate financial relationships with or influence over those HCPs or HCIs.

Importantly, the process by which authors are selected and compensated, if not structured appropriately, may violate federal or various states’ anti-kickback statutes. For example, if an HCP is being paid to author publications, but in reality is just “rubber-stamping” an article written by a third-party, the government might investigate whether that HCP has been chosen and/or paid as an inducement for his or her continued or increased prescribing of a Pfizer product.

Even if an HCP has contributed substantially to the development of a publication, the government may assess whether any compensation received was based on FMV, or could instead be viewed as a potential kickback.

Conversely, omitting an individual’s name as an author on a scientific article, when the individual’s contribution satisfied the ICMJE criteria, may be viewed as a form of research misconduct.

**Publication Planning**

Pfizer publication activities involving a payment to an author are subject to a **needs assessment process** prior to engaging any HCP or HCI to work on a publication. The needs assessment must include specific details about the publication activities to be performed (e.g., a description of the proposed work to be done, the type of work product to be generated, and the purpose of the work). Currently, the needs assessment must be documented using the “Development & Publications Business Rationale/Needs Assessment Form” available in the **ENGAGE system in Op Source**. Contact the relevant product attorney if the proposed publication relates to a U.S.-approved Pfizer product.
Further, publications supported by a Pfizer product team are managed by the product’s multidisciplinary **Publications Subcommittee (PSC)**, which is responsible for developing and implementing the publications plan for a product within Pfizer. The PSC’s purpose is to ensure that clinical study results are published in a timely way, identify gaps in medical knowledge about the product, determine whether existing science can address those gaps through a Pfizer-supported publication, and ensure publication integrity and compliance with Pfizer publication policies and procedures.

The PSC is chaired by the Clinical/Medical Lead responsible for overseeing the publication program for a product, and includes Medical or Clinical Directors (who can also be *ad hoc* members), a Biostatistician, and a Publications Specialist. Marketing and Sales Colleagues are not permitted to be members of the PSC.

In addition, Marketing and Sales Colleagues are not permitted to:

- Attend PSC meetings;
- Influence the PSC decision-making process;
- Make decisions regarding prioritization of publications;
- Select congresses, authors, or journals for a publication;
- Author a medical or scientific publication;
- Comment on draft publications;
- Contract with a vendor for a publication; or
- Liaise with vendors or authors to discuss publications.

**Authorship and Disclosures**

Pfizer has adopted the authorship criteria established by the **International Committee of Medical Journal Editors (ICMJE)** as well as the **Pharmaceutical Research and Manufacturers of America (PhRMA) Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results**. In accordance with these guidelines, authors should meet all four of the following conditions:

- Substantial contributions to the conception or design of the study, acquisition of data, or analysis and interpretation of data; and
• Drafting the publication or revising it critically with respect to important intellectual content; and
• Final approval of the version to be published; and
• Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Only individuals who meet all of the ICMJE criteria should be named as authors on any medical or scientific publication. All those who are assigned authorship credit based on these criteria should be named in the byline. Any Pfizer employee who meets the criteria for authorship should be listed as an author. All those who do not meet the criteria for authorship but have contributed in some way to the publication should be acknowledged elsewhere, as appropriate. Pursuant to the ICMJE criteria, general supervision of the research group that is conducting or supervising a project is not sufficient for authorship. Participation solely in collection or analysis of data also does not justify authorship. Actual involvement in drafting or revising important content in the publication is required. All individuals providing editorial support must work under the direction of the authors.

In addition to the ICMJE criteria, authors of a Pfizer-supported publication must ensure that development of a publication is consistent with journal or congress guidelines, including applicable disclosure obligations. Further, the authors should obtain and adhere to the publisher’s requirements for acknowledging financial and material support. Authors must acknowledge in the publication all those who provided editorial support, the funding source, and the author’s relationship with Pfizer. Authors must also determine the content and type of publication, the order of names on the byline, and where the publication will be submitted. All potential external authors should be given a reasonable amount of time to review and approve a proposed publication.

Clinical and Medical Controlled Document (CMCD) CT37-GSOP: Development of Pfizer Publications includes specific recommended wording for disclosure/acknowledgement statements in a variety of situations. For example, where a publication reports the results of a Pfizer-sponsored study, the statement should read, “This study was sponsored by Pfizer Inc.”

Either prior to or during development of a publication, the Publications Specialist (or designee) is responsible for ensuring that a letter is sent to each potential external author that describes, and requests written acknowledgment of, Pfizer’s policies on authorship and disclosure of Pfizer support. In addition, prior to submission of a manuscript or abstract reporting the results of a Pfizer-sponsored
interventional study, Pfizer requires the completion of a Data Checklist to help ensure the quality of the underlying data. The Publications Specialist must also perform a final check to confirm that drafts are compliant with Pfizer’s policy and that the data are accurate and support the statistical interpretation.

**Compendia**

Generally, Pfizer does not actively engage with compendia regarding Pfizer products. Colleagues in U.S. Medical Information who receive an information request from an External Drug Compendium to review a product monograph may review the document for accuracy and completeness. All other Pfizer colleagues who receive an information request from an External Drug Compendium should consult with the relevant Product Counsel prior to responding.

In addition, colleagues in U.S. Medical Information may be notified of, or independently identify, inaccurate or incomplete product information (e.g., errors in dosages, omissions of safety information) in External Drug Compendia product monographs. Such colleagues may proactively inform the External Drug Compendia of any such errors pursuant to the [Guidance Document: Contacting External Drug Compendia](#). Any other Pfizer colleague that identifies or is made aware of any errors should notify the U.S. Medical Information colleague responsible for the relevant product.

**Payments to Authors and Contracts**

In general, Pfizer does not compensate authors for work associated with the development of publications. Pfizer may pay authors for such services, however, if the individual is providing legitimate services or work product to Pfizer for preparation of a review article, supplement, manuscript, abstract, or congress presentation where the author was not a Clinical Investigator on a covered study (if a primary publication).

All compensated external authors of Pfizer publications must enter into written agreements describing the scope of work to be performed, the fees to be paid in connection with the publication, and the compliance obligations of the authors, including representations that they will adhere to the authorship criteria and disclosure obligations described above. For payments related to the development of a publication, Pfizer must contract with and make payments to HCPs and HCIs directly. A vendor may not contract with, and may not make payments to, an HCP or HCI on Pfizer’s behalf.
All payments to authors must be in accordance with a centrally managed, pre-set rate structure that is determined based on an FMV analysis conducted for Pfizer, and all payments to HCPs or HCIs must be recorded and disclosed pursuant to governmental and other transparency requirements. Author payment requests that are greater than $4,000 per abstract, $10,000 per poster, and $25,000 per manuscript must be approved by Legal.

Note that Pfizer does not compensate authors for their time presenting a poster or an oral presentation at a congress or similar meeting. However, Pfizer may provide authors with funding for registration and travel associated with such presentations. Such funding may only be granted if the presentation satisfies a bona fide business purpose set forth in a Business Rationale Form approved by the responsible R&D or product attorney. The relevant Publications Specialist should also be made aware of such activities.

**Supplements**

Journal supplements are collections of papers that deal with related issues or topics. They are published as part of a regular issue of a journal or as a separate issue, and generally are funded by sources other than the journal’s publisher. Pfizer-funded supplements are permitted under Pfizer policy. However, because supplements are a paid communication mechanism, they are viewed as intrinsically promotional in nature. As a result, supplements cannot contain off-label information or information about products that are not yet approved. To ensure compliance with this restriction, an overview or synopsis of the supplement must be reviewed and approved by the product attorney prior to contracting. The needs assessment process must also be completed if an HCP or HCI will be engaged to develop the supplement. All contracts must ensure that Pfizer has the final decision on the supplement’s content. In addition, unlike other types of publications, supplements must be reviewed by the relevant product Review Committee (RC) prior to final submission to the journal. Because Medical is the common point of contact between the PSC and RC, it is Medical’s responsibility to ensure the PSC-reviewed supplement is brought to the RC for review. In the RC meeting, Marketing also has an opportunity to review the supplement.

**Publication of IIR Study Results**

As with publications related to the results of Pfizer-sponsored studies, Pfizer supports the exercise of academic freedom and encourages investigators to publish the results of an Investigator-Initiated
Research study (IIR) or CR-Collaboration, whether or not the results are favorable for a Pfizer product.

In our contracts, Pfizer requests an opportunity to review proposed publications or other public disclosures of the results of such studies prior to publication. Pfizer also expects the investigator or institution to comply with recognized ethical standards concerning publications and authorship, including the disclosure of Pfizer support of the study in any publication of study results.

Support for and management of IIRs and IIR publications (as well as publications related to Pfizer-sponsored clinical studies) is described in White Guide Chapter 9: Clinical Research and Investigator-Initiated Research (IIR).

FOR MORE INFORMATION

- Corporate Policy #207: Global Policy on Interactions with Healthcare Professionals (GPIHP)
- My Anti-Corruption Policies and Procedures (MAPP)
- Clinical and Medical Controlled Document (CMCD) CT20-POL: Public Disclosure of Pfizer Clinical Study Data and Authorship
- Clinical and Medical Controlled Document (CMCD) CT37-GSOP: Development of Pfizer Publications
- ICJME Guidelines on Authorship and Contributorship
- PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results
- Guidance Document: Contacting External Drug Compendia
- White Guide Chapter 9: Clinical Research and Investigator-Initiated Research (IIR)
- Refer any other questions or concerns to a member of Pfizer’s Publications Management Team/External Medical Communications or your team attorney
Chapter 18: MEALS, EDUCATIONAL ITEMS, AND HCP PAYMENT DISCLOSURE

CONTENTS

Meals, Educational Items, and HCP Payment Disclosure
Introduction ....................................................................................................................................................................2
Key Points to Ensure Compliance ........................................................................................................................................3
Meals to HCPs ................................................................................................................................................................ 5
General Rules and Restrictions .........................................................................................................................................5
Meals Provided by Field Sales Colleagues and Their Managers ....................................................................................7
Approved Attendees List............................................................................................................................................... 8
Meals Provided by Senior Sales Colleagues and Headquarters Colleagues .................................................................12
Educational Items to HCPs ...........................................................................................................................................14
HCP Payment Disclosure Policy ....................................................................................................................................15
Overview .............................................................................................................................................................. 15
Items Included in Reporting ..........................................................................................................................................15
Reporting of Indirect Payments or Other Transfers of Value ....................................................................................... 16
Disclosure of Monetary Compensation and Business Travel Expenses................................................................. 16
Disclosure of the Value of Meals ..................................................................................................................................17
Disclosure of the Value of Educational Items and Non-Disclosure of Patient Materials ...........................................18
Recording Disclosable Payments and Items ..................................................................................................................19
Opting Out of Receiving Disclosable Items .................................................................................................................. 20
FOR MORE INFORMATION ....................................................................................................................................... 22

Rev. 01/16

Page 1 of 23
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.

In early 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, beginning in 2010. Pfizer also committed to disclose all payments to U.S. institutions in connection with clinical research, along with the names of the associated principal investigators.

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). Those requirements are commonly referred to as “the Sunshine Act” or “Open Payments” provisions.

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.

**Key Points to Ensure Compliance**

- Except where restricted by state 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 amount spent cannot exceed $135 per attendee, including tax and tip. For in-office or in-hospital meals, the cost, including tax and tip, 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. Any individual who is unable to stay for an educational discussion with the Sales representative, regardless of role, must abstain from having a meal.

- The PhRMA Code prohibits Sales representatives and their 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 purpose. Account Managers (see chart below for definition) may provide out-of-office meals to HCPs that 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 prescribers, including physicians, nurse practitioners, physician assistants, osteopaths, 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

- Pfizer’s disclosures for the period July 2009 through December 2014 are posted on the Pfizer website at [http://www.pfizer.com/responsibility/working_with_hcp/working_with_hcp.jsp](http://www.pfizer.com/responsibility/working_with_hcp/working_with_hcp.jsp). In addition, disclosures pursuant to the Sunshine Act are posted on the Open Payments website maintained by CMS at [http://www.cms.gov/OpenPayments/index.html](http://www.cms.gov/OpenPayments/index.html).

- In general, the reported individual meal value equals the total meal charge divided by the number of attendees, regardless of the number of attendees who consumed the meal. However, Pfizer will report for only those who actually ate. U.S. prescribers at a speaker program where a meal is provided can “opt out” of eating a meal, 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.

- 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 transferred 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 HCPs 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 and tip) and meals in an in-office or in-hospital setting cannot exceed $40 (including food, beverage, tax, and tip). 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 an appropriate and legitimate business purpose. 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>

Rev. 01/16
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 representatives should consult the physician profiles on their Veeva CRM, and other colleagues should consult the Customer Master at 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.

<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>Account Manager, including AD, DE, KAM, VAM, ADM (only if such colleague does not directly supervise Sales representatives)</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>HQ Marketing/Medical</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
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 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 Colleague 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 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 Sales 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 (“Approved Attendee”).

For both live and remote out-of-office branded and unbranded speaker programs that are product-related and hosted by Pfizer (as opposed to a co-promote partner), Sales Colleagues must have a legitimate expectation that at least three individuals who are Approved Attendees and not affiliated with the speaker (i.e., not part of the speaker’s medical practice, practice group, or institution) will attend. It is each Sales Colleague’s responsibility to determine that an individual has an Approved Attendee designation, using the HCP Look-Up Tool at http://hcplookup.pfizer.com/. Additionally, the Sales Colleague must confirm that: (1) each Approved Attendee has appropriate responsibility for

Rev. 01/16

Page 7 of 23
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 speaker programs.

<table>
<thead>
<tr>
<th>Approved Attendees List</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced Nurse</td>
</tr>
<tr>
<td>Certified Nurse Anesthetist</td>
</tr>
<tr>
<td>Clinical Nurse Specialist/Certified Nurse Specialist</td>
</tr>
<tr>
<td>Chiropractor</td>
</tr>
<tr>
<td>Doctor of Dental Surgery</td>
</tr>
<tr>
<td>Doctor of Osteopathy</td>
</tr>
<tr>
<td>Doctor of Podiatric Medicine</td>
</tr>
<tr>
<td>Lab Director <em>(Xalkori only)</em></td>
</tr>
<tr>
<td>Licensed Practical Nurse</td>
</tr>
<tr>
<td>Medical Doctor</td>
</tr>
<tr>
<td>Medical Student</td>
</tr>
<tr>
<td>Naturopathic Physician</td>
</tr>
<tr>
<td>Nurse-Midwife</td>
</tr>
<tr>
<td>Nurse Practitioner</td>
</tr>
<tr>
<td>Doctor of Optometry</td>
</tr>
<tr>
<td>Physician Assistant</td>
</tr>
<tr>
<td>Approved Attendees List</td>
</tr>
<tr>
<td>--------------------------------------</td>
</tr>
<tr>
<td>Pharmacist</td>
</tr>
<tr>
<td>Doctor of Pharmacy</td>
</tr>
<tr>
<td>Pharmacy Intern/Pharmacist Intern</td>
</tr>
<tr>
<td>Pharmacist</td>
</tr>
<tr>
<td>Pharmacy Technician</td>
</tr>
<tr>
<td>Psychologist</td>
</tr>
<tr>
<td>Quality Director (Xalkori only)</td>
</tr>
<tr>
<td>Registered Nurse</td>
</tr>
<tr>
<td>Registered Pharmacist</td>
</tr>
<tr>
<td>Respiratory Therapist</td>
</tr>
<tr>
<td>Social Worker/Master of Social Work</td>
</tr>
<tr>
<td>Tobacco Treatment Specialist (Chantix only)</td>
</tr>
</tbody>
</table>

If Sales Colleagues have a legitimate expectation that at least three Approved Attendees who meet criteria 1 and 2 above will attend a speaker program, and their RSVPs have been recorded in the system, appropriate Medical Assistants (MAs) with an identified role in and responsibility for patient care may also attend. MAs need not be from the same office as any Approved Attendee. Other office staff, spouses, guests, and individuals not on the Approved Attendees List remain prohibited from attending out-of-office programs. If a Sales Colleague is unable to verify whether an individual is an Approved Attendee using the HCP Look-Up Tool, but has a legitimate reason to believe that the individual holds one of the degrees/titles/state license types listed above, that individual may be added to the HCP section in EZSpeak for future validation. The requirement to have three Approved Attendees...
Attendees participate does not apply to programs listed in EZSpeak 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 3 appropriate attendees based on their 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.

It is never appropriate for a Sales representative to offer “take-out” meals or meals to be eaten without the Sales representative present. Meals must be incidental to the provision of informational presentations and discussions. Therefore any individual who is unable to stay for an educational discussion with the Sales representative, regardless of role, must abstain from having a meal. For this reason, and to ensure proper reporting for disclosure purposes, Sales representatives should instruct HCPs and their staff not to unwrap or consume meals provided by Pfizer prior to the arrival of the Sales representative.

**PhRMA Code “Meals” Defined**

Q. What is considered a “meal” under the PhRMA Code?

A. Anything more than a nominal food or beverage item is considered a meal and, thus, may not be provided by Sales Colleagues 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. In accordance with the PhRMA Code, food or beverage items of nominal value – such as coffee, other non-alcoholic beverages, pastries, or snacks – are not considered a meal. Pfizer policy permits a Sales representative to make an 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 such nominal food or non-alcoholic beverage items, unless further restricted by state law or other laws or policies.

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 must properly record the expense as described later in this Chapter.
### Sales Colleagues Providing a Meal to Office Staff

**Q.** If a Sales representative is bringing lunch to a medical office for HCPs to eat during a product discussion, can the representative also provide lunch to non-HCPs (e.g., office staff) in attendance?

**A.** Yes, the PhRMA Code provides that when Sales representatives conduct 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 Sales representative provide a 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 Sales representatives who agree to bring lunch to the clinic. They have offered to schedule a recurring lunch appointment for a Sales representative on the first and third Wednesday of each month. Can the Sales representative 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-Hospital Meals

**Q.** What qualifies as an appropriate “in-hospital” meal? Can a Sales representative 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 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 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, but they should not use them as a means to conduct promotional activities that they cannot host on their own. 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.

<table>
<thead>
<tr>
<th>Colleagues Permitted to Host Non-Speaker Program Restaurant Meals</th>
</tr>
</thead>
<tbody>
<tr>
<td>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?</td>
</tr>
<tr>
<td>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.</td>
</tr>
<tr>
<td>Q. Does that mean that all colleagues who meet with customers are prohibited from providing these types of presentations in restaurants?</td>
</tr>
<tr>
<td>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 (formerly Customer Alliance Directors), VAMs, and Alliance Development Managers.</td>
</tr>
</tbody>
</table>
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.

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.

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.

Legitimate Business Reason

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 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 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 could appear to be an attempt to illegally influence prescribing in violation of anti-kickback laws. 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, 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. That website is: http://www.pfizer.com/responsibility/working_with_hcp/working_with_hcp.jsp.

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 health care professionals (including, among others, licensed U.S. prescribers and U.S. clinical investigators) or to U.S. institutions who may employ such health care professionals. Colleagues must be familiar with the policy and should proactively discuss our disclosure policies with all U.S. health care 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. health care 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; 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.

*Rev. 01/16*
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. health care professionals 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 who can prescribe medicines, regardless of value. Although not treated as “meals” under the PhRMA Code, snacks and refreshments of nominal value are categorized as meals for purposes of Pfizer’s disclosures. Therefore, Pfizer colleagues must appropriately record any coffee, snacks, or refreshments in their 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 the total cost of the meal and dividing it by the total number of attendees. To ensure appropriate accounting for the per-person value, all attendees (including administrative staff, non-prescribing HCPs, nurses, physical therapists, etc.) should be tracked.
Tracking and Calculating the Disclosable Value of Meals

Q. I am a Sales Colleague planning to provide an out-of-office dinner with an appropriate speaker program that will be attended by six U.S.-licensed physicians and four other appropriate attendees (e.g., Pfizer colleagues or appropriate HCP staff). I intend to spend $120. How will the value of the meal be disclosed?

A. The total value of the meal will be divided by the total number of people who actually attend your meeting. Therefore, if all ten individuals attend, a $12 transfer of value will be disclosed for each of the U.S.-licensed physicians who consume the meal. However, if only eight individuals attend, $15 will be disclosed for each of the physicians who ate.

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 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) are categorized as meals for purposes of Pfizer’s HCP Payment Disclosure and State Reporting SOP. 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, credentials, 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 dummy 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; EZSpeak’s “Attendee & Guests” 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

Rev. 01/16
• 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 representative 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 representative 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 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 MA 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 Sales 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.

If an HCP who has opted out subsequently chooses to opt back in, the notified colleague or the HCP should contact PTI@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 about the PhRMA Code, refer to the PhRMA website at http://www.phrma.org/code-on-interactions-with-healthcare-professionals.
- For more information on Pfizer’s meal and educational item guidelines based on the PhRMA Code, including an updated FAQ on the PhRMA Code, refer to the PhRMA Guidelines tab on OpSource and under the Compliance tab on PfieldNet, or e-mail PhRMA_Code@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 License List 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.
- For more information on the National Physician Payment Transparency Program (Open Payments) under the Affordable Care Act of 2010, commonly known as the Sunshine Act, and