

U.S. Pharmaceuticals Compliance
Policies and Procedures

Table of Contents

Introduction 4
// 1. Operating the Confidential Disclosure Program(Compliance Hotline) 10
// 2. Ineligible Persons 12
// 3. Disciplinary Action 14
// 4. Interactions with HCPs and HCOs (Focus Arrangements) 15
// 5. Interactions with Government Investigators 18
// 6. False Claim Act 21
// 7. Vendor Credentialing 22
// 8. Prescriber Data 24
// 9. Special Requirements for Federal Government Employees 25
// 10. Business Meals with Healthcare Professionals 28
// 11. Educational Items for Healthcare Professionals 37
// 12. Patient Education 41
// 13. Fee-For-Service Arrangements 43
// 14. Contracting with Members of Formulary or Clinical Practice Committees 50
// 15. Medical Practice Training 51
// 16. Corporate Sponsorships 52
// 17. Providing Free Product for Charitable Purposes 56
// 18. Displays and Exhibits 57
// 19. Corporate Memberships 61
// 20. Healthcare related Charitable Contributions (other than Free Bayer Products) 64
// 21. Medical Education Grants (Including Continuing Medical Education) 69
// 22. Providing Samples and Device Evaluations at No Charge 77
// 23. Patient Protection and Affordable Care Act (PPACA) Transparency Requirement 79
// 24. State Laws – Overview 82
// 25. State Laws – Data Collection 83
// 26. State Laws 84
// California 84
// Colorado 85
// Connecticut 86
// District of Columbia 88
// Florida 94
// Illinois 95
// Louisiana 98
// Maine 101

// Massachusetts 103
// Minnesota 105
// Nevada 107
// New Jersey 109
// New York 111
// Oregon 112
// Vermont 114
// 27. Restrictions on Interactions with Certain State and Local Executive and Legislative Officials/Employees 119
// 28. Promotion and Government Reimbursement 120
// 29. Appropriate Target Audience for Promotional Activities 122
// 30. Promotional Practices Outside the United States 124
// 31. Materials for External Use 125
// 32. Materials for Internal Use Only 126
// 33. Inquiries About Off-Label Uses of Bayer Products 127
// 34. Adverse Events/Product Technical Complaints/Device Complaints Involving Bayer Products 129
// 35. Clinical Research and Clinical Study Support 131
// 36. Investigator/Institution Initiated Research (IIR) 134
// 37. Price Reporting 138
// 38. Reviewing and Approving Customer Contracts 140

Introduction

Compliance is the foundation for everything you do in marketing and selling Bayer's products. Compliance's mission is to partner with employees to do the right thing, protect Bayer's reputation by providing guidance to empower responsible decision making and foster a culture based on integrity, ethical principles and transparency aligned with our values. The Bayer U.S. Pharmaceuticals Compliance Policies and Procedures are designed to guide your daily ethical decisions with ourselves, our employees and, most importantly, our customers. These policies apply to products within each therapeutic area of the Bayer U.S. Pharmaceuticals division: Cardiovascular and Renal, Oncology, Radiology, Specialty, and Women's Health. You are accountable for understanding and following these policies, which are part of the Bayer U.S. Compliance Program (Compliance Program). Should you have any questions about these policies, you and your manager are responsible for seeking additional guidance from the U.S. Office of Compliance.

The Compliance Program includes four categories of Policies and Procedures: Integrated Compliance Management (ICM), the Bayer AG Code of Conduct and its associated U.S. Training, U.S. Compliance Training, and applicable global policies. The Compliance Program is designed to provide employees, contractors, consultants and agents with the knowledge and training to act ethically and with proper judgment in various activities related to sales, marketing, and reporting prices for prescription pharmaceutical biologics and device products or any Government reimbursed products, as well as interactions between Bayer employees, contractors, consultants or agents with healthcare professionals (HCPs) and/or healthcare organizations (HCOs). Any reference to Bayer employees, contractors, consultants, HCPs or agents within this document refers to individuals affiliated with the aforementioned therapeutic areas of the Bayer U.S. Pharmaceuticals division or corporate functions supporting such division.

"Healthcare Professionals" (HCP) is a very broad term and includes individuals who directly interact with patients and/or have a role in diagnosing or treating patients. This includes individuals who work for entities that provide healthcare services and/or items to patients. These individuals may purchase, lease, recommend, give information on, use, arrange for the purchase or lease of, or prescribe Bayer's pharmaceutical, biologics or device products in the U.S. Generally, this definition includes physicians, nurses, nurse practitioners, physician assistants, and medical assistants. In addition, those closely connected to the patient's experience, such as pharmacists, radiology technologists and therapists, also fit into Bayer's definition of an HCP. However, this definition is not limited to these individuals alone; the term includes any person, whether licensed or not, who is in a position to recommend, influence or provide information about the purchasing or prescribing of Bayer's pharmaceutical, biologics or device products. In some instances, this may include individuals who do not work directly with patients but have influence over or provide information about the recommendation, purchase or prescribing of Bayer's pharmaceutical products such as: billing or office managers, agents at hospitals, physician practice managers, management personnel within group purchasing organizations (GPOs), managed care organizations (MCOs), pharmacy benefit managers (PBMs), Specialty Pharmacies (SPs), health plan administrators, wholesalers, distributors, pharmacies, Pharmacy & Therapeutics Committee members, Formulary Committee members or other customers who do not see patients. In addition, some positions and titles within the industry are not considered healthcare professionals, such as Original Equipment Manufacturers (OEMs), retail managers or back-office staff. Accordingly, such persons are not considered HCPs under Bayer's policy.

Bayer's HCP definition differs from a "covered recipient" used for reporting purposes under the Sunshine Act. As a reminder, as of January 2023, HCPs with the following credentials are reportable under the federal Sunshine Act: APRN, CNM, CNS, DO, MD, NP, and PA and must always be documented as an HCP, including capturing their license number, regardless of the state where they practice or where you interact with them. In addition, specific states require reporting interactions with certain, locally defined HCP credentials (*e.g.,* RNs, LPNs, pharmacists). The chart below lists HCP credentials for whom payments and exchanges of goods or services, otherwise referred to as "transfers of value" (ToVs), are reportable.

Reportable Healthcare Professional Credentials by State

Healthcare Professional	Credential	Connecticut	Massachusetts	Minnesota	Nevada	Washington, DC
Registered Nurse	RN				✓	✓
Licensed Practical Nurse	LPN		✓		✓	✓
Pharmacist	PHAR	✓	✓	✓	✓	✓
Registered Pharmacist	RPh	✓	✓	✓	✓	✓
Doctor of Pharmacy	PharmD	✓	✓	✓	✓	✓

When conducting an event that includes an HCP attendee with a credential in one of these identified states, you must record this attendee as an HCP and include the state license information; otherwise, the attendee should be recorded as a Business Guest.

The Compliance Program Documents (*e.g.,* Policies and Procedures, Forms) are accessible via go/USPHcompliancepolicy.

Importance of Complying with these Compliance Policies and Procedures

The laws governing our conduct are enforceable by criminal, civil and administrative penalties. Violations may result in jail sentences, fines, or exclusion from federal and state healthcare programs such as Medicare, Medicaid, Department of Defense or Department of Veterans Affairs programs, as well as reputational harm to the company. Bayer is committed to complying with all applicable laws, regulations and industry codes (including the PhRMA Code on Interactions with Health Care Professionals, the AdvaMed Code of Ethics and materials from the Medical Device Manufacturers Association (MDMA)) governing the sale and marketing of pharmaceutical, biological and device products, as well as laws and regulations governing the reporting of prices and reimbursement information for government reimbursed products. Failure to comply with Bayer's U.S. Pharmaceuticals Compliance Policies and Procedures may result in your violating federal and state laws and regulations. It can have direct and severe consequences for you and Bayer.

Any Bayer employee, contractor, consultant, or agent who violates, counsels or encourages others to violate these Compliance Policies and Procedures is subject to discipline, up to and including termination of employment.

Adherence to these Compliance Policies and Procedures will be considered in connection with employee performance evaluations.

Direct line supervisors/managers are primarily responsible for ensuring that their employees become familiar with and understand these Policies and Procedures, complete training, and certification by the due date, as well as for appropriate and timely communication with the Human Resources Department and the Law, Patents and Compliance (LPC) Department if an employee, contractor, consultant, or agent has not adhered to all these Compliance requirements. Compliance may rely on the Supervisor/Manager to confirm that all Compliance requirements are followed. For more information on the compliance responsibilities of managers, please refer to the Management of Compliance Incidents policy.

Employees, contractors, consultants, and agents must report suspected Compliance Policies and Procedures violations to their supervisor, LPC Department, or the Vice President and Head, U.S. Office of Compliance. Reports may also be made anonymously and confidentially via Bayer's Confidential Disclosure Program, which includes the choice of using a toll-free number (the Bayer Compliance Hotline), 1-888-765-3846 or by visiting www.bayer.us/speakup.

Any employee, contractor, consultant, or agent who, in good faith, reports a suspected violation of these Compliance Policies and Procedures or raises any other compliance matter will not be subject to any retaliation or adverse actions based upon their reporting.

Anti-Kickback Statute

Bayer U.S. Pharmaceuticals has policies and procedures in place to help ensure that the Company does not violate the Anti-Kickback Statute. The Anti-Kickback Statute is a federal law that prohibits entities such as manufacturers of drugs or medical devices from offering or giving "remuneration" (*e.g.,* anything of value or "Transfers of Value" (ToV)) directly or indirectly in exchange for the purchase or recommendation of a product or to induce the purchase of such product – either now, in the future, or as a reward for past purchases.

Many states have enacted laws similar to the Federal Anti-Kickback Statute. Two primary concerns about kickbacks are that (1) they encourage the healthcare professional to make decisions based on personal financial gain and not necessarily on what is best for the patient, and (2) kickbacks encourage the over-prescribing of medications.

Third-Party Due Diligence (TPDD)

Bayer developed its group-wide Third-Party Due Diligence process to comply with strict legal standards across the globe and establish a clear and uniform method to conduct and document risk-based due diligence. This rigorous process will empower Bayer's businesses and Compliance Officers to make informed decisions when engaging Third Parties.

Use of the TPDD process is mandatory for any Bayer employee seeking to engage a Third Party in scope to interact with government officials/institutions or HCPs and HCOs on Bayer's behalf. The web-based application for TPDD and guidance on how to use the tool are available on the LPC Express Platform: go/lpcx.

Data Privacy

Personal Data is information that directly or indirectly identifies a particular individual, such as a customer, healthcare professional, patient, employee, business partner, shareholder or supplier.

Your home address, personal or business email address, mobile phone number and credit card information are examples of Personal Data. In addition, any information related to an identified or identifiable individual also constitutes Personal Data, including characteristics or preferences (*e.g.,* gender, marital status, income, photo or video recordings), behavior (*e.g.,* job performance, purchasing activities or hobbies) or communications (*e.g.,* an individual's opinions, beliefs or written text).

Proper Handling of Personal Data

As part of our normal business operations, we may collect, process, store and/or transfer personal data about various individuals, including customers, employees, healthcare professionals, patients, vendors or other business entities. We handle personal data only to the extent we have a specific, definable business need for the information. In handling that information, we maintain compliance with Bayer's corporate policy on Data Privacy and applicable data privacy laws, including those that impose additional protections for personal data considered particularly sensitive, require consent of the individual whose data we handle, and require statements about our privacy practices, such as those that Bayer provides to users of its websites and mobile apps. Such data can include government identification numbers, financial account information, date of birth, home address, health information, labor union membership, political affiliation, or criminal record. We should obtain consent before collecting sensitive personal data and take extra care when handling this data.

If you receive an individual's request to access, correct, or delete personal information, please contact the U.S. Data Privacy team immediately for support in processing the request at usprivacy@bayer.com.

Preventing Data Breach and Data Loss

We must act reasonably to protect personal data from a breach or loss. A data breach can occur when an unauthorized person gains access to personal data due to intentional or unintentional acts by a Bayer employee or a third party. A data loss can occur when personal data is disclosed, lost or mistakenly destroyed, as might happen when a laptop or other device containing a copy of unencrypted information is misplaced or stolen.

Some steps to minimize the risk of data breach or loss include obtaining prior approval from U.S. Data Privacy or the local LPC Department before transferring data and using technical measures such as encryption and access controls. Should a data breach or loss occur, Bayer will promptly notify government authorities and/or any affected individuals as and when required by applicable law. For additional information, please contact the U.S. Data Privacy team or reference the Corporate Policy on Data Privacy.

Social Media

Social media is used for external and internal business communications. All Bayer employees, contractors, consultants, and agents who utilize social media are required to use these services responsibly and in the company's interests with due consideration of the related opportunities and risks. Before engaging in any social media activity, please review the Corporate Policy on Social Media Usage. If you have questions, contact the LPC Department.

- Corporate policy states that employees may share corporate post topics if they wish and use #TeamBayer in posts to clearly identify themselves;
- You may share posts from Bayer (e.g., @BayerUS on Twitter);
- It is not permissible to add commentary or data pertaining to a Bayer product in your own commentary *(e.g.,* no brand names, no clinical data, no claims); and
- When you comment or post about Bayer and its activities, you should always make it clear that it's your opinion. Always use "I" and not "we."

Bayer Global Corporate Compliance Policy

In addition to Bayer's U.S. Compliance Program, the Bayer Code of Conduct covers all of Bayer's global businesses. This policy guides important areas of corporate responsibility, including the laws of various countries that impose obligations on Bayer and its employees, contractors, consultants, and agents. The global Corporate Compliance Policy principles represent a broad outline of the minimum standards of business conduct that Bayer expects each of its employees globally to follow. These minimum standards are derived from globally applicable laws, industry codes and internal regulations. They are consistent with the laws, regulations, guidelines and Compliance Policies and Procedures applicable in the U.S. ***However, where stricter local standards exist, such as your business's Compliance Policies and Procedures, the more stringent Policies and Procedures always take precedence.***

In addition, the global Integrated Compliance Management provides a process (*e.g.,* policies, processes, monitoring, and training) relative to identified substantive risk areas, including anti-corruption, conflict of interest, and antitrust.

Bayer Anti-Corruption Policy

The principles outlined in the Bayer Anti-Corruption Policy also represent a broad outline of the minimum standards of business conduct that Bayer expects each of its employees globally to follow. These minimum standards are derived from globally applicable laws, industry codes and internal regulations. They are consistent with the laws, regulations, guidelines, and Compliance Policies and Procedures applicable in the U.S.

The Foreign Corrupt Practices Act

Bayer conducts business with the highest legal and ethical standards and will not tolerate corruption. Similar to requirements in acting within the U.S., each employee, contractor, consultant, and agent must perform his/her job in full compliance with the Foreign Corrupt Practices Act (FCPA) and must never conduct business through unlawful payments, bribes, kickbacks, gifts, or other questionable inducements.

The FCPA specifically prohibits Bayer employees, contractors, consultants, or its agents from offering, promising, making, authorizing, or providing directly or indirectly any payments, gifts, or anything of value to a non-U.S. government official, political party, party official, or candidate for foreign political office, or an official of an international organization (such as the World Bank), with the intent to:

- Improperly influence or reward the official's actions;
- Improperly influence decision-making to obtain or retain business; or
- Secure an improper advantage.

Each Bayer employee, contractor, consultant, and agent is responsible for ensuring that their dealings with non-U.S. government officials — including government-employed healthcare professionals — comply with the FCPA. Likewise, employees, contractors, consultants, and agents are prohibited from making payments to any third party whom the employee, contractor, consultant or agent knows will, or believes is likely to, make an unlawful payment related to Bayer's business. In addition, there are U.S. Federal and State laws that make it unlawful to bribe or attempt to bribe U.S. government officials.

Auditing and Record Retention

All Compliance policies are subject to audit by Bayer Internal Audit and the LPC Department to ensure compliance with these policies. The government (*e.g.,* IRS) may also request to audit/review any of these policies. Therefore, all documents related to these policies must be retained in accordance with laws and regulations and the Bayer Corporation Records Management Policy and Records Retention and Disposal Schedule.

Questions

Bayer expects that every employee, contractor, consultant and agent will have a working knowledge of the laws affecting their responsibilities and the scope of permissible activities involved in their work and will seek guidance from a supervisor, U.S. Office of Compliance or go/lpcx for any questions.

// 1. Operating the Confidential Disclosure Program(Compliance Hotline)

The Bayer Confidential Disclosure Program allows employees, contractors, consultants, and agents to disclose, anonymously, confidentially and without retaliation, any issues or questions associated with Bayer's policies, practices, procedures or with any federal healthcare programs believed by the individual in good faith, to be a potential violation of criminal, civil or administrative law. The Confidential Disclosure Program is the Bayer Compliance Hotline, a toll-free telephone line at 1-888-765-3846 or www.bayer.us/speakup administered by a third-party vendor. The third-party vendor provides services 24 hours a day, seven days a week and prepares reports of all disclosure calls. The reports are transmitted to the Vice President and Head, U.S. Office of Compliance (or designee).

Publication of Compliance Hotline

Information about the Bayer Compliance Hotline is advertised to all Bayer employees, contractors, consultants, and agents. The following information will generally be included in the notice:

- The toll-free telephone number.
- The fact that the caller need not disclose their identity.
- The Bayer Compliance Hotline should be used to report issues or questions associated with Bayer's policies, practices, procedures or any federal healthcare programs believed by the individual to be a potential violation of criminal, civil or administrative law.
- Reports may be made confidentially and without retaliation for reports made in good faith to the Bayer Compliance Hotline.

The Compliance Hotline Reports

The third-party vendor provides reports to the Bayer AG LPC Department as they are received. This allows the status of any subsequent investigation to be tracked. The report from the third-party vendor includes all disclosures made to the Bayer Compliance Hotline. Reports involving U.S. federal healthcare programs and/or Bayer U.S. Pharmaceuticals Compliance Policies and Procedures will be routed to Bayer US Compliance and processed as described below. Reports not involving U.S. federal healthcare programs or Bayer's U.S. Pharmaceuticals Compliance Policies and Procedures, such as those involving employment or human resource issues, will be directed to the appropriate Human Resources Department within the related Bayer business.

Procedure upon receipt of hotline report involving federal healthcare programs

Upon receipt of a disclosure report involving federal healthcare programs and/or Pharmaceuticals Compliance Policies and Procedures, the Vice President and Head, U.S. Office of Compliance (or designee) makes a preliminary good faith inquiry into the allegations outlined in the disclosure to ensure that they have obtained the information necessary to determine whether further review must be conducted.

An internal review is initiated to investigate any sufficiently specific disclosure so that it reasonably permits a determination of the appropriateness of the alleged improper practice and provides an opportunity for taking corrective action. The Vice President and Head, U.S. Office of Compliance (or designee) initiates the investigation by providing a summary of the allegation, including the case number, to the U.S. Compliance Department and/or the applicable Human Resource Department, as appropriate.

After a reasonable investigation period, depending upon the circumstances, the Vice President and Head, U.S. Office of Compliance (or designee) will provide a statement of closure or a request for additional information to the third-party vendor to be provided to the caller as appropriate.
Once all necessary information is obtained and the investigation is finalized, the third-party vendor will document the disclosure report as closed.

A final report is maintained in the U.S. Compliance Department and will include, as appropriate, the investigation results and corrective actions taken.
Corrective actions may include, but are not limited to, the following:

- Modifications to appropriate policies or procedures.
- Additional or remedial training.
- Disciplinary action, including verbal or written warnings or termination.

// 2. Ineligible Persons

Bayer U.S. Pharmaceuticals does not hire Ineligible Persons. Bayer also may not bill federal healthcare programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Ineligible persons are individuals who are excluded, suspended, debarred or otherwise ineligible to participate in federal healthcare programs or federal procurement or non-procurement programs or have been convicted of a criminal offense related to federal healthcare programs.

Scope

This Policy applies to all Bayer Pharmaceuticals and Consumer Health employees, contractors, consultants, agents, and additional Bayer personnel identified as supporting these businesses.

Procedures

New Hires

As part of the New Hire Offer Letter, employees, contractors, consultants and agents are required to self-disclose and attest that they are:

- Not excluded, debarred, or suspended from participating, and are eligible to participate in federal or state healthcare programs;
- Have not been convicted of a criminal offense involving a federal or state healthcare program;
- Have not been convicted of a federal or state law relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance; and
- Will disclose immediately to the LPC Department if he/she becomes an “Ineligible Person” (as defined in this Policy).

The third-party vendor who conducts the government exclusion checks will check the prospective employee’s, contractor’s, consultant’s, or agent’s name against three government exclusion lists: the Department of Health and Human Services-Office of Inspector General’s (HHS-OIG) List of Excluded Individuals/ Entities, the General Services Administration’s List of Parties Excluded from Federal Programs and the U.S. Food and Drug Administration (FDA) Debarment List. If any potential Bayer employee, contractor, consultant or agent fails to satisfy these requirements or is determined to be an Ineligible Person, Bayer will not hire that person.

The Human Resources Department retains the Self-Disclosure in the employee’s electronic personnel file. Contingent Labor or Bayer Sponsor will retain the self-disclosure and make it available upon request from Bayer.

Within 30 days of hire date, the employee must read and certify that they understand and will abide by the Bayer U.S. Code of Conduct.

Continuous Monitoring of Exclusion Lists

On an ongoing basis, the third-party vendor will monitor all three-government exclusion lists for all employees, contractors, consultants, and agents in Bayer Pharmaceuticals and Consumer Health, as well as additional Bayer personnel identified as supporting these businesses.

If it is determined that a Bayer employee, contractor, consultant, or agent is listed as ineligible, written notice records will be forwarded to the Human Resource Business Partner, Contingent Labor or Bayer Sponsor by the Vice President and Head, U.S. Office of Compliance (or designee).

The responsible Human Resource Department, Contingent Labor or Bayer Sponsor will suspend the Bayer employee, contractor, consultant, or agent with pay for one week to enable the employee, contractor, consultant, or agent to resolve the issue or correct any identity issues with the government.

If the individual is determined to be eligible within the one-week suspension, the Bayer employee, contractor, consultant, or agent will be reinstated to their current position. If the individual is not reinstated during the one-week suspension period, the Bayer employee, contractor, consultant, or agent will be terminated or transferred to a position that does not involve responsibility for or involvement with Bayer business operations related to federal healthcare programs or a position for which the Bayer employee, contractor, consultant and agent's compensation or the items or services furnished, ordered, or prescribed by the Bayer employee, contractor, consultant or agent are not paid in whole or part, directly or indirectly, by federal healthcare programs or otherwise with federal funds.

// 3. Disciplinary Action

General Rule

Bayer takes seriously all violations of (1) applicable federal, state, or local laws or regulations, (2) applicable industry guidelines, and (3) the Compliance Program, Bayer Corporate Compliance Policy and its U.S.-specific supplement, and the Bayer U.S. Pharmaceuticals Compliance Policies and Procedures. Violations may result in disciplinary action up to and including termination of employment of any Bayer employee, contractor, consultant, or agent.

Disciplinary action may be taken against any Bayer employee, contractor, consultant, or agent who: (1) authorizes or participates in a violation of any federal, state or local law or regulation, industry guidelines or the Bayer U.S. Pharmaceuticals Compliance Policies and Procedures; (2) knowingly withholds relevant or material information concerning an actual or suspected compliance issue or other inappropriate activity; or (3) fails to cooperate with an investigation by Human Resources, the Vice President and Head, U.S. Office of Compliance (or designee), or the LPC Department.

Any Bayer employee, contractor, consultant, or agent who fails to report an actual or suspected compliance issue or other inappropriate activity brought to their attention may be subject to disciplinary action up to and including termination of employment.

Any proposed disciplinary action to be taken by Bayer in response to any such violation will be reviewed by an appropriate Sanction Committee (organized and conducted consistent with Management of Compliance Incidents policy and Bayer U.S. HR policies and processes), and any such discipline should be commensurate with the severity of the violation, as determined in Bayer's sole discretion. In the case of material violations of federal, state, or local laws or regulations, it may be necessary to refer the compliance matter to appropriate law enforcement officials.

Non-Retaliation

Bayer will not retaliate, or tolerate retaliation, against any Bayer employee, contractor, consultant, or agent for reporting in good faith any alleged compliance issue or other inappropriate activity involving applicable federal, state, or local laws and/or regulations, industry guidelines, the Bayer Code of Conduct or the Bayer U.S. Pharmaceuticals Compliance Policies and Procedures.

// 4. Interactions with HCPs and HCOs (Focus Arrangements)

When interacting with HCPs and HCOs, Bayer has established data collection methods for certain transactions and arrangements involving individuals or entities that may prescribe, purchase, supply, recommend, administer, or provide information about Bayer's drugs, biologics or devices. This Policy defines those interactions with HCPs and HCOs and outlines the policies and procedures Bayer U.S. Pharmaceuticals must follow when entering these interactions. The specific procedures that must be followed for each type of interaction (*e.g.,* Lunch and Learn, Advisory Boards, etc.) are incorporated into the individual procedures particular to that arrangement or interaction.

Definitions

Focus Arrangements – can also be referred to as interactions with an HCP or HCO - is how interactions with HCPs and HCOs are referred to in contracts and describes an interaction between Bayer and a healthcare provider (HCP) or healthcare organization (HCO) that involves a payment or Transfer of Value (ToV) in exchange for a service provided. For Compliance reporting purposes, an HCP is defined as a person who may prescribe, purchase, supply, recommend, administer or provide information about drugs, biologics or devices. In this context, this term has a broad application and includes, but is not limited to, physicians, nurses, midwives, technologists, pharmacists and others, all HCPs who hold a license in their field issued by the state or federal government. For further definition details, refer to this document's "Introduction" section.

Government Reimbursed Products – are all drugs, biologics, devices, and other items that are marketed, distributed, sold or promoted by Bayer or any Bayer Affiliate and reimbursed in whole or in part by federal healthcare programs.

Source of Sales or Referrals – are any distributor, wholesaler, supplier, physician, other HCPs, contractor, or agent. Referrals or sales include referring, recommending, arranging for, ordering, prescribing, or purchasing Government Reimbursed Products.

As a practical matter, it may be difficult for Bayer to determine whether a source of sales or referrals is an actual or potential source. For example, Bayer could enter into an agreement with a physician who currently does not recommend or prescribe Bayer products and thus would not be an actual source of referrals or sales. However, it is possible that tomorrow, that same physician will start prescribing Bayer products and thus become an actual source. For this reason, you should treat potential sources of sales or referrals as actual sources.

Third-Party Personnel – are personnel (*e.g.,* contracted sales organizations, CROs, etc.) of the entities with whom Bayer or any Bayer affiliate has or may in the future enter into agreements to co-promote a Government Reimbursed Product or engage in joint promotional activities relating to such product.

Examples of Focus Arrangements/Interactions with HCPs and HCOs

Below are some examples of Focus Arrangements/Interactions with HCPs and HCOs where the other party is an actual or potential source of referrals or sales of Government Reimbursed Products:

- Speaker agreements
- Consultant agreements
- Advisory board agreements
- Exhibit or display fees

- Clinical research or clinical trial grants
- Medical education grants
- Sponsorships
- Investigator sponsored studies
- Vendor credentialing/hospital registration fees paid directly to a customer (*e.g.,* hospital)

The above list is not all-inclusive, and activities not listed may still be considered a Focus Arrangement/Interaction with an HCP or HCO. If you have any questions about whether a potential activity or transaction may constitute an interaction with HCPs or HCOs that is a reportable interaction with a healthcare professional, you must consult the LPC Department.

Procedures for Focus Arrangements/Interactions with HCPs and HCOs

Bayer has established a written review and approval process for Focus Arrangements/Interactions of a contractual nature with HCPs and HCOs. If you are unsure whether a transaction, contract, program, or other activity constitutes a Focus Arrangement/Interaction with an HCP or an HCO, you must consult the LPC Department for assistance to ensure proper procedures are followed.

Specific procedures for each type of Focus Arrangement or interaction with HCPs and HCOs are found in the policy specific to that type of interaction (*e.g.,* policy on fee-for-service agreements). The first step in the review and approval process for all Focus Arrangements/Interactions with HCPs and HCOs is to comply with the Bayer policy specific to that individual interaction. The purpose of the following procedures is to help ensure that all interactions with HCPs and HCOs do not violate the Anti-Kickback Statute. For each contractual interaction with HCPs and HCOs, the following must be done:

- Agreement must be outlined in writing before any services are performed.
- Agreement must be signed by Bayer and the HCP/HCO party to the agreement before any services are performed.
- Agreement must include a certification by the parties to the Focus Arrangement/Interaction with HCPs and HCOs that the parties shall not violate the Anti-Kickback Statute with respect to the performance of the HCP or HCO.
- If the party to the Interaction with HCPs and HCOs (Focus Arrangement) is a person who is involved in, or an entity whose employees are involved in, Promotional and Product Services Related Functions, Bayer U.S. Pharmaceuticals must send each involved entity a copy of Bayer's Code of Conduct and with the applicable Anti-Kickback Statute Policies and Procedures attached. These attachments may be sent electronically and included as an exhibit to the contract or as separate documents.

Law, Patents and Compliance Review of Focus Arrangement/Interactions with HCPs and HCOs

The LPC Department evaluates whether each proposed interaction satisfies the requirements of the Anti-Kickback Statute and assesses compliance with relevant Safe Harbor(s). The designated reviewing LPC member is identified in CLMS as the person by whom the assessment was conducted. The designated member in LPC also confirms that the proposed payment (*e.g.,* speaker compensation or fees for a service) represents fair market value. Fair Market Value is based on an independent third-party provider who benchmarks industry standards. Any deviation from the fair market value methodology and the rationale for such deviation must be approved by the Vice President and Head, U.S. Office of Compliance (or designee) and documented and maintained in the LPC Department.

Proof of Service

The Requestor of the arrangement must be able to confirm that the services and/or items required to be provided pursuant to the interaction with the HCP or HCO were, in fact, provided. The form of the proof of service will differ depending on the type of interaction with the HCP or HCO (*e.g.,* speaker sign-in sheets, slide decks, timesheets, or exhibit booth attendance forms). The Requestor of the arrangement owner must retain proof of service in case of a future audit or review.

Payment for Focus Arrangement/Interactions with HCPs and HCOs

All fees and expenses associated with these interactions must be correctly linked with the contract for reporting purposes. The contract number assigned to each arrangement must be used when payment of fees and expenses is requested. Failure to associate such fees with the correct contract number violates this policy and can result in inaccurate reporting to the government.

Aggregate Spend Database

Bayer maintains an aggregate spend database tracking all interactions with Focus Arrangements (Interaction with HCPs and HCOs), which also ensures the interaction is reviewed and does not violate the Anti-Kickback Statute. In particular, the database:

- Allows Bayer to track remuneration to and from all parties associated with the interaction with an HCP or HCO; and
- Includes appropriate documentation of required internal controls.

The following information must be included in the database for each arrangement:

- Name of each party involved.
- Type of interaction (*e.g.,* medical education grant, clinical research agreement, fee for service).
- Compensation to be paid and any related expenses.
- Source system (*e.g.,* SAP, CyberGrants, VEEVA, FA Upload) from which Bayer compensation is paid (*e.g.,* check, product, periodic payments).
- Verification of payments made by Bayer.
- Itemized details of expense payments provided in conjunction with the contractual agreement (*e.g.,* lodging, air, ground, meals, and the city and state where the travel took place).
- Fair market value documentation.
- Bayer product associated with HCP/HCO interaction.
- The date of any deliverable or services that have been provided.
- Name and title of attorney who reviewed the Focus Arrangement and determined that it satisfies the requirements of an Anti-Kickback Statue and relevant Safe Harbor(s), the date(s) the review was made.

// 5. Interactions with Government Investigators

General Rule

Bayer may be contacted by or receive requests for information from various government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (including its Office of Inspector General (OIG)), the Federal Bureau of Investigation (FBI), local prosecutors 'offices, or other law enforcement or regulatory agencies. It is Bayer's policy to cooperate fully with federal, state, and local government officials or agents who conduct an inquiry, audit, or otherwise investigate Bayer. Bayer expects all employees, contractors, consultants, or agents (collectively, "Bayer Professionals") to extend the same cooperation within the guidelines of this Policy.

Reporting Government Inquiries or Audits

All Bayer Professionals must immediately report any notice of a government inquiry or audit with respect to Bayer-related activities to the LPC Department. Notice of a government inquiry may include but is not limited to (1) telephone calls or letters from government officials or agents to Bayer Professionals, (2) execution of search warrants, (3) on-site visits to or inspections of Bayer's premises by government officials or agents, or (4) visits by government officials to the homes of Bayer Professionals.

Steps Upon Contact by Government Investigator

In the event a Bayer Professional is contacted by a government investigator concerning Bayer-related activities, the Bayer Professional must first confirm that individual is, in fact, a government investigator by asking to see proper identification, such as a badge or a business card, from the government investigator before answering questions. The Bayer Professional should memorialize the government agent's name, agency, and, if present, any identification numbers.
If a government investigator attempts to contact or interview a Bayer Professional regarding Bayer-related activities, the Bayer Professional has the right:

- To decide whether or not to agree to an interview;
- To consult legal counsel – either their own or Bayer's counsel – before answering any questions;
- To have such counsel present during questioning by a government investigator; and
- To stop the government investigator's interview at any time.

In addition, if the government investigator's attempted contact regarding Bayer-related activities takes place at the Bayer Professional's home and/or any other location that is not on Bayer premises, the Bayer Professional has the right to request that an appointment be scheduled at a Bayer location during regular business hours or at an alternate time and place that is otherwise convenient.

If a Bayer Professional wishes to have Bayer counsel present during questioning by the government agency, please call LPC.

Guidelines for Government Interviews

If a Bayer Professional decides to be interviewed or to respond to questions from a government investigator regarding Bayer-related activities, the Bayer Professional must answer all questions completely, accurately, and truthfully. Bayer Professionals must not guess, speculate, or make up

answers to any of the government investigator's questions. If you do not know the answer to any question with certainty, it is appropriate to say that you do not know the answer.

Requests to Consult with an Attorney

If, at any time, the Bayer Professional feels uncomfortable or uncertain about whether to proceed with the interview or feels the need to consult with their own attorney or a Bayer attorney, the Bayer Professional may stop the interview or tell the investigator that they wish to consult with counsel. The Bayer Professional may also request that counsel – either Bayer counsel or their own attorney – be present during the interview.

After consultation with Bayer counsel, Bayer may recommend that the Bayer Professional retain qualified independent counsel. Under appropriate circumstances, Bayer will pay such counsel to represent the Bayer Professional.

Privileged and Confidential Information

If the Bayer Professional consents to an interview, the Bayer Professional must obtain specific authorization from the LPC Department before discussing the company's privileged and confidential information. The Bayer Professional must refuse to discuss any communications they may have had, or of which they may be aware, that included the LPC Department or Bayer's outside legal counsel. If the Bayer Professional does not know whether the information they are being asked to discuss is privileged, the Bayer Professional must consult with the LPC Department to determine whether that information is privileged to ensure that no unauthorized disclosures of privileged information are made.

Corporate Documents

Bayer Professionals must contact the LPC Department if asked for Bayer documents by a government investigator or anyone outside the company. Bayer documents include all documents, whether in paper format or electronically stored, that are held or created in connection with your employment at Bayer and/or operation of Bayer's businesses. For example, Bayer documents may include but are not limited to (1) files, (2) notes, (3) memoranda, (4) e-mails, (5) correspondence, (6) reports, (7) sales information, (8) marketing information, (9) financial information, (10) project plans, (11) design documentation and (12) TEAMS messaging. Likewise, company-issued computers, cell phones, and tablets are Bayer property subject to this policy.

Further to the point discussed above, Bayer Professionals must not provide privileged Bayer documents to the government or anyone outside the company without specific authorization from the LPC Department. Privileged documents include, but are not limited to, any documents involving the LPC Department or Bayer's outside legal counsel. If the Bayer Professional does not know whether the documents being requested are privileged, the Bayer Professional must consult with the LPC Department to determine whether that information is privileged. This will ensure that no unauthorized disclosures of privileged Bayer documents are made.

Signing Documents

During an interview, a Bayer Professional may be asked to sign an affidavit or sign or initial another legal document as the company's representative. Bayer does not authorize any Bayer Professionals to sign or initial any such documents or statements as a Bayer employee, contractor, consultant, or agent unless expressly authorized by the LPC Department. If a Bayer Professional is asked to sign or

initial a document as the company's representative, the Bayer Professional must decline to sign and tell the government investigator that Bayer's policy prohibits them from signing or initialling the document.

// 6. False Claim Act

The Federal Civil False Claims Act (FCA) (31 U.S.C. §3729, et seq.) imposes fines and penalties on individuals and entities that file, or cause others to file, false or fraudulent claims for payment or approval from Medicare, Medicaid, or other federal healthcare programs or that knowingly conceal or knowingly and improperly avoid or decrease an obligation to pay money, such as Medicaid drug rebates, to the government. Violators of the FCA are liable for damages up to three times the amount the Government is defrauded, plus a range of penalties (which depend on the date of each false claim submitted). As of January 30, 2023, the range is $13,508 to $27,018 per claim. Sales and marketing activities that might violate the FCA include, but are not limited to:

- Submitting or facilitating the submission of claims for reimbursement for services not performed or items not delivered;
- Failing to report and return an overpayment of federal healthcare program funds (*e.g.,* Medicare or Medicaid funds) to a government agency or contractor within 60 days after the date the overpayment is identified or the date any corresponding cost report is due, if applicable; and
- Knowingly reporting false or fraudulent pricing information to a government agency.

The FCA and some state false claims acts include provisions under which individual citizens with evidence of fraud against the government may sue on behalf of the government to recover the lost funds (*a.k.a.* whistleblower suits). These laws also prohibit retaliation against persons who file such lawsuits.

The Federal Deficit Reduction Act of 2005 (DRA) requires healthcare entities that receive $5 million or more annually in Medicaid reimbursement to establish written policies to prevent false claims and to provide detailed information about the FCA to employees, contractors, consultants, and agents. As a result, many of Bayer's customers may submit information to Bayer on their policies and procedures related to the FCA. Please direct all such submissions to the Vice President and Head, U.S. Office of Compliance.

Bayer has established comprehensive policies and procedures to prevent, detect, and correct violations of law and company policy. Bayer employees, contractors, consultants, and agents must report actual or potential violations of law or company policy. There are several mechanisms to report such issues. First, you may report compliance issues to your supervisor. Second, you may contact anyone in the LPC Department. Third, you may file an anonymous report via the confidential disclosure process using the Bayer Compliance Hotline, at 1-888-765-3846 or www.bayer.us/speakup.

// 7. Vendor Credentialing

This policy describes the process for complying with vendor credentialing requirements. Many customers, such as hospitals, require manufacturing representatives to undergo a credentialing process before obtaining access to a facility and paying a registration fee. Following registration, the institution may appropriately require representatives to check in and obtain a badge for each sales call. Bayer representatives must follow all institutional access policies pertaining to restricted areas and restrictions involving meals and educational items.

Bayer representatives must not sign any documents (hard copy or electronic) or make any representations on behalf of Bayer without prior written approval from the LPC Department.

Scope

This policy is designed to allow compliance with credentialing requirements imposed by hospitals and other healthcare facilities. Bayer is committed to protecting employees' privacy and personal information. This process is administered through a third-party vendor who will guide the Bayer representatives. In addition, upon hire, all Sales Consultants will be assigned, via the LMS, an informative video outlining the vendor credentialing process. For additional guidance or if you have any questions, you can contact the Bayer Credentialing Office at support@credentials.Bayer.com or 1-855-221-2219.

As a condition of employment, all field sales employees are required to comply with registration requirements imposed by their accounts to the extent those requirements comply with Bayer policies. Failure to do so may result in discipline, up to and including termination.

Registration Fees Paid to Non-Customers

Registration fees paid to non-customers are permitted only under the following circumstances:

- Registration fees must be reasonable and not exceed $500 for an Individual Registration (valid for a single representative). Should you be presented with fees exceeding these amounts, you must contact the LPC Department before paying any fee.
- Registration fees must be paid directly to a third-party vendor (*e.g.,* Vendormate, Reptrax, VendorClear) that manages vendor access programs for the hospital or healthcare entity.
- Fees may only be paid to vendors representing customers to which Bayer sales consultants have a legitimate need for access.

Registration Fees Paid to Customers

In the rare instance where registration fees are paid directly to a customer (*e.g.,* a hospital), the payment of fees constitutes an Interaction with HCOs because the hospital or healthcare entity is a source of referrals or sales of Bayer's pharmaceutical products. Under no circumstances may registration fees be paid directly or indirectly to a physician's practice or paid to obtain access to a physician's private practice group. Questions regarding whether the payment of registration fees constitutes an Interaction with HCOs must be directed to the LPC Department.

Timely and Accurately Reporting Registration Fees

It is each employee's, contractor's, consultant's, and agent's responsibility to report accurate, complete, and timely data regarding registration fee payments. The Physician Payments Sunshine

Act, which is part of the Patient Protection and Affordable Care Act, requires that any transfer of value given to an HCP, teaching hospital and/or all employees of a teaching hospital be reported to the Centers for Medicare & Medicaid Services (CMS). This includes registration fee payments. Bayer reports the payment data received from its employees, contractors, consultants, and agents to CMS, so timely submission and accuracy of that data is essential.

Law, Patents and Compliance Review of Interactions with HCPs and HCOs

The LPC designee generates an agreement that meets the requirements for Interactions with HCPs and HCOs, or if a contract is provided, reviews the contract to ensure that it meets those same requirements. The agreement must be signed by both parties to the arrangement (*e.g.,* Bayer and the customer) and must contain a certification by the parties that the parties shall not violate the Anti-Kickback Statute for the performance of activities related to the interaction with HCPs and HCOs.

The LPC Department evaluates whether each proposed interaction satisfies the requirements of the Anti-Kickback Statute and assesses compliance with relevant Safe Harbor(s). The designated reviewing LPC member is identified in CLMS as the person for whom this assessment was conducted, as well as their name and the date it was conducted. The designated member in LPC also confirms that the proposed payment (*e.g.,* speaker compensation or fees for a service) represents fair market value. Fair Market Value is based on an independent third-party provider who benchmarks industry standards. Any deviation from the fair market value methodology and the rationale for such deviation must be approved by the Vice President and Head, U.S. Office of Compliance (or designee) and documented and maintained in the LPC Department.

The contracted party to the Interactions with HCPs and HCOs will receive a copy of the approved contract and a copy of (1) Bayer's Code of Conduct and (2) applicable Anti-Kickback Policies and Procedures.

// 8. Prescriber Data

Some physicians do not wish to be contacted by third parties that would otherwise have access to a physician's prescribing data through a Health Information Organization (HIO) licensing arrangement. Physicians who do not wish to receive marketing communications from pharmaceutical companies or other third parties can opt out of the American Medical Association's (AMA) Physician Data Restriction Program (PDMA) by making a "no contact" request to the AMA, thereby restricting third-party access to their prescribing data except in the case of important drug safety and related notifications such as drug recalls. The AMA also provides a mechanism by which physicians may report specific instances of inappropriate behavior by pharmaceutical sales consultants or others. Any prescriber wishing to opt out of the AMA PDRP may do so on the PDRP resource page. Pharmaceutical companies must review the PDRP opt-out list at least quarterly and have 90 days to comply with each new request.

State Laws

The LPC Department tracks federal and state legislation regarding the use of prescriber data. HIOs also regularly monitor legislation relating to the license and use of prescriber data.

A few states have passed laws restricting the use of prescriber data for commercial purposes. Many other states have introduced bills with similar provisions. For those states that have imposed limitations, Bayer has added PDRP opt-out flags to the relevant physician profiles per the process described below.

PhRMA Code

The PhRMA Code encourages pharmaceutical companies to (a) respect the confidential nature of prescriber data, (b) develop policies regarding the use of prescriber data, (c) educate employees and agents about those policies, (d) maintain an internal contact person to handle inquiries about the use of the data, and (e) identify appropriate disciplinary actions for the misuse of data. This policy and the processes noted herein are consistent with the PhRMA Code.

Bayer's System Process for PDRP Opt-Out Flags

Bayer obtains monthly HIO prescriber data update files, including the AMA PDRP opt-out flags. The updates are processed as follows:

- Monthly, the HIO data, including any PDRP opt-out flags related to specific physician profiles, is loaded into:
    - The Bayer Enterprise Data Warehouse (EDW); and
    - Veeva.
- Additional PDRP opt-out flags based on state laws and Bayer-specific opt-out requests are added to the EDW and Veeva systems as necessary.

Violations and Sanctions

Employees, contractors, consultants, and agents misusing prescriber data are subject to disciplinary action up to and including termination of employment.

// 9. Special Requirements for Federal Government Employees

The federal laws and regulations governing items of value, including meals and educational items, provided to federal government employees, including part-time federal government employees, are much stricter than the laws and regulations for non-government healthcare professionals. This Policy and Procedure will help you avoid any conduct that appears improper when conducting business with federal government employees.

Who Qualifies as a Government Employee

Federal government employees include anyone (military or civilian) who is employed by a facility associated with the Department of Defense (***e.g.,*** military or "DoD"), the Department of Veterans Affairs ("VA"), Federal Public Health Service ("PHS"), the Indian Health Service ("IHS"), National Institutes of Health ("NIH"), or other federal government entities.

According to federal law, a government employee includes part-time employees of the government and part-time workers at a government facility.

For example, the following are considered government employees:

- A resident who is doing a rotation at the VA.
- A physician who works part-time at the VA and part-time at a civilian institution (the amount of time spent at the VA hospital is irrelevant).
- A patient advocate employed by the DOD and provides speaker services.

Note: You may not avoid the restrictions in this policy by providing educational items or business meals to a government employee at a civilian location. For example, if a physician works at Johns Hopkins and the Baltimore VA, that physician is still considered a government employee when they are physically located at Johns Hopkins.

The following is NOT considered a government employee:

- An individual who works at a civilian facility has a contract with the government to treat government beneficiaries (*e.g.,* a civilian physician at a TRICARE facility).

General Rule

You may not offer or provide anything of value, regardless of the amount, to a federal government employee to influence them to prescribe, purchase, order, refer, use or recommend any Bayer pharmaceutical product(s) or to encourage that employee to take, or not take, any action in their official capacity (***e.g.,*** signing a contract, agreeing to purchase Bayer pharmaceutical products, agreeing to put Bayer products on formulary, etc.). Before providing any item of value to a healthcare professional, you must determine whether they are a federal government employee. Generally, you may not do indirectly what is prohibited when performed directly. For example, you may not hire third-party vendors to perform services that would otherwise violate this policy if you performed them yourself.

Prohibition of Educational Items and Business Meals

Federal law prohibits contractors such as Bayer from providing educational items or business meals to federal government employees exceeding $20 per government employee per event or a total of

$50 per government employee in a calendar year. This federal regulation is often referred to as the "20/50 Rule." These limits apply to the entire Bayer organization (all divisions and subsidiaries), not an individual sales consultant.

To ensure Bayer complies with this law, Bayer (only the sales representative that calls on the DOD account) may provide a meal (lunch) to the DOD clinic once per calendar year with a $15 per person cap. Meals associated with a fee-for-service arrangement (see section "Fee for Service Arrangements") are also allowed. All other government agencies and/or employees are prohibited from receiving meals from Bayer employees. Regardless of dollar value, educational items (*e.g.,* textbooks, anatomical models) to federal government employees are prohibited.

Product samples are not considered "educational items" and may be provided to federal employees if permitted by the government entity and under these Compliance Policies and Procedures. You must check with the relevant authority at the government entity regarding their position on samples and product provided for evaluation before giving such items.

Limited Exceptions - Widely Attended Gatherings

Executive Branch employees, other than presidential appointees, are permitted by federal law to attend certain group events, referred to as "widely attended gatherings," sponsored by contractors such as Bayer, even if the cost of attendance at these events exceeds the 20/50 Rule. When it has been determined that the government employee's attendance is in the agency's interest because it will further agency programs and operations, Bayer may offer free attendance to the government employee. Still, the offer may not include travel expenses, lodging, entertainment collateral to the event, or meals taken other than in a group setting with all other attendees. Widely attended gatherings include events sponsored by industry associations open to government and civilian officials (e.g., AMA conference, ASCO). For the Bayer-sponsored event to be considered a "widely attended gathering," the event must be open to all conference or convention attendees (e.g., a Bayer-sponsored keynote address at the annual AMA convention). Note that the sponsored event/meal itself, not just the conference, must be open to all attendees. Thus, you may not invite government employees to attend a Bayer-sponsored limited target audience event (e.g., dinner at a "Bayer table" at ASCO) or invite individual government physicians to dinner at an AMA conference or similar event. Bayer may offer to such government officials' free attendance at widely attended gatherings that Bayer does not sponsor if (i) more than 100 persons are expected to attend the event and (ii) the gift of free attendance has a market value of $375 or less.

Fee-for-Service Arrangements

Special rules and limitations apply to fee-for-service arrangements with federal government employees. Prior to any discussions regarding speaker services, consultant, or any other fee-for-service arrangement with a federal government employee, you must contact the LPC representative (if you are interested in contracting with a federal government employee). Please refer to the "Fee-for Service Arrangements" Policy for further details.

Modest business meals may be provided to a federal government employee if there is a fee-for-service arrangement (consultant or speaker) with the federal employee and the meal is provided in connection with the fee-for-service arrangement (*e.g.,* meal at an investigator meeting, meal at a speaker event). Because this exception is limited, you must consult your supervisor or the LPC department before providing a meal to any federal employee.

Grants for Government Employees to Speak at or Attend Medical Education and Training Events

Federal law requires that entities such as Bayer follow appropriate procedures in paying for expenses in connection with official travel for education and training activities for federal government employees. This Policy is designed to protect Bayer and its employees from criminal and civil penalties resulting from providing improper items to government employees.

Grants to support government speakers may only be provided to bona-fide third-party organizations (such as the Jackson Foundation, True Foundation, Geneva Foundation, or similar organization) established to accept and disseminate grant funds on behalf of federal entities, including the DOD and VA. Bayer may provide funds to these organizations for educational purposes, such as sponsoring a government official to speak at or attend a medical conference, only if the third-party organization, not Bayer, determines how the funds are allocated. The provision of funds must be consistent with the third-party organization's charter or authority.

All grant requests for funding Government speakers and Government attendance at medical education and training events must follow the process described in Policy and Procedure, "Medical Education Grants (Including Continuing Medical Education)."

// 10. Business Meals with Healthcare Professionals

The Physician Payments Sunshine Act, which is part of the Patient Protection and Affordable Care Act, requires that any transfer of value given to an HCP, teaching hospital and/or all employees of a teaching hospital must be reported to the Centers for Medicare & Medicaid Services (CMS). Employees, contractors, consultants, and agents are responsible to report accurate, complete, and timely data to applicable Bayer systems, as this is the data Bayer will report to CMS.

Scope

Bayer policies for business meals conform to the most recent PhRMA Code, the AdvaMed Code of Ethics, as well as guidance from HHS-OIG. The policy covers interactions with all healthcare professionals who may purchase, prescribe, order, refer, use or arrange for a purchase of Bayer's pharmaceutical products.

Bayer has additional corporate policies regarding business meals and other business interactions that fall outside this policy and do not cover healthcare professionals specifically: Corporate Policies.

Healthcare Professionals (HCP) is a very broad term and includes individuals who directly interact with patients and/or have a role in diagnosing or treating patients. This includes individuals who work for entities that provide healthcare services and/or items to patients. These individuals may purchase, lease, recommend, give information on, use, arrange for the purchase or lease of, or prescribe Bayer's pharmaceutical, biologics or device products in the U.S. Generally, this definition includes physicians, nurses, nurse practitioners, physician assistants, and medical assistants. In addition, those closely connected to the patient experience, such as pharmacists, radiology technologists, and therapists, also fit into Bayer's definition of an HCP. However, this definition is not limited to these individuals alone; the term includes any person, whether licensed or not, who is in a position to recommend, influence, or provide information about the purchasing or prescribing of Bayer's pharmaceutical, biologics, or device products. In some instances, this may include individuals who do not work directly with patients but have influence over or provide information about the recommendation, purchase or prescribing of Bayer's pharmaceutical products, such as billing or office managers, agents at hospitals, physician practice managers, management personnel within group purchasing organizations (GPOs), managed care organizations (MCOs), pharmacy benefit managers (PBMs), Specialty Pharmacies (SPs), health plan administrators, wholesalers, distributors, pharmacies, Pharmacy & Therapeutics Committee members, Formulary Committee members, or other customers who do not see patients. In addition, some positions and titles within the industry are not considered healthcare professionals, such as Original Equipment Manufacturers (OEMs), retail managers or back-office staff. Accordingly, such persons are not considered HCPs under Bayer's policy.

Bayer's HCP definition differs from a "covered recipient" used for reporting purposes under the Sunshine Act. As a reminder, as of January 2023, HCPs with the following credentials are reportable under the federal Sunshine Law: APRN, CNM, CNS, DO, MD, NP, and PA and must always be documented as an HCP, including capturing their license number, regardless of the state where they practice or where you interact with them. In addition, specific states require reporting interactions with certain, locally defined HCP credentials (*e.g.,* RNs, LPNs, pharmacists). The chart below lists HCP credentials for whom payments and exchanges of goods or services, otherwise referred to as "transfers of value" (ToVs), are reportable.

Reportable Healthcare Professional Credentials by State

Healthcare Professional	Credential	Connecticut	Massachusetts	Minnesota	Nevada	Washington, DC
Registered Nurse	RN				✓	✓
Licensed Practical Nurse	LPN		✓		✓	✓
Pharmacist	PHAR	✓	✓	✓	✓	✓
Registered Pharmacist	RPh	✓	✓	✓	✓	✓
Doctor of Pharmacy	PharmD	✓	✓	✓	✓	✓

When conducting an event that includes an HCP attendee with a credential in one of these identified states, you must record this as an HCP and include the state license information; otherwise, the attendee should be recorded as a Business Guest.

General Rule

Meals may be provided (where such offices/organizations will allow such meals to be delivered and offered) to healthcare professionals if they are: (1) incidental to a bona fide presentation or discussion of Bayer's pharmaceutical products, disease states relevant to products, or other legitimate business discussions related to Bayer's pharmaceutical products; (2) occasional; (3) modest; (4) take place in a setting conducive to such discussion; and (5) involve only individuals who are necessary for the conduct of Bayer business.

Consistent with the PhRMA Code, incidental meals can be provided only where there is a reasonable expectation and reasonable steps are taken to confirm that each attendee has a substantive interaction or discussion with the company representative. Therefore, for meals with large groups of appropriate attendees (*e.g.,* more than 25 appropriate attendees present), we ask that you take particular care to ensure that you comply with this provision. Offering 'grab-and-go' meals is not appropriate. The number of meals ordered and distributed to the office are for those HCPs, licensed and non-licensed, that are planned for and necessary for the educational discussion.

Providing a healthcare professional with a meal solely for "relationship building" is unacceptable. Further, it is inappropriate for Bayer employees, contractors, consultants and agents to pay for or reimburse healthcare professionals for personal meals. Offering meals in any location without a Bayer representative present (virtual or face-to-face) or providing "take-out" meals is not allowed. Even though attending virtually, the Bayer representative must ensure all requirements of this policy are met and that the Bayer representative orders the food, has it delivered, and pays over the phone with their Bayer credit card. Virtual meals require all attendees to be on camera.

All Bayer employees, contractors, consultants and agents must exercise sound judgment and discretion when providing modest food or beverages to HCPs in conjunction with product promotion or disease state education. The central focus must be the product education or disease state education provided, with the meal being incidental to that primary purpose. Consistent with the

PhRMA Code, providing alcoholic beverages in connection with an in-office or in-hospital meal, or at speaker program, is prohibited.

Setting for Business Meals

All business meals must be provided in a setting (private area within a hospital, medical office, or restaurant where others outside the discussion cannot reasonably hear or view the Bayer information, either virtual or face-to-face) that is conducive to an educational product discussion and/or other legitimate business discussion related to Bayer's pharmaceutical products.

Drug field sales representatives and immediate managers (including AGMs): According to Bayer policy and the PhRMA Code, **out-of-office meals with HCPs are prohibited for pharmaceutical drug field sales representatives (including Radiology KAMs) and immediate managers (including AGMs).** Instead, they can provide business meals only in the healthcare professional's office or in the hospital (face-to-face or virtually) during their regular working hours. Appropriate places within a hospital include the cafeteria or a coffee shop located within the hospital facility.

Device field sales representatives (e.g., Radiology Portfolio reps) and immediate managers are not restricted to in-office or in-hospital meals. While it is preferred that such meals take place in the clinic or hospital, if circumstances require (*e.g.,* meetings can only occur outside of regular business hours), they may take place in a local restaurant. In all cases, the other principles of this Policy apply to all representatives and their managers (*e.g.,* venues and meals must be modest and conducive to bona fide scientific, educational, or business discussions).

All Other Bayer employees as not defined above, may provide business meals only in a venue that is conducive to the educational or product discussion. All business meals must be "modest" as judged by local standards.

Frequency of Business Meals

Consistent with PhRMA and AdvaMed Codes and OIG guidelines, business meals may be provided on an "occasional" basis. For in-office meals, Bayer's policy is that "occasional" should generally mean no more than eighteen (18) meals to any individual healthcare professional, including licensed and non-licensed HCPs, as defined by Bayer's definition during the calendar year. Furthermore, the PhRMA Code states that such incidental meals in connection with an educational presentation can only be provided to appropriate attendees and where there is "a reasonable expectation and reasonable steps are taken to confirm, that each attendee has a substantive interaction or discussion with the company representative." Therefore, for meals with large groups of appropriate attendees (*e.g.,* more than 25 appropriate attendees present), we ask that you take particular care to ensure that you comply with this provision.

For Speaker Programs, a healthcare professional can attend one program per topic per year with a meal and up to 3 programs if all are virtual with no meal.

Spending Limits

Business meals must be "modest" in cost as judged by local standards. A modest business meal for an in-office or in-hospital meal typically should consist of sandwiches, pizza, snacks, or soft beverages and must cost no more than $35 per person (including tax, gratuity, delivery charges and any paper products or supplies needed for the meal). An independently run restaurant within a hospital is considered an in-office meal and thus may be used by a field sales consultant and/or

their immediate manager as a meal setting. A modest business meal must cost no more than $150 per person when provided outside of an office environment (*e.g.,* restaurant, hotel, conference center). Any food or drinks Bayer personnel provide to healthcare professionals before and/or after a business meal must be included in the $150 per person limitation. The limit includes food, beverages, tax, gratuity, and delivery charges.

For in-office or in-hospital meals, meals must be provided only for the healthcare professionals who are the audience for the product promotion or disease state education (*e.g.,* if there are four healthcare professionals, whether they are licensed or non-licensed, the maximum number of meals ordered is four and not to exceed $140 total including tax, gratuity, and delivery). If there is any food that remains after the in-office or in-hospital educational discussion with the healthcare professionals, it may be made available to the remainder of the office staff (*e.g.,* staff not part of the Bayer business discussion).

It is important to remember that the government may view business meals provided too frequently or too expensive as an improper inducement to purchase or recommend the purchase of Bayer pharmaceutical products.

State Spending Limits

Some states have laws regarding providing business meals and other promotional activities that are more restrictive than Bayer's general policy. Certain states have "meal bans" or an "annual dollar cap" in which HCPs licensed in these states cannot consume a meal paid for by Bayer, no matter what location the meal takes place in. It is important to know the state of licensure for the HCPs to whom Bayer is providing meals. Please refer to the Policy and Procedure section on "State Laws" prior to providing any item of value to those healthcare professionals.

Retail Value – Amount to be Recorded

The retail value of a meal, not the amount you or Bayer paid for it, determines whether the meal is modest and within the guideline dollar limits in this policy. When providing business meals, you or Bayer may take advantage of discounts (*e.g.,* discount coupons, 2-for-1 specials), such that the retail value of a meal may be higher than what you or Bayer actually paid for it. When listing the value of any meal, you must list its retail value and the amount you or Bayer paid for it if the amounts differ. Retail value must also be used to determine if the cumulative value of educational items or meals is appropriate.

Special Requirements for Federal Government Employees

Federal laws restrict business meals provided to federal government employees (*e.g.,* Department of Defense (DOD) and Department of Veterans Affairs). To ensure that Bayer does not violate these laws, Bayer employees, contractors, consultants and agents may not provide any business meals or food/drinks (except for meals provided under a contracted fee-for-service arrangement or the once-per-year meal to DOD facilities) to federal government employees. For more information on this policy, including who constitutes a federal government employee, consult Policy and Procedure, "Special Requirements for Government Employees," in these policies.

Other Limits

No Spouses or Guests – Business meals are for legitimate business purposes only, so spouses or other guests may not be included.

No Entertainment – You may not provide entertainment, nor must the meal be secondary to, or a part of, an entertainment or recreational event, even if you include an informational presentation as part of the event.

No Cash or Cash Equivalents – You may never give a healthcare professional cash or cash equivalents (*e.g.,* checks, gift cards/certificates, reward points, vouchers, your credit card, etc.) to purchase a meal. Under no circumstances can this Policy be circumvented by using the employee, contractor, consultant, or agent's own cash or personal credit card.

Additional Guidance

- It is inappropriate to pay or reimburse a healthcare professional for personal meals.
- Bayer **may only pay** for meals for healthcare professionals who actually have a substantive interaction or discussion with a Bayer representative for whom Bayer is legitimately sponsoring a meal under this Policy.
- Meals are only provided to individuals who need training/education or a business discussion. Leftovers (food remaining from meals of those HCPs who attended the education) may be provided to office staff at the end of the meal.
- It is inappropriate to pay for a meal where the Bayer representative is not present (virtual or face-to-face) while the meal is consumed.
- An attendee can refuse a meal. Bayer will still need to capture the attendees on the sign-in sheet, whether they ate or not, to calculate the meal cost for the remaining attendees accurately. The attendee must complete the sign-in sheet and check the meal refused box. In Concur, those who refuse a meal should be reported as "no-shows."

Examples

The following are examples of **appropriate business meals** for sales representatives and their immediate managers:

- Providing breakfast sandwiches, coffee, and juice to a physician's office for an educational presentation on the approved uses of a Bayer pharmaceutical product.
- Providing a physician with a meal in the hospital cafeteria to discuss a newly approved indication for a Bayer pharmaceutical product.

The following are examples of meals that are **NOT appropriate for sales representatives and their immediate managers:**

- Taking a cardiologist to a modest restaurant around the corner from their office for a meal to discuss the use of Bayer pharmaceutical product (a restaurant is not an appropriate venue, limited to in-office meals only).
- Catering a meal from a 5-star restaurant to a physician's office or hospital for a product discussion on Bayer pharmaceutical product (too expensive to be modest).

The following are examples of meals that are **NOT appropriate for any Bayer representative:**

- Providing a meal to an HCP with whom you did not have, or did not reasonably expect to have, a substantive business discussion.
- Meeting a physician at a "take-out" restaurant and discussing Bayer pharmaceutical products

while waiting for the food (venue/location not conducive to an educational discussion; no Bayer representative present when the meal is consumed).
- Giving your credit card to a healthcare professional or their office staff and telling them to "buy a meal" or make some other purchase (credit card provided in this manner is a "cash equivalent;" no Bayer employee present; no educational presentation).
- Inviting a group of residents to a baseball game where there is a substantive presentation on kidney cancer before the start of the game (entertainment is not permitted).
- Taking a nurse practitioner and spouse to a restaurant dinner with your spouse (including a spouse or guest is inappropriate).
- Providing a meal for a physician's practice or hospital physicians group (journal club) and waiting outside of the meeting room while the meal is consumed (no Bayer employee present when the meal is consumed).

Procedure

Before providing a business meal, ask yourself:

- Will there be a product or scientific discussion and/or a bona fide business and/or educational purpose?
- Is the location of the meal conducive to an educational discussion and for sales representatives and their immediate managers, is the setting either in the healthcare professional's office or an appropriate hospital venue?
- Is the amount and meal choice modest?
- Is a Bayer representative present (virtual or face-to-face) when the meal is consumed?
- Is the frequency of meals provided to this healthcare professional occasional (it is Bayer's policy that "occasional" generally means no more than 18 meals per healthcare professional within a calendar year), and is the total value of meals modest?
- Am I reasonably certain that each participant in the meal is not a federal government employee?
- Am I reasonably certain that each participant in the meal does not practice in a state with special restrictions or reporting requirements?
- Am I reasonably certain that each participant is relevant and required for the educational discussion and that I will have or reasonably expect to have such a discussion?

The answers to all questions must be "yes" for the business meal to be appropriate.

Meals at Speaker Programs, Speaker Training, Consultant/Advisory Board Meetings

Business meals provided in the context of company-sponsored and controlled educational meetings, speaker training and/or consultant/advisory boards must also be modest as judged by local standards and may not exceed $150 (including food, beverage, tax, and gratuity) per person. Company-sponsored Speaker programs held at a customer site instead of an outside venue due to convenience for the HCPs are limited to $75, all-inclusive of food, beverages, tax, gratuity and delivery charges. Consistent with changes to the PhRMA Code effective January 1, 2022, alcohol cannot be purchased or provided by Bayer at Speaker Programs. Likewise, Bayer employees must not order or consume alcohol at Speaker Programs. Those HCPs who choose to purchase their own alcohol must do so outside the program room. There will be no order or service of alcohol in the Speaker program room.

Speaker Program venues are to be selected by the Bayer Speaker Bureau vendor to ensure that the venue has areas conducive to such a program and that the meal cost does not exceed $150.

Documentation of Business Meals with Healthcare Professionals

Business meals with healthcare professionals, including non-licensed HCPs (business guest), must be recorded through your T&E Expense Report ("T&E") in Concur in the Healthcare Professional Expense, HCP Business meals category and attendee type "Healthcare Professional" (Licensed HCP) or "Business Guest (Non-licensed HCP)." All employees must document the details of business expenses according to IRS rules, Compliance Policies and Procedures, and the Travel and Expense Procedure. An accurate description of what product you are discussing and the purpose for the visit to the HCP's office must be documented. Instructions on how to complete your Travel and Expense Report when providing a business meal to healthcare professionals can be found on the Lunch & Learns resource page.

Understanding how to set up an HCP Business Meal in Concur

Start by adequately distinguishing between a healthcare professional and a business guest.

Who is a healthcare professional for the purposes of Concur?

A healthcare professional (HCP) is anyone who requires a license and is subject to federal or state reporting. This may be an individual with a license to prescribe or who is involved in the provision of healthcare services or products to patients. For federal reporting purposes, these licenses are: APRN, CNM, CNS, DO, MD, DO, NP, and PA. In certain states, the following licenses are also included: RN, LPN, RPh, PHAR, PharmD.

Who is a business guest?

A business guest is anyone who is included within Bayer's definition of HCP but is either not licensed or is licensed and is not reportable. Accordingly, business guests include but are not limited to:

- Executives or staff of a healthcare entity
- Employees of a Hospital
- Employees of a Group Practice Organization (GPO)
- Distributors
- Mail Order Companies
- Medical Office Assistants
- Lab or Pharmacy Technicians
- Technologists
- Purchasing Agents
- Interns

Reporting in Concur

If a licensed reportable HCP has attended and consumed the meal, they must be documented in Concur, in the Healthcare Professional Expense, HCP Business meals category with the attendee type "healthcare professional," not "business guest." Failure to properly categorize attendees under the appropriate attendee type in Concur leads to inaccurate government reporting.

All business meals where healthcare professionals (licensed and non-licensed) are in attendance, whether in or out-of-office, regardless of amount, require an itemized (detailed) receipt and completed sign-in sheet that documents each individual's attendance and meal consumption. These two requirements supersede the Corporate T&E Procedure. If the Bayer employee pays for the meal on their Bayer credit card and will expense the meal through the Concur system, the sign-in sheet and itemized receipt must be attached to the T&E report.

Ensure you have a three-way match: the total number of anticipated attendees for which meals were purchased matches the number of attendees captured on the sign-in sheet and the number of attendees submitted in Concur.

Meals paid on behalf of Bayer through a third-party vendor also require sign-in sheets (*e.g.,* speaker training, advisory boards, investigator meetings, speaker programs, etc.). Sign-in sheets used at third-party meals (such as speaker programs or advisory boards) must be submitted following the Policy and Procedure "Focus Arrangements/Interactions with HCPs and HCOs." The Bayer employee hosting (on site or virtual) at the event is responsible for ensuring the sign-in sheet is completed accurately and legibly and submitted promptly. While a third-party vendor assists with the logistics at the event, only the Bayer employee should handle and remain responsible for the accurate and timely completion of the sign-in sheet.

The sign-in sheet must be printed from your Bayer laptop or another Windows-based computer. Printing from an iPad or any other Apple or Android device will not generate the correct date and time stamp. If you are traveling and unable to print your sign-in sheets the day of your event, you may print out the number of sign-in sheets you will need for your events in advance. Make sure that the auto-generated date and time stamp is within 30 days of the actual event date.

The failure to submit for reimbursement for the business meal by paying with personal funds does not circumvent the business meal policy.

The sign-in sheet must have the following information:

General

- Event date.
- Event location (in-office or out-of-office).
- Event type (education session, speaker program, patient program, ad board, speaker training, etc.).
- Program/Event number (if applicable).
- Event host (Bayer employee).
- Bayer Product discussed.
- Signatures of all Bayer employees in attendance, including event host.
- Speaker name (if applicable) printed and signature.
- Contract number (if applicable).
- Name and address of venue.
- Number of attendees who consumed the meal.
- Number of no-shows.
- Number of licensed HCPs and non-licensed HCPs (business guests), including Bayer employees, as a total number of attendees. Double-check the attendees' meal opt-ins/opt-outs, which impacts the cost-per-attendee.

Per Individual HCP

- Printed name.
- Title (credentials).
- Full address (address, city, state, zip).
- HCP license number (if applicable).
- State of license (if applicable).

- Signature. Signatures of all reportable licensed attendees are required. Bayer employees should pre-populate information about meeting attendees, but reportable licensed attendees must personally provide their signature on the sign-in sheet. Each reportable licensed HCP must sign for themselves. If you are unable to obtain a signature, please indicate the reason on the sign-in sheet.

Please find the links to the In-Office and Out-of-Office sign-in sheets and instructional guide on the Lunch & Learns resource page.

// 11. Educational Items for Healthcare Professionals

The Physician Payments Sunshine Act requires that any transfer of value given to an HCP, teaching hospital and/or all employees of a teaching hospital must be reported to the Centers for Medicare & Medicaid Services (CMS). Employees, contractors, consultants, and agents are responsible for reporting accurate, complete, and timely data to applicable Bayer systems, as this is the data Bayer will report to CMS.

Bayer representatives may provide educational items that are modest and designed primarily for the education of patients and healthcare professionals (HCPs). Any other items are prohibited, including practice-related and logo "reminder" items. Bayer policy prohibits employees, contractors, consultants, and agents from offering anything of value, including an educational item, to an HCP or provider to encourage the HCP or provider to prescribe, purchase, order, refer, use or recommend Bayer's pharmaceutical product(s). Doing so could lead to a violation of the Federal Anti-Kickback Statute and other relevant state statutes. Many customers also have very specific policies in this area, often precluding the receipt of any items.

Scope

The Bayer policy for educational items conforms to the PhRMA and AdvaMed Codes and the HHS-OIG guidance. The policy covers interactions with all healthcare professionals who may purchase, recommend, order, refer, use, or prescribe Bayer's pharmaceutical products.

Under Bayer's policies, "Healthcare Professionals" (HCP) is a very broad term and includes individuals who directly interact with patients and/or have a role in diagnosing or treating patients. This includes individuals who work for entities that provide healthcare services and/or items to patients. These individuals may purchase, lease, recommend, give information on, use, arrange for the purchase or lease of, or prescribe Bayer's pharmaceutical, biologics or device products in the U.S. Generally, this definition includes physicians, nurses, nurse practitioners, physician assistants, and medical assistants. In addition, those closely connected to the patient experience, such as pharmacists, radiology technologists, and therapists, also fit into Bayer's definition of an HCP. However, this definition is not limited to these individuals alone; the term includes any person, whether licensed or not, who is in a position to recommend, influence, or provide information about the purchasing or prescribing of Bayer's pharmaceutical, biologics or device products. In some instances, this may include individuals who do not work directly with patients but have influence over or provide information about the recommendation, purchase or prescribing of Bayer's pharmaceutical products, such as: billing or office managers, agents at hospitals, physician practice managers, management personnel within group purchasing organizations (GPOs), managed care organizations (MCOs), pharmacy benefit managers (PBMs), Specialty Pharmacies (SPs), health plan administrators, wholesalers, distributors, pharmacies, Pharmacy & Therapeutics Committee members, Formulary Committee members, or other customers who do not see patients. In addition, some positions and titles within the industry are not considered healthcare professionals, such as Original Equipment Manufacturers (OEMs), retail managers or back-office staff. Accordingly, such persons are not considered HCPs under Bayer's policy.

Bayer's HCP definition differs from a "covered recipient" used for reporting purposes under the Sunshine Act. As a reminder, as of January 2023, HCPs with the following credentials are reportable under the federal Sunshine Law: APRN, CNM, CNS, DO, MD, NP, and PA and must always be documented as an HCP, including capturing their license number, regardless of the state where they practice or where you interact with them. In addition, specific states require reporting interactions with certain, locally defined HCP credentials (*e.g.,* RNs, LPNs, pharmacists).

The chart below lists HCP credentials for whom payments and exchanges of goods or services, otherwise referred to as “transfers of value” (ToVs), are reportable.

Reportable Healthcare Professional Credentials by State

Healthcare Professional	Credential	Connecticut	Massachusetts	Minnesota	Nevada	Washington, DC
Registered Nurse	RN				✓	✓
Licensed Practical Nurse	LPN		✓		✓	✓
Pharmacist	PHAR	✓	✓	✓	✓	✓
Registered Pharmacist	RPh	✓	✓	✓	✓	✓
Doctor of Pharmacy	PharmD	✓	✓	✓	✓	✓

When conducting an event that includes an HCP attendee with a credential in one of these identified states, you must record this attendee as an HCP and include the state license information; otherwise, the attendee should be recorded as a Business Guest.

Special Requirements for Federal Government Employees

Federal laws restrict business or educational items provided to federal government employees (*e.g.,* military and Department of Veterans Affairs). To ensure that Bayer does not violate these laws, Bayer employees, contractors, consultants, and agents may not provide any educational items, including textbooks, to federal government employees, regardless of value (this excludes patient starter kits and samples). For more information on this policy, including who constitutes a federal government employee, consult Policy and Procedure, “Special Requirements for Federal Government Employees,” in these Policies and Procedures.

Spending Limits and Frequency for Educational Items

Under the PhRMA and AdvaMed Codes, educational items may be offered only “occasionally.” Bayer’s policy is that no more than one educational item valued at less than $100 is provided to any healthcare professional in a calendar year.

Educational items provided to HCPs solely for distribution to and for use with patients, such as patient starter kits and approved disease state brochures, do not count toward the annual limit of one educational item per HCP. However, any item intended for use by the healthcare professional, such as an anatomical model, medical textbook, resident handbook, or similar item, counts toward the annual limit of one item per HCP and must be valued at less than $100.

State Spending Limits

Some states have laws regarding providing educational items that are more restrictive than Bayer's policies. Please refer to the Policy and Procedure section on State Laws before providing any item of value to healthcare professionals in those states.

Retail Value – Amount to be Recorded

The retail value of an educational item provided to an HCP is determined by the amount Bayer paid for the item.

The functional areas responsible for distributing educational items, textbooks and clinical reprints must include a list with each shipment that indicates the amount Bayer paid for each item. These amounts may be close estimates if the actual cost and/or an exact retail value are unavailable. These costs are loaded into Veeva.

Educational Purpose Required

You may provide educational items to healthcare professionals designed primarily for educating patients or healthcare professionals. Examples of appropriate educational items include medical textbooks, anatomical models, patient self-assessment and tracking tools, written materials that inform patients about adherence to medicine regimens, information about the availability of patient assistance programs, and patient starter kits – to the extent relevant laws permit any such items. ***It is Bayer's policy not to provide subscriptions to scientific journals to a healthcare professional. Bayer may provide transcripts, journal articles, or reprints if the value does not exceed $100 per year.***

Printed medical booklets and text materials, such as review guides, pocketbooks, and handbooks, may be obtained from the Marketing Department. The Marketing department is responsible for obtaining approval from the Promotional Review Team (PRT) review committee. Purchasing any medical books or text materials not on this list is prohibited. These materials count toward the one educational item per healthcare professional per calendar year limit.

Adherence to the textbook program and following proper procedures for other booklets and printed materials ensure that the text in the materials you distribute is properly reviewed and approved for promotional distribution. Distribution of any printed material, textbook, or any other publication without proper review and approval violates multiple elements of Bayer's Compliance Program. Please refer to "Materials for External Use" in this policy document for further details. All questions regarding availability and title suggestions for textbooks and other printed booklets must be directed to your manager, who will contact the appropriate person in the Marketing Department. All Educational items may only be procured through Marketing. Providing medical books, text materials or other educational items not procured through Bayer (*e.g.,* purchased at a local bookstore or online) is prohibited. ***Do not procure any educational items on your own, whether using your T&E corporate card or personal funds.***

Examples of Acceptable Educational Items

The following are examples of appropriate educational items that may be provided to healthcare professionals:

- Anatomical model
- Medical textbook

- Educational materials and/or books on the management of disease
- Clinical Reprints can be delivered in person or digitally to an HCP

Under federal and state law and regulations, Bayer is required to report applicable transfers of value (*e.g.,* clinical reprints) to certain government agencies. Bayer will, as needed, disclose the name, address, monetary value of the received item and any other information required by the relevant laws and regulations. All transfers of value to statutorily defined "covered recipients" (*e.g.,* MDs, DOs, NP/PA, RNs, teaching hospitals) are also subject to public disclosure.

Examples of Unacceptable Educational Items

"Reminder" items such as pens, note pads, mugs, magnets, and similar items with or without the Bayer or product logos are not educational and not permissible. In addition, stethoscopes, pedometers, stopwatches, and general fitness items intended primarily for patient treatment and not for patient or healthcare professional education are also prohibited. Likewise, samples of over-the-counter ("OTC") Bayer products such as Aleve and Bayer Aspirin may not be provided to healthcare professionals. The prohibited items described above are also barred from distribution at conferences or third-party professional or scientific meetings.

Items that the healthcare professional can also use for personal use unrelated to patient education (such as tablet computers, electronic or digital devices, or peripherals) may not be provided to healthcare professionals, even if the healthcare professional indicates the item will be used solely for educational purposes. The PhRMA and AdvaMed Codes expressly prohibit providing these items.

Items provided to a healthcare professional may also never include payments in cash or cash equivalents, including but not limited to items such as (a) gift cards/certificates, (b) checks, (c) loans or savings bonds, (d) lottery tickets, (e) airline upgrade coupons or reward points, or (f) gas cards. Items of a personal nature, such as flowers, gift baskets, and holiday or celebratory items, are also prohibited.

Under no circumstances can this policy be circumvented by use of the employee, contractor, consultant or agent's cash and/or personal credit or debit card.

Procedures

Before providing an educational item to a healthcare professional, ask yourself:

- Is this the only educational item (including textbooks) that I'm giving this healthcare professional for their professional use in this calendar year?
- Is it designed primarily to educate the healthcare professional or to benefit patients?
- Am I confident that the recipient is not a federal government employee or does not practice in a state with special restrictions or reporting requirements?
- Is the retail value of the gift less than $100?

The answers to all questions must be "yes" for the educational item to be appropriate.

Documentation of Educational Items through Veeva

All educational items, including reprints provided by Bayer's pharmaceutical sales representatives and MSLs, must be recorded in Veeva. An accurate description of the business purpose of the educational item must be documented.

// 12. Patient Education

Bayer supports providing patient education programs so patients may better understand their disease and how to cope with the challenges of managing their disease with drug therapy. However, Bayer policy prohibits employees, contractors, consultants, and agents from offering patient education, patient support groups, educational/treatment items or meals for the express purpose of encouraging a patient to purchase, order, refer, use or recommend Bayer's pharmaceutical product(s). Bayer does not sponsor and/or provide funding for patient education events, including patient support groups where the individual healthcare professional delivers lectures to their own patients to educate them on disease states and treatment options. All patient education/support group programs must be unsolicited and in conjunction with the approval of U.S. Advocacy Relations.

Meals

It is generally appropriate for Bayer sales representatives to provide an occasional and modest meal in a setting (face-to-face or virtual) conducive to patient education to patients/caregivers. *Caregivers* are people who may be parents, grandparents, guardians, spouses, siblings or other family members providing care. Virtual meals require that all attendees be on camera. It is inappropriate for Bayer to pay for or reimburse patients/caregivers for personal meals. Providing a patient/caregiver with a meal solely for "relationship building" is unacceptable. Offering patients/caregivers a meal outside the context of an educational program is also unacceptable. Lastly, offering meals in any location without a Bayer representative present (live or on camera) or providing "take-out" meals is not allowed.

Meals (offsite at a venue such as a restaurant or virtual) provided to patients/caregivers must be "occasional" and "modest" in cost as judged by local standards. A modest business meal must cost no more than $75 per person (including food, beverage, tax, and gratuity). Such meals should include sandwiches, pizza, snacks, or soft drinks. Meals cannot include alcohol or be accompanied by alcohol. Caregivers also have a $75 per attendee meal cap per person, with no alcohol allowed.

If patient support groups (meetings onsite such as at hospitals, clinics, chapters) solicit funding for their group meetings, Bayer representatives may provide light snacks such as coffee, cookies, or donuts, not to exceed $15 per patient.

Educational, Disease or Treatment Related Items

Per the provisions of this policy, Bayer representatives may provide patients with items intended to educate patients or are essential for patient treatment and/or disease management. These items may only be distributed to patients at health fairs, medical screenings, walks, bike events, and patient educational events or programs (***e.g.,*** National Hemophilia Foundation) where healthcare professionals are not reasonably expected to attend. Bayer is prohibited from distributing such materials with the expectation that a charitable contribution or an educational grant will be provided. Charitable donations and educational grants are determined independently.

Educational and treatment items as defined and permitted by this policy may not be distributed to or provided at events for healthcare providers (***e.g.,*** medical society meetings).

The retail value of any individual item provided to a patient may be no more than $15. The retail value of any combination of items given at any one time, not exceeding three items, must not be more than $40. Educational and treatment items should be provided only occasionally to patients, and the total value of all educational/treatment items offered to any single patient must be modest.

Examples of **appropriate** educational, disease or treatment-related items may include, but are not limited to, ice packs, squeeze balls, disease state brochures, calorie counters, or pedometers. For example, disposable water bottles intended for single use only can be provided at a charity walk. Such educational and treatment-related items may be Bayer branded and must be approved through PRT and Compliance.

Items unrelated to patient education, disease or treatment are prohibited, regardless of whether they contain a Bayer or brand logo. Supplies, such as pens, folders and paper may only be provided for patient/caregiver use during an educational session/program. However, such items may not have a Bayer or brand logo.

Examples of **inappropriate** items include but are not limited to, key chains, golf balls, note pads, magnets, pens, mouse pads, stuffed animals, etc. Specific questions regarding educational/disease state items should be directed to the U.S. Office of Compliance.

All patient education and treatment items must be obtained directly from Marketing and approved by the LPC Department and PRT. You may not procure items to provide to patients on your own through the Bayer Mall, Company Store, Amazon, or any other retailer.

Documentation of Patient Meals

Patient meals – in conjunction with a Speaker Program educational event with a paid speaker or Bayer employee must be arranged through the Bayer Speaker Bureau. Sign-in sheets are required for meals organized by the Speaker Bureau for appropriate cost-per-attendee documentation and for adherence to IRS rules. All other patient/caregiver-only meals accompanying an education presentation must be recorded in Concur.

Bayer cannot require patients and caregivers to provide their names on the sign-in sheet; however, the patient/caregiver can opt-in to provide their name. Patient/caregiver meals are recorded in Concur as Business Meal and the total number of patients and caregivers are recorded under the attendee type “patient” or “caregiver” as a total number of patients or caregivers in attendance to calculate the appropriate cost per attendee.

The instructional guide for recording patient programs in Concur can be found on the Lunch & Learns resource page.

Itemized (detailed) receipts must be included with every patient business meal expense entered into Concur, regardless of the amount.

// 13. Fee-For-Service Arrangements

The Physician Payments Sunshine Act requires that any transfer of value given to an HCP, teaching hospital and/or all employees of a teaching hospital must be reported to the Centers for Medicare & Medicaid Services (CMS). It is the responsibility of each employee, contractor, consultant and agent to report accurate, complete and timely data to applicable Bayer systems, as this is the data Bayer will report to CMS.

The Personal Services Safe Harbor of the Anti-Kickback Statute allows Bayer to enter into certain fee-for-service arrangements with healthcare professionals, provided specific criteria are met. Bayer's policy on fee-for-service arrangements is consistent with the Personal Services Safe Harbor, the PhRMA Code, the AdvaMed Code and other applicable laws and industry guidance. Arrangements to pay individuals for speaking engagements, consulting fees or participation on advisory boards, as well as fee-for-service agreements with customers, data purchases, market research or advertising space, may never be used to encourage the recipients to purchase, order, refer, use or recommend Bayer's pharmaceutical products nor should these arrangements be used to reward "high prescribers." These fee-for-service arrangements are also subject to federal, state and global reporting requirements.

Fee-for-service transactions include, but are not limited to, arrangements with healthcare professionals for speaker agreements, consulting, advisory board participation, data purchases, service agreements with customers, patient education programs, medical writers and other activities where Bayer compensates individuals (or the companies that employ them) for services rendered. Contracted partners may opt out of any compensation if they wish to; however, Bayer cannot transfer intended compensation to a charity or other party not party to the contract.

Clarification of Terminology and Programs

Advertising space in newsletters or other printed materials, whether or not contracted through a third party such as an advertising agency, are not "fee-for-service" arrangements. Payment for advertising space must not be contingent on or used as a reward for the purchase, prescription, or recommendation of Bayer's pharmaceutical products.

Advisory Boards are conducted to gain expert feedback or advice on commercial or clinical/medical topics or other relevant medical/scientific information exchange. They are not intended to provide a forum for product promotion. Bayer representatives should ensure that advisory board participants are selected because of their knowledge, education, experience, and/or expertise about the topic under consideration. They clearly understand that they are retained to provide a service and not receive promotional presentations. Advisory board participants must actively engage and participate by providing expert advice on the contracted topic. Bayer employees may attend an Advisory Board if they have a legitimate business need based upon the objectives of the meeting and the job responsibilities of the Bayer personnel. While this Policy does not provide a specific maximum, the number of Bayer personnel in attendance should be small relative to the number of paid advisors (*e.g.,* 3 HCPs to 1 Bayer attendee). First-line sales personnel (including nurse educators, radiation therapy specialists, diagnostic account managers, etc.) and immediate managers are prohibited from attending Advisory Board meetings. An advisory board meeting cannot be designed to (1) influence the invited consultants or to change their prescribing preferences; (2) provide participants with anopportunity to meet and mingle with their peers; or (3) have participants merely listen to information about Bayer's pharmaceutical products. It is Bayer's policy not to video or audio-record advisory boards.

Consultants are generally healthcare professionals contracted with a fee-for-service agreement and paid by Bayer to provide needed information about its products, sales and marketing activities, and related issues (*e.g.,* disease states), among other potential areas, based on their education, training, experience and/or expertise.

Data purchases include any compiled information offered by a customer that may have commercial value, such as product utilization information or clinical or sales data necessary for a commercially reasonable Bayer business purpose. Permissible data purchases and other arrangements are those designed to (1) foster an increased understanding of scientific or clinical issues to improve patient care and/or (2) provide information not otherwise available to Bayer in areas that are relevant to its business activities. Bayer may not purchase data unless it has established a legitimate need for the data and intends to use it for legitimate business purposes.

Market research aims to obtain information on customer requirements, preferences, product performance, and purchasing options for Bayer U.S. Pharmaceuticals to develop, evaluate or change its product or service offerings or marketing, promotional or educational activities. Market research may be conducted in person (*e.g.,* focus groups), by mail (*e.g.,* surveys) or electronically. Compensation must be at fair market value for single-blinded research. Double-blinded research does not require a formal fair market value assessment; however, compensation must be reviewed for reasonableness. Participants in Marketing Research Studies may not be selected or compensated by the sales force or other employees, contractors, consultants or agents involved in direct promotion. For example, it is inappropriate for sales personnel to design marketing research questionnaires for physicians or pay physicians for completing these surveys. Market research or focus groups involving healthcare professionals hired by or on behalf of Bayer U.S. Pharmaceuticals, in which Bayer Pharmaceuticals knows the participant's identity, are Interactions with HCPs and HCOs and, as such, may be reportable to federal, state and global agencies. Market research or focus groups where the participants' identities are blinded to Bayer U.S. Pharmaceuticals are not considered Interactions with HCPs and HCOs.

Physician Training allows healthcare professionals to be trained by other qualified healthcare professionals proficient in using Bayer U.S. Pharmaceutical's products. The training content must be designed to develop the skills of healthcare professionals who will provide valuable patient services through the use of Bayer U.S. Pharmaceutical's products. All training materials must go through the PRT review process and be on-label.

Promotional speaker events include speakers acting or speaking on Bayer U.S. Pharmaceutical's behalf using content developed and approved by Bayer. Such events (*e.g.,* speaker programs branded and unbranded, national broadcast) are considered promotional events. First, the brand teams must identify a need to do speaker programs after they have done market analysis and have identified an unmet educational need in the market. Speaker fees must be consistent with fair market value and provided under a written agreement approved by the LPC Department. The total amount of annual compensation to any one healthcare professional in connection with all Bayer pharmaceutical products that fall within a therapeutic area of the Bayer U.S. LLC Pharmaceuticals division (Cardiovascular and Renal, Oncology, Radiology, Specialty and Women's Health) and speaking arrangements (including the speaker's training compensation) may not exceed $100,000 annually. Before the speaker's first speaker event, the speaker must complete Speaker Training, which includes training on the respective Bayer product or product-related disease state, products, Bayer Compliance and FDA regulatory requirements, and compliance-related procedures and expectations.

Speaker training can be done at meetings or using webinars and must be managed through Bayer's approved Speaker Bureau. The training should cover the content to be presented and develop speakers to deliver presentations effectively. Bayer U.S. Pharmaceuticals must ensure that the number of speakers trained is closely related to the number of speakers Bayer U.S. Pharmaceuticals plans to use. Training more speakers than is reasonably necessary may give the perception of a violation of the Anti-Kickback Statute.

All speaker training meetings must be initiated through either the Marketing Department or the Medical Affairs Department and planned using Bayer's approved Speaker Bureau. All meeting content must be approved through the PRT review process and relate to approved/cleared uses of Bayer U.S. Pharmaceutical products.

The speaker and the materials must clearly identify that Bayer is sponsoring the presentation, that the speaker is presenting on behalf of and being paid by Bayer, and that the speaker is presenting information consistent with FDA laws and regulations. A Bayer representative must attend each program.

The promotional program must be open to the community and not limited to a specific physician practice or healthcare organization. Generally, Bayer prohibits promotional speakers from presenting only to their staff and/or patients in their own practice. If the speaker is part of a larger organization where HCPs do not routinely work alongside each other and have no reporting relationship (*e.g.,* other locations, other affiliates, etc.), they can attend consistent with the following guidelines:

- If the HCP who wishes to attend and the speaker works primarily in the same location, the HCP cannot attend.
- If the HCP who wishes to attend and the speaker works in different locations within the same organization, the HCP can attend as long as there are 5 HCPs in attendance who are from locations other than the speaker's primary location.
- If the HCP who wishes to attend and the speaker works as part of a multi-state organization, then the 5:1 ratio does not apply; however, there should be HCPs from multiple (at least 3 in total) locations attending the program.

If you have questions or encounter a scenario not covered by this guidance, please contact your Compliance Business Partner.

Bayer may also enter into Promotional Speaker Event Agreements with speakers who do not wish to be paid. Such arrangements follow the same policies as Bayer Promotional Speaker Events, including all required approvals and PRT review of presentation content. For information on entering into such agreements, please contact the Compliance Business Partner.

The Bayer employee hosting or attending the speaker training or promotional speaker program event is responsible for ensuring an accurate check for the meal, all attendees sign in, stopping any off-label discussions and re-directing the conversation back to the approved slides, obtaining PIRs and recording any adverse events reported during the program. While a third-party vendor assists with the logistics at these events, the Bayer employee remains responsible for ensuring a complete and timely submission of the sign-in sheet.

Scanner Testing allows Bayer to test Radiology products with the site or hospital equipment. A Bayer engineer performs the testing, and the hospital may require a Radiology Technician employed by the facility to be present during the testing. Payment for scanner testing must not be contingent on or used as a reward for purchasing or recommending any Bayer Radiology products.

Service agreements are contractual agreements typically initiated with a healthcare organization to provide certain services that include, but are not limited to, managed care organizations calling patients and reminding them to refill their Bayer prescriptions, disease awareness programs, customers mailing physicians information regarding the addition of a Bayer U.S. Pharmaceuticals product to its formulary, or providing "patient information cards" to patients who may be using a Bayer product for the first time.
For these agreements, Bayer pays the customer a fair market value fee in exchange for their services.

Service agreements may not substitute for or subsidize activities that are part of a customer's normal costs of providing healthcare services or running a business, nor may fees paid under an agreement be determined by considering pricing terms in product purchase agreements. In addition, service fees paid to customers may not be used to reward the customer for a patient "switch" program (*e.g.,* a program intended to convert patients from a competitor product to a Bayer product).

Permissible Fee-For-Service Agreements

Fee-for-service arrangements are permitted if ALL the following are true:

- A legitimate need for the services has been clearly identified before requesting the services.
- The compensation paid represents fair market value for the services rendered.
- Individuals are chosen based on relevant qualifications, experience, expertise, and the value their services would provide Bayer. They cannot be chosen based on the volume or value of business they have generated or may generate.
- Field sales representatives may not be involved in selecting and/or contracting potential speakers of the speaker bureau or engaging healthcare professionals to serve as consultants. Medical Affairs is ultimately responsible for evaluating whether a healthcare professional has the necessary and required qualifications to serve as a speaker or consultant.
- The venue and circumstances of consultant meetings must be conducive to the consulting services. Exotic and/or resort locales are prohibited. Bayer may not provide entertainment or recreational activities in connection with any Bayer contractual agreement (*e.g.,* speaker training event, advisory board, or consultant) with no purpose other than social.
- Consultant meetings, speaker training meetings and advisory board meetings must be approved by PRT before invitations are sent and before venues are booked.
- The number of participants, speakers, advisors and/or consultants chosen must be consistent with the business need.
- The contract must specify the nature of the services and the basis of payment for those services. The contract must be approved for fair market value by an LPC Representative before all parties sign it. No Bayer employee may execute any contract or other legally binding document without review and approval from the LPC Department. If a healthcare professional refuses to sign the agreement provided by the LPC Department before initiating the program, they cannot be retained to provide the service.

Procedure for Fee-For-Service Arrangements (excluding HCPs and HCOs)

Initial Request

The initial request for a fee-for-service arrangement must be made using the Contract Life Cycle Management System (CLMS). The approved request is submitted to the LPC Department for legal review and contract generation. The Agreement Request must include the following:

- Name and address of the speaker(s), consultant(s), advisory board member(s), and HCP state license number and state of licensure if required, etc.;

- Bayer's legitimate business needs for the arrangement as described by the purpose and nature of the services being purchased;
- A statement of the participant's qualifications (the participant's title may be sufficient to reveal the qualifications based on the description of Bayer's need or purpose for the services);
- Term of the agreement, including any automatic renewal provisions;
- The proposed fee uses fair market value calculations; and
- Description of the expense to be reimbursed, if any.

All pertinent information is captured in the CLMS metadata fields and transferred into the contract.

Procedure for Healthcare Professionals and Healthcare Organizations

The initial request for a fee-for-service arrangement with either a healthcare professional or healthcare organization must be made using Cvent. The approved request is submitted to CLMS by Meetings and Conventions Management. The designated LPC member will review it and send to the Contract Center for DocuSign. The Agreement Request must include the following:

- Name and address of the speaker(s), consultant(s), advisory board member(s), and HCP state license number and state of licensure if required, etc.;
- Bayer's legitimate business needs for the arrangement as described by the purpose and nature of the services;
- When known in advance, the schedule on which the services will be provided;
- A statement of the participant's qualifications (the participant's title may be sufficient to reveal the qualifications based on the description of Bayer's need or purpose for the services);
- Specific duration of the services to be provided or a contractual term of at least one year;
- The maximum aggregate compensation to be paid for the services;
- A certification by the parties to the arrangement that the parties shall not violate the Anti-Kickback Statute with respect to the performance of the contractual agreement;
- The proposed fee is within fair market value calculations; and
- Description of the expenses to be reimbursed, if any.

Third Party Contracts

Bayer may work with third parties who contract with speakers, moderators, or consultants on Bayer's behalf. The Law, Patents and Compliance Express (LPCx) Department will generate all agreements (except for Speaker Bureau contracts) in accordance with the procedures described above. If the third party engages the consultant or speaker, the third party must send Bayer the proposed list of speakers, moderators, or consultants it plans to use for the event. Certain payments made by third parties on Bayer's behalf are reportable for federal, state and global reporting requirements. For additional reporting requirements, please refer to Policy, Focus Arrangements (Interactions with HCPs and HCOs).

Special Rules for Contracting with a Federal Government Employee

Federal government employees include anyone who works (either full-time or part-time) at a facility associated with the Department of Defense (*e.g.,* military), the Department of Veterans Affairs ("VA"), Federal Public Health Service ("PHS"), Indian Health Service, the National Institutes of Health ("NIH"), or other federal government entities.

Special rules and limitations apply to fee-for-service arrangements with federal government employees. Before any discussions regarding speaker services, consultant or any other fee-for-service arrangement with a federal government employee, you must contact the Government Affairs Manager responsible for that state (if you are interested in contracting with a state employee) or contact the LPC Department (if you are interested in contracting with a federal government employee).

In addition, and to comply with the Department of Veterans Affairs requirements, certain language (excerpted below) must be included in all fee-for-service agreements with VA employees. Therefore, any fee-for-service request involving a VA employee must clearly state that the party involved is an employee of the Department of Veterans Affairs. To fulfill this requirement, the VA employee status must be included under "Further Information" section in CVENT/CLMS in the Comment box.

The Following, or Similar, Language must appear in Agreements with VA Employees:

Department of Veterans Affairs (VA) Employee Provisions

Services provided must occur outside of duty hours or during administrative or personal leave to not affect the performance of official duties. Invitations for services are extended solely based on expertise, not due to employment with the VA.

VA Employees may not be compensated for any service in which VA research programs or matters related to official duties are discussed, nor may the employee discuss any research they have conducted, participated in, or supervised. Employees may not refer patients to Bayer-sponsored clinical trials.

A VA employee may not receive compensation from Bayer if they serve in a position of decision-making authority (e.g., formulary committee) in which purchasing or prescribing choices are made that might favor or disfavor any of Bayer's products (other than in the capacity to prescribe drugs/device for patients).

The VA employee's official title or position may only be used when listed as a biographical detail.

Law, Patents and Compliance Review of Interactions with HCPs and HCOs

An LPC-designated member evaluates whether each proposed interaction satisfies the requirements of the Anti-Kickback Statute and assesses compliance with relevant Safe Harbor(s). The designated reviewing LPC member identified in CLMS confirms that this assessment was conducted and the date it was conducted. The designated member in LPC also confirms that the proposed payment (*e.g.,* speaker compensation or fees for a service) represents fair market value. Fair Market Value is based on an independent third-party provider who benchmarks industry standards. Any FMV exception for an individual HCP must be approved by the Vice President and Head, U.S. Office of Compliance (or designee) and documented and maintained in the LPC Department. The contract may indicate that Bayer will reimburse reasonable expenses for travel, lodging, and meals incurred by the speaker or consultant in connection with the services provided to Bayer, as described in the approved written contract. Bayer will not reimburse incidental expenses, such as gift shop purchases or personal items. Bayer will not pay for any additional costs associated with the spouse or guest of a consultant, such as travel or meals.

Proof of Service

The requestor of the goods or services must retain and present, if necessary, proof that the services purchased were performed and/or satisfactorily received before payment is generated. The requestor formally confirms proof of service by providing documentation (*e.g.,* a timesheet, slide deck or sign-in sheet) related to services being provided. The Requestor must retain the records demonstrating the appropriate use of the consultant's services. Where a tangible deliverable is provided, such as a report, the requestor must retain the deliverable as proof that the service was performed.
The deliverable must be retained following laws and regulations and the Bayer Corporation Records Management Policy and Records Retention and Disposal Schedule. The contract must permit Bayer to observe the services rendered or obtain proof of service.

Payment Generation

- Payment for fee-for-service arrangements is contingent upon:
- Approved and executed written contract;
- Documentation as to the need for service;
- Completed fair market value analysis; and
- Proof that the service has been provided.

The Requestor (or their delegate) generating the initial fee-for-service request is responsible for preparing the payment request documentation, obtaining necessary approvals, and submitting it by following all Bayer Pharmaceutical Procurement processes. When using the “Internal Payment Demand (IPD),” it must contain the contract number (formatted as “US2083####”). On the “Internal Payment Demand (IPD)” the contract number must be in the “GL Text Field” to match the payment with the contract in the Focus Arrangements Database and be paired with the contract for government reporting purposes.

The approval process for the payment request must follow the spending approval levels within the Management of Signature Authorizations policy.

// 14. Contracting with Members of Formulary or Clinical Practice Committees

Healthcare professionals who are members of committees that set formularies of covered medicines or develop clinical practice guidelines that may influence prescribing medications generally have significant experience in their fields. That experience can greatly benefit pharmaceutical companies and patients if these individuals choose to serve as speakers or consultants.

Consistent with the PhRMA Code, Bayer requires any healthcare professional who is a member of a committee that sets formularies or develops clinical practice guidelines and also serves as a speaker or commercial consultant for Bayer to disclose to the committee the existence and nature of his or her relationship with Bayer during the period of the contract and two years after contract termination. If these healthcare professionals serve as speakers or consultants for Bayer, they must also follow the procedures set forth by the committee(s) of which they are members. This may include recusing themselves from decisions relating to the products and/or companies for which they have provided speaking or consulting services.

This disclosure requirement and associated expectations must be documented in the Bayer contract with the healthcare professional. The specific contract language is as follows:

> In connection with the implementation of this Agreement, the Parties shall comply with all Applicable Laws. The Parties shall inform each other if they become aware of violations of Applicable Laws in relation to the implementation of this Agreement. Contract Partner further agrees to comply with all applicable U.S. federal, state and local laws and regulations relating to the privacy of patient health information, including, but not limited to, the Standards for Individually Identifiable Health Information, 45 C.F.R. §§ 160 and 164 (the HIPAA Privacy Regulation) promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996. If Consultant deems it necessary in the performance of the Services under this Agreement to disclose to Bayer the Protected Health Information (as such term is used in the HIPAA Privacy Regulation) of a patient, then, in advance of any such disclosure, Consultant shall obtain a written authorization executed by such patient for the use and disclosure of such Protected Health Information in accordance with the HIPAA Privacy Regulation. The parties acknowledge and agree that the compensation payable by Bayer pursuant to this Agreement is consistent with arms-length transactions and has not been determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under any federal health care program, as such term is defined in 42 U.S.C. § 1320a-7b(f).

Some states, as well as the District of Columbia, have separate laws that prohibit certain interactions with members of formulary or clinical practice committees. Please refer to Policy and Procedure, “State Laws” in this booklet for details of these restrictions.

// 15. Medical Practice Training

The Physician Payments Sunshine Act requires that any transfer of value given to an HCP, teaching hospital and/or all employees of a teaching hospital must be reported to the Centers for Medicare & Medicaid Services (CMS). Employees, contractors, consultants, and agents are responsible for reporting accurate, complete, and timely data to applicable Bayer systems, as this is the data Bayer will report to CMS.

Bayer recognizes the need to provide medical practice training to healthcare professionals, sales consultants and other employees, contractors, consultants and agents to educate them on medical practice and treatment protocols and does provide such training as organized and directed by Pharma Learning & Development. Bayer does not engage in preceptorship arrangements as traditionally defined within the pharmaceutical industry.

Procedures

A healthcare professional must be contracted as a consultant before providing medical practice training. All requests for medical practice training must be processed as fee-for-service arrangements using the procedures described in Policy and Procedure, “Fee-for-Service Arrangements.”
Medical practice training must comply with the following:

- Training must take place in an environment conducive to education. The training may occur in a private practice or clinic office.
- As with all consulting arrangements, payment must be disclosed and represent the fair market value of the teaching services provided.

Bayer employees may not:

- Select a healthcare professional to conduct medical practice training to encourage them to prescribe or purchase Bayer’s pharmaceutical products or to reward a referral source.
- Follow a physician to observe procedures during hospital rounds or in the physician’s office.
- Pay an institution or physician to learn about a physician’s billing practices, obtain the opportunity to speak to the physician or pay a physician to critique a “sales pitch.”

Bayer may hire a healthcare professional proficient in using Bayer’s pharmaceutical products to provide hands-on training to other healthcare professionals. The training content must be on-label, approved through PRT and designed to develop the skills of healthcare professionals who will provide valuable patient services through the use of Bayer’s pharmaceutical products. The training may be provided in a hospital or office setting. Training attendees may not be compensated for attending the training.

// 16. Corporate Sponsorships

Bayer may fund sponsorships to various trade, medical, professional, patient, scientific and community organizations. The recipient organization's mission should be to increase understanding of scientific, clinical, or healthcare issues that contribute to improving patient care or continuing education of professionals.

Under appropriate circumstances, Bayer may give general funding for a professional association's patient support group or other organization's activities or meetings. The recipient organization must have sole control over the sponsorship funding paid by Bayer. The Sponsorship may be recognized by the organization, including the level of support provided (*e.g.,* platinum, gold, silver) on its meeting brochures or banners, website, or other materials. Sponsorship of meetings or activities that will be attended primarily by healthcare professionals must be open to other pharmaceutical or medical device companies.

Sponsorship funds may not be paid to Bayer customers or to entities controlled by or affiliated with Bayer customers, except in limited circumstances and with prior written approval by the LPC Department, where the event is open to all potential sponsors and the same sponsorship opportunity is given to other similarly situated entities. Sponsorships paid to customers must comply with all requirements of Policy and Procedure, "Focus Arrangements/ Interactions with HCPs and HCOs."

Sponsorships may not be paid to encourage the recipient organization to purchase, order, refer, use or recommend Bayer products. Bayer's policy is to pay the same fee as other corporate sponsors for the same level or type of sponsorship. Sponsorships may not be provided to individuals or private physician practice groups.

Sponsorship funding must not be used to reimburse attendees' travel, lodging, or other personal expenses, compensate attendees for their time, or provide any gift to the attendees or presenters. Sponsorship funding also may not be provided on behalf of any customer, patient, or other individuals.

It is essential to determine whether a request for support is a charitable contribution, corporate sponsorship or medical education grant. The terminology used by the entity requesting the funding (*e.g.,* "charitable contribution," "grant") is not the determining factor because organizations may submit funding requests using inconsistent or incorrect terminology. The key factors are the type of entity requesting the funding (*e.g.,* non-profit, patient organization, hospital) and the focus of the event or activity (*e.g.,* education or fundraising). For example:

- *Charitable contribution* is funding provided to a non-profit organization to support the organization's activities where Bayer does not receive anything of value in return.
- *Sponsorship* is funding provided to support the activities of a professional, medical or patient association or organization where Bayer receives something of value, such as banners or signage at a conference, an opportunity to advertise in the organization's publication, or the primary purpose of the event/activity is fundraising/charity with a tangible benefit (*e.g.*, seats at a gala, tickets to an event). The sponsorship opportunity is offered to other similarly situated industry members, not just Bayer.
- *Medical education grant* is funding to support an event whose primary focus is educating the HCP participants/attendees.

Key Characteristics:

Charitable Contributions vs. Corporate Sponsorships vs. Education Grants

Characteristics	Charitable Contributions	Sponsorships	Education Grants
Promotional in nature	No	Maybe	No
Payee must be a 501(c)(3) or other tax-exempt organization	Yes	No	No
Bayer receives something of value in return	No	Yes	No
Payment can be made to an individual HCP or private practice group	No	No	No
Tickets or invitations received as a result can be offered to physicians or other customers	No	No	No
Sales and Marketing Involvement	No	Maybe	No

Examples of Permissible Sponsorships

- “Gold” level annual sponsorship of the American Heart Association for general educational programs regarding heart disease prevention and awareness.
- Sponsorship funding of appropriate, non-educational activities, such as a modest hospitality suite at national meetings of medical societies or organizations, such as the American Society of Clinical Oncology (ASCO) or the American Heart Association (AHA) or a Wi-Fi Café during medical society meetings.
- Accepting a seat on an advisory council to the Kidney Cancer Association if this benefit is also provided to other pharmaceutical or medical device companies with similar sponsorship levels.

Examples of Impermissible Sponsorships

- Sponsorship of a hospitality suite at a disease-state awareness program sponsored by the American College of Obstetrics & Gynecology (ACOG) that is intended specifically for a discussion of a disease state for which Bayer’s pharmaceutical products are not indicated.
- Sponsorship funding for American Society of Health System Pharmacy (ASHP) members to attend a Broadway show one evening during the ASHP meeting. This is not allowed because Bayer may not provide funding for entertainment, social, cultural or recreational activities or items at such meetings or events.

Requirements

The recipient organization receiving Bayer sponsorship funds must support or conduct activities related to healthcare, scientific, or clinical issues that contribute to improving patient care, education, or advocacy.

Under no circumstances may sponsorship funds be offered or provided with the intent to directly or indirectly encourage the recipient organization to purchase, order, refer, use or recommend Bayer's pharmaceutical products or to reward any recipient organization for a past purchase, prescription, recommendation, or formulary placement of a Bayer pharmaceutical product or service. Payment of sponsorship funds may also not be used to provide a direct or indirect discount on product purchases or to influence any recipient's conduct or decisions in connection with clinical or other research or the dissemination of medical or scientific data.

Invitations for Exhibit Space at the Charity Event

It is inappropriate to receive exhibit or advertising space within a general sponsorship. It is Bayer's practice to request a separate invoice for exhibit fees. However, in certain limited circumstances, separating the exhibit fee in the documentation submitted by the requesting organization may not be possible.

Limited Attendance at Events

When sponsoring events where Bayer receives tickets as part of a fundraiser (*e.g.,* galas, golf, charity walks, etc.), only Bayer employees are allowed to attend for Bayer to demonstrate support for the patient group. No more than three Bayer representatives from pharmaceutical sales and marketing functions may attend. This three-person restriction does not apply to Bayer attendees not part of the commercial organization (such as LPC, Government Relations & Policy, Regulatory, or Medical Affairs). The representative(s) of Bayer who attend approved events must not engage in any promotional activity at the event or use the event as a promotional opportunity. Extra tickets need to be returned to the requesting organization. Tickets cannot be provided to customers, patients, family of the patient, or Bayer employee's families. Individual tickets for galas or fundraisers are not allowed. In most cases, the level of sponsorship includes tickets to these events.

Health Fairs/Medical Screenings

Under certain circumstances, Bayer may provide support at health fairs and medical screenings. These events must be offered by organizations other than customers free of charge to the general community, promote disease awareness, or be intended to detect medical issues. Examples include free prostate exams, blood pressure screenings, and mammograms.

Bayer may contribute funds to support a health fair or medical screening conducted by a charitable organization if the following requirements are met:

- The request for funds must be received from an independent third party that qualifies as a 501(c)(3) or otherwise IRS tax-exempt charitable organization. Bayer cannot provide funds to a customer, or any charity controlled by, related to, or operated by a customer or physician practice group.
- More than one medical group or more than one healthcare professional from different medical groups must participate in the health fair or medical screening.
- The health fair or medical screening must be free and open to the community at large (*e.g.,* it may not be limited to patients of a particular hospital, health organization, or physician practice group).

- Any Bayer employee who attends the event as a representative of the Company must not engage in any promotional activity at the event or use the event as a promotional opportunity.
- Bayer may provide disease state brochures to the organization for distribution at the event upon the organization's approval. However, Bayer may not provide product-specific information of any type.
- Bayer may provide educational, disease or patient treatment-related items to support the event in compliance with Policy and Procedure, "Educational Items and Meals Provided to Patients."

Procedures

Requestor

A medical or professional society or other organization may solicit sponsorship through a website (Hematology only), e-mail, or paper mailing. No Bayer employee may commit the Company to funding a sponsorship request without review and approval under this policy. The requester will use the Letter of Agreement template for Sponsorships and attach it to payment documents. Requests are processed through SmartBuy or the Bayer website (Hematology only). Concur T&E may not be used for Sponsorships. All sponsorship requests must be written in writing from the requesting organization on its letterhead and include a completed W-9 form. The request must specify:

- The purpose of the request;
- The types of sponsorship opportunities available and the cost(s) thereof;
- The name and address to which the check must be payable;
- The Federal Tax ID number of the payee; and
- Whether the organization is affiliated with a Bayer customer.

Law, Patents and Compliance Review of Focus Arrangements (Interactions with HCPs and HCOs)

All requests involving interactions with HCPs and HCOs are reviewed by an LPC member who must verify that the Letter of Agreement contains a certification by the parties that the parties shall not violate the Anti-Kickback Statute concerning the performance or activities related to the sponsorship. LPC also evaluates whether the proposed arrangement satisfies the requirements of the Anti-Kickback Statute and assesses compliance with relevant Safe Harbor(s). The reviewer must document that this review and assessment was conducted, their name, and the date it was conducted.

The LPC Department also confirms whether the sponsorship amount represents fair market value in that the proposed amount is fair and reasonable and represents support for necessary expenditures based on the nature and the extent of the event for which the sponsorship requestor seeks support. Any deviation from the fair market value methodology and the rationale for such deviation must be approved by the Vice President and Head, U.S. Office of Compliance (or designee) and will be documented and maintained in the LPC Department.

Law and Patents Review of Non-Focus Arrangements (Not Specifically with HCPs and HCOs)

The LPC Department reviews all documentation and makes an independent judgment whether the interaction and associated requested fees are reasonable and the request is consistent with Bayer's policies. If appropriate, the LPC Department approves the request.

// 17. Providing Free Product for Charitable Purposes

Pursuant to this policy, Bayer may only provide Bayer pharmaceutical products for legitimate charitable purposes. As with any charitable donation, product may not be provided to encourage the recipient to prescribe, order, refer, use, purchase, or recommend Bayer pharmaceutical products. Bayer does not provide product as a price term or in lieu of price discounts.

Scope

This policy covers all products provided by the Patient Assistance Program or product donations to established non-profit partners following the Bayer Corporate Charitable Giving procedure.
This policy does not cover:

- Product shipped under a zero-dollar invoice to correct billing or shipping errors or to replace damaged or short-dated product.
- Products and/or samples that are provided free of charge to healthcare professionals for free distribution to patients under the Prescription Drug Marketing Act are not charitable products as defined by this policy and must comply with the provisions of Policy and Procedure, “Providing Samples at No Charge and Device Evaluations.”

Bayer U.S. Patient Assistance Foundation

The Bayer U.S. Patient Assistance Foundation (BUSPAF) is a charitable organization that helps eligible patients get their Bayer prescription medicine at no cost. For uninsured or certain underinsured patients, the Foundation may provide free product to patients who meet certain eligibility criteria. Patients must: (1) reside in the U.S. or Puerto Rico, (2) meet certain income limits, (3) not have insurance, or the Bayer prescription medicine is not covered, and (4) have a valid prescription from a healthcare provider for the product. Bayer has contracted with a third-party vendor to administer the Patient Assistance Program (the “PAP”). The Foundation is solely responsible for its own governance and operations, including establishing patient eligibility criteria for the PAP and approving patient enrollment applications. Decisions on patient enrollment applications must be made without any consideration given to the patient’s prescribing provider or any other prescriptions that the provider may have written in the past or may write in the future for Bayer products.

- Patients may contact the Foundation at 1-866-2BUSPAF (228-7723) Monday–Friday, 9 am–6:00 pm EST, or visit the foundation website at https://www.patientassistance.bayer.us/en/ for more information.

The third-party periodically monitors the program by reviewing internal transaction reports.

Approvals

Product provided to patients at no cost from the Foundation must be processed in compliance with the procedures applicable to the program.

Product provided for the established non-profit partners need to follow the approvals outlined in Procedure No. PAS-PUB-9-327007 “Corporate Charitable Giving” (Version 5.0).
The LPC Department must approve all requests to provide free product under any program not listed in this Policy.

// 18. Displays and Exhibits

The Physician Payments Sunshine Act requires that any transfer of value given to an HCP, teaching hospital and/or all employees of a teaching hospital must be reported to the Centers for Medicare & Medicaid Services (CMS). Employees, contractors, consultants, and agents are responsible for reporting accurate, complete and timely data to applicable Bayer systems, as this is the data Bayer will report to CMS.

Displays of Bayer's pharmaceutical products potentially implicate prohibitions against off-label promotion under the Federal Food, Drug, and Cosmetic Act and prohibitions on offering illegal remuneration under the Anti-Kickback Statute. This Policy and Procedure is designed to allow Bayer to provide product displays while abiding by the legal requirements.

Scope

This policy covers both table-top product displays as well as commercial exhibits. In all cases, an equal opportunity for display participation must be afforded to other pharmaceutical and/or biotech companies.

The purpose and business need for a product display or exhibit is for Bayer to display products and provide approved disease state and product information to healthcare professionals, patients or other individuals attending the event.

Questions regarding whether a product exhibit or display request constitutes an Interaction with HCPs and HCOs (Focus Arrangement) must be directed to the LPC Department.

Displays are typically tabletop units used by sales personnel for educational discussions at such locations as hospitals or other healthcare facilities, a retailer or wholesaler, or a medical or patient organization that sponsors these educational events.

- An on-site display is used to display approved Bayer pharmaceutical product information onsite at a hospital or non-profit healthcare organization with an educational mission. On-site display opportunities occur within the organization's own facilities.
- An off-site display is used to display approved Bayer pharmaceutical product information for healthcare conference attendees at an off-site event organized by a hospital or non-profit healthcare or patient organization with an educational mission. Off-site display opportunities occur at locations such as hotel meeting rooms, convention centers, etc.

Exhibits are booths at conventions or trade shows sponsored by wholesalers, chain pharmacies, GPOs, or PBMs and typically include exhibit property from the exhibit house vendor.

The requesting Bayer employee may not pay fees for displays and exhibits directly. Display fees may never be paid to individual physicians or private physician practice groups.

Appropriate Promotional Activities

U.S. Displays and Exhibits are promotional forums, whether branded or disease-state unbranded. All discussions with healthcare professionals must be consistent with product label (*e.g.,* they must be on-label) within the United States. Any discussion with non-U.S. healthcare professionals in a U.S. promotional forum is also limited to the U.S. product label. Sales and Marketing personnel may not discuss an unapproved Bayer product or an unapproved use for an approved Bayer product.

Only promotional materials that have been approved for distribution through the PRT process may be located in and distributed from a product display or exhibit. Likewise, any items (beverages or snacks) provided in the booth must also be approved by PRT. Samples of over-the-counter Bayer items are prohibited.

If a healthcare professional asks an off-label question about a Bayer product, including questions regarding uses that have not received FDA approval, Bayer Sales or Marketing personnel may not answer the question and must send the healthcare professional to the medical/scientific booth. If there is no medical/scientific booth, the healthcare professional must complete a PIR with the Bayer commercial representative and will receive a response from the Bayer Medical Affairs Department for off-label inquiries. If the healthcare professional is walked over to the Medical Booth by the Bayer commercial representative, the commercial representative must not enter the Medical Booth nor congregate outside the Medical Booth. Medical discussions must be separate from commercial discussions.

If a patient asks a question that is not within Bayer's product label, you must refer the patient to their personal physician.

Relationship to Medical Education Grants, Charitable Contributions and Corporate Sponsorships

There may be limited situations where an organization submits a request for a medical education grant, charitable contribution, or corporate sponsorship that also offers Bayer the opportunity to display or exhibit at the event. Ideally, the requesting entity must process these activities as separate transactions. However, there may be limited occasions where it may not be possible to separate the product display fee in the documentation submitted by the requesting organization. In these situations, the Bayer Pharmaceutical's Grant Review Committee will determine whether the grant will be approved and/or whether Bayer Pharmaceuticals may display at the event.

Separation from the Medical/Scientific Booth

Medical/scientific booths are resource forums for healthcare professionals to obtain clinical information. At conventions or other venues where Bayer has both a commercial exhibit and a medical/scientific booth, the commercial exhibit booth must be physically separated from the medical/scientific booth to distinguish promotional activities by Sales and Marketing from non-promotional activities by scientific representatives.

- The medical/scientific booth must be separated from the commercial exhibit booth by walls so that one must walk out of one booth to enter the other.
- The medical/scientific booth must have a different look than the commercial exhibit booth, be marked, and have no product-specific banners or panels.
- Only Medical Affairs (Medical Information/Medical Communications) and Medical Science Liaisons (no Sales and Marketing personnel) may be in or near the medical/scientific booth. Conversely, these individuals must not be in or near the commercial booth.

Attendance

All Bayer staff scheduled to work at the commercial or medical exhibit booth must have completed the "Interactions with U.S. Customers at Industry Meetings and Conventions" training. All commercial employees with an exhibitor badge must have approval from their manager before attending any scientific sessions to ensure the topics of sessions are appropriate for the employee's position.

Procedures for Requesting Displays/Exhibits

Requestor

The Requestor of arrangement, at least six weeks before the product display date, submits a request in the Veeva Digital Events (VDE) portal, including:

- A written request, invitation, brochure, pamphlet, flyer or agenda from the organization containing;
- A brief description of the service offered (display space, exhibit space);
- The date and duration of the event and display;
- The amount of the fee;
- A completed current W-9 from the entity hosting the display; and
- A completed Display Agreement from the entity hosting the display.

Field Operations (or designee) will review, accept, or reject the package. Once accepted, the package will flow to the requestor's manager.

Supervisor

The Supervisor (or designee above the requestor level) reviews and approves the product display request only after receiving the complete request package. The Supervisor (or designee) reviews all documentation and independently judges whether the product display is consistent with Bayer's policies. If appropriate, the Supervisor (or designee) approves and then forwards the request to Field Operations.

If the Supervisor (or designee) does not approve the request, they inform the Requestor that the proposed request has been denied.

Law, Patents and Compliance Review

The LPC Department reviews and approves display or exhibit requests only after receiving the complete request package and the expense is greater than $5,000. The LPC Department reviews all documentation and makes an independent judgment as to whether the requested fees are reasonable, and the request is consistent with Bayer's policies. If appropriate, the LPC Department approves the request and generates a written agreement to be signed by all parties.

Law, Patents and Compliance Review of Focus Arrangements (Interaction with HCPs and HCOs)

For all product display and exhibit requests involving payments to actual or potential Bayer customers, the LPC Department generates a written agreement that meets the requirements for the arrangements, or if a contract is provided, reviews the contract to ensure that it meets those same requirements. The written agreement must be signed by all parties to the arrangement. It must include a certification by the parties that they shall not violate the Anti-Kickback Statute concerning the performance or activities related to the product display. The LPC Department evaluates whether the proposed arrangement satisfies the requirements of the Anti-Kickback Statute and assesses compliance with the relevant Safe Harbor(s). The reviewing attorney must document that this review and assessment was conducted, their name, and the date it was conducted.

The LPC Department confirms whether the proposed payment represents fair market value. The methodology used to determine fair market value will be based on information in a database of fair market values or other relevant sources available to Bayer. Any deviation from the fair market value

methodology and the rationale for such deviation must be approved by the Bayer Vice President and Head, U.S. Office of Compliance (or designee) and documented and maintained in the LPC Department.

Proof of Service

The Requestor of the arrangement must confirm that they conducted the display or exhibit. The Requestor formally confirms proof of service by proving attendance at the event with the product display by completing the Proof of Service Exhibits Form. If the Requestor is unable to confirm this (*e.g.,* Requestor was unable to attend due to illness), the Requestor of the arrangement must document why the event did not occur.

// 19. Corporate Memberships

Bayer participates in corporate memberships with various trade, distribution, medical, patient and scientific organizations, as well as legislative policy groups and community organizations, to foster increased understanding of scientific, clinical, or healthcare issues that contribute to the improvement of patient care, including support for advocacy groups and/or Bayer's goodwill in the community.

Scope

Trade, distribution, medical, patient and scientific organizations (*e.g.,* American Society of Clinical Oncology (ASCO), Kidney Cancer Association, Hemophilia Federation of America, American College of OB&GYN (ACOG), International Society of Pharmaceutical Engineering (ISPE), HealthCare Distribution Management Association (HDMA)), as well as legislative policy groups, may require payment of a fee as a condition of membership. To the extent Bayer wishes to become a member of such an organization, it is Bayer's policy to establish these memberships for the Corporation or Division and not for individual Bayer employees.

Legislative policy groups offer Bayer relevant industry information, provide Bayer visibility within the pharmaceutical industry, and promote goodwill within organizations that maintain a political voice. Membership in medical and patient organizations allows Bayer to support the organization's educational and advocacy programs and participate in membership benefits. Membership benefits vary depending on the organization and may include allowing Bayer to attend educational meetings and to interact with fellow attendees such as healthcare professionals and/or patients. This policy does not cover an individual Bayer employee's membership in professional organizations for the individual's professional growth and awareness, such as the National Association of Accountants, National Association of Pharmaceutical Sales Representatives, Medical Marketing Association, etc. Individual professional organization memberships must be submitted through Concur T&E upon your supervisor's approval.

This policy does not cover medical education grants or charitable contributions Bayer may provide to a patient advocacy group or medical organization. Such payments must comply with Policy and Procedure, "Medical Education Grants (Including Continuing Medical Education)," and Policy and Procedure, "Related Charitable Contributions (other than Free Bayer Products)," respectively. Payment for a corporate membership/partnership is not a charitable contribution.

Requirements

An organization may solicit membership through a website, e-mail, or paper mailing, or Bayer may seek out an organization and request to become a member. The organization should focus on increasing understanding of scientific, clinical, or healthcare issues that improve patient care, including support for advocacy groups and/or Bayer's goodwill in the community. Membership in organizations primarily consisting of healthcare professionals offered to Bayer, must be open to other pharmaceutical or biotech companies. Membership fees cannot be paid to Bayer Pharmaceuticals customers, entities controlled or legally affiliated with Bayer Pharmaceuticals customers or other entities that may purchase, order, refer, use, prescribe, or recommend Bayer's pharmaceutical products, such as private practice groups, managed care organizations, pharmacy benefits managers, or hospitals. Paying membership fees to any organization or basing the level of membership/partnership selected (*e.g.,* platinum, gold, silver) may not be contingent on the purchase of Bayer pharmaceutical products or used as a price term. It is Bayer's policy to pay fair market value for corporate memberships. Thus, Bayer will pay the same fee as other corporate members for the

level or type of membership. The organization has sole control over the membership fees paid by Bayer. The membership must be for a Bayer Division or the Corporation (Bayer U.S., LLC), not an individual employee. Individual Bayer employees may attend the organization's events to gain knowledge of the topic, interact with fellow attendees, demonstrate Bayer's general support for the advocacy effort and/or the organization's mission, etc.

Procedures for Approvers

Requestor of Arrangement

The Bayer "Requestor" must be entitled to complete the "Bayer Certification for Corporate Membership Form." Administrative Assistants and other employees in clerical support positions cannot legitimately certify the points listed on the certification form and must not sign as the Requestor.

The Requestor must:

- Complete the "Bayer Certification for Corporate Membership" form.
- Generate an internal spending request by completing an Internal Payment Demand (IPD).
- Include any supporting documentation.
- Forward the completed payment request package to the Supervisor.

Supervisor

The Supervisor reviews all documentation and makes an independent judgment on whether the Corporate Membership is consistent with Bayer's policies. If appropriate, the Supervisor approves by signing the "Bayer Certification for Corporate Membership" and "Internal Payment Demand "and forwards both documents to the U.S. Government Relations Department.

If the Supervisor does not approve the request, they inform the Requestor that the proposed request has been denied.

U.S. Government Relations Department

The U.S. Government Relations Department reviews all documentation and makes an independent judgment on whether the Corporate Membership is consistent with Bayer's policies. It also confirms that the membership request does not duplicate an existing membership with the same organization. If appropriate, the U.S. Government Relations Department approves by signing the "Bayer Certification for Corporate Membership" form and "Internal Payment Demand" and forwards both documents to the LPC Department. If the U.S. Government Relations Department does not approve the request, it informs the Requestor that the proposed request has been denied.

Law, Patents and Compliance Review

The LPC Department reviews all documentation and independently judges whether the contribution is consistent with Bayer's policies. If appropriate, the LPC Department approves by signing the "Bayer Certification for Corporate Membership" form and "Internal Payment Demand" and forwards both documents to the Accounting Department.

Form: Bayer Certification for Corporate Membership Fees

Name of Organization:

_____

Amount of Membership Fee $:

_____

Indicate by check mark whether the following apply:

____The organization's primary mission is to increase understanding of scientific, clinical, healthcare or community issues that contribute to improving consumer/patient care or consumer/patient advocacy.

____Membership in this organization is for Bayer and not an individual employee.

____The membership fee is not being paid to a customer or other entity that can purchase, prescribe, or recommend Bayer products.

____The organization offers other corporations the same membership or membership level for the same fee.

____The organization, not Bayer, controls the disbursement of the membership fees.

____The membership fees are not charitable contributions or medical education grants.

____The membership fee is not contingent on the price or purchase of Bayer products.

____The membership fee is not contingent on lobbying activities on behalf of Bayer.

____To the best of my knowledge, the information contained in this certification form is true.

Requestor Certification

Printed name: _____ Date: _____ Signature: _____

Supervisor Certification and Approval

Printed name: _____ Date: _____ Signature: _____

Government Relations Certification and Approval

Printed name: _____ Date: _____ Signature: _____

Law, Patents and Compliance Certification and Approval

Printed name: _____ Date: _____ Signature: _____

// 20. Healthcare related Charitable Contributions (other than Free Bayer Products)

The Physician Payments Sunshine Act requires that any transfer of value given to an HCP, teaching hospital and/or all employees of a teaching hospital must be reported to the Centers for Medicare & Medicaid Services (CMS). Employees, contractors, consultants, and agents are responsible for reporting accurate, complete, and timely data to applicable Bayer systems, as this is the data Bayer will report to CMS.

Bayer provides charitable contributions to support legitimate professional, patient and scientific organizations that are registered as tax-exempt under section 501(c)(3) of the Internal Revenue Code. The requesting organization's mission should be for independent scientific and educational purposes that contribute to improving patient care, education or advocacy. All requests must be unsolicited, with no Bayer employee or contractor involvement. Bayer employees and contractors must disclose memberships and Board positions in the electronic Conflict of Interest system: go/USConflictofInterestDisclosureSystem. Provision of charitable contributions can implicate various laws, such as the Anti-Kickback Statute and the False Claims Act. This policy is designed to enable Bayer to provide legitimate philanthropic contributions in a manner that does not create an appearance of impropriety contributions in a manner that does not create an appearance of impropriety.

Scope

A charitable contribution is anything other than free product provided to an IRS tax-exempt charitable organization, for which Bayer does not expect to receive anything of value in return. Charitable contributions can be monetary and non-monetary. Bayer will only consider unsolicited requests from charitable contributions for 501C (3) and will not support organizations that discriminate based on race, color, creed, gender, gender identity, sexual orientation, or national origin. Furthermore, Bayer will not make charitable donations to individuals, political parties or causes, or religious groups for religious purposes. In addition, it is Bayer's policy not to provide charitable donations to physicians, physician practice groups or any organization that may be considered a direct purchaser of our products or to non-profit entities controlled by or affiliated with physicians, physician practice groups or organizations that may be viewed as a direct purchaser of our products.

It is Bayer policy not to provide charitable donations to Bayer customers or potential customers (*e.g.,* hospitals, clinics, of any Bayer pharmaceutical product or physician practice groups, medical schools, or to non-profit entities controlled by or affiliated with Bayer customers or potential customers (*e.g.,* hospital foundations, foundations run by physician practice groups) of any Bayer pharmaceutical product or physician practice groups, except in the limited circumstances referenced above. Requests are only for U.S. organizations; for non-U.S. organizations, you must contact the local country Compliance Officer.

This policy does not cover the provision of free Bayer product for charitable causes. All contributions of free product must comply with Policy and Procedure, "Providing Free Product for Charitable Purposes," in this booklet.

It is crucial to determine whether a request for funding support should be processed as a charitable contribution, corporate sponsorship or medical education grant. The terminology used by the entity requesting the funding (*e.g.,* "charitable contribution," "grant") is not the determining factor because organizations may submit funding requests using inconsistent or incorrect terminology.

The key factors are the type of entity requesting the funding (*e.g.,* non-profit, patient organization) and the focus of the event or activity (*e.g.,* education or fundraising).

- *Charitable donation* is funding provided to a non-profit organization to support the organization's activities where Bayer does not receive anything of value in return.
- *Sponsorship* is funding provided to support the activities of a professional, medical or patient association or organization where Bayer receives something of value, such as banners or signage at a conference, an opportunity to advertise in the organization's Publication, recognition of being a sponsor of the event or the primary purpose of the event/activity is fundraising/charity with a tangible benefit (*e.g.,* seats at a gala, tickets to an event). The sponsorship opportunity is offered to other similarly situated industry members, not just Bayer.
- *Medical education grant* is funding to support an event whose primary focus is educating the HCP participants/attendees.

The Company spending policy is designed to allow Bayer to take advantage of appropriate IRS tax deductions.

Key Characteristics:

Charitable Contributions vs. Corporate Sponsorships vs. Education Grants

Characteristics	Charitable Contributions	Sponsorships	Education Grants
Promotional in nature	No	Maybe	No
Payee must be a 501(c)(3) or other tax-exempt organization	Yes	No	No
Bayer receives something of value in return	No	Yes	No
Payment can be made to an individual HCP or private practice group	No	No	No
Tickets or invitations received as a result can be offered to physicians or other customers	No	No	No
Sales and Marketing Involvement	No	Maybe	No

The organization requesting funding must submit the request for a charitable contribution via the website: https://www.grants-contributions.bayer.com/home/contributions.

Exclusion of Sales and Marketing Personnel

Under no circumstances may Sales or Marketing personnel engage in discussions, negotiations or unsolicited requests with an organization for the support of charitable contributions for legitimate professional, patient and scientific organizations, community organizations within a Bayer business community affiliated with, or potentially affiliated with, any Bayer pharmaceutical products or any other charitable events that directly benefit patients. These are all considered charitable contributions under Bayer's U.S. Pharmaceuticals Compliance Policies and Procedures. In addition, Sales and Marketing may not be included in any communication regarding the status of a request. If Sales or Marketing is approached by an organization regarding a charitable contribution, they are to direct the organization to the grants and contributions website.

Requirements

Charitable contributions are permitted only if they meet all of the following requirements:

- The contribution is intended solely for charitable purposes;
- Bayer receives nothing of value in return other than an acknowledgment of Bayer's funding by the charitable organization;
- The recipient is a qualified 501(c)(3) or otherwise IRS tax-exempt charitable organization that is not a Bayer customer (except in the limited circumstances referenced above) or physician practice group, or an organization controlled by or affiliated with a Bayer customer or physician practice group; and
- The required tax-exempt letter for the submission of a charitable contribution has been provided.

A charitable contribution is **NOT** permitted if it is any of the following:

- Intended as a price term or offered in place of a price concession.
- Contingent on the purchase of or recommendation to purchase any Bayer pharmaceutical product.
- Intended to encourage the recipient to order, prescribe, or recommend Bayer pharmaceutical products or to reward the recipient for doing so.
- Made at the request of a healthcare professional in their individual capacity (*e.g.,* a request by a physician to support their favorite charity).
- Intended as payment for services or goods.
- Provide a benefit to Bayer.

Sales and marketing involvement in the solicitation, review or approval is prohibited, resulting in automatic denial.

Any questions from a customer regarding a charitable contribution request must be addressed to the Bayer Donations Manager.

Procedures

Requestor

The requesting organization must submit all Charitable Contribution requests electronically. The requesting organization shall electronically input all required charitable contribution information and attach a copy of its IRS 501(c)(3) determination letter indicating its status as a tax-exempt charitable organization. Additional backup documentation (*e.g.,* agenda, budget, W-9) may also be required. The requesting organization is responsible for submitting all documentation related to charitable contributions.

Under **NO** circumstances will the LPC Department accept a charitable contribution request after the event has occurred.

Donations Manager

The Donations Manager will first review the Charitable Contribution request. The Donations Manager will review for whether:

- The request is to support independent scientific and educational purposes that contribute to improving patient care, education or advocacy.
- The support request is within the budget.
- The support request is aligned with Bayer's strategy, community, and therapeutic focus.
- The request will be used solely for charitable purposes, and Bayer expects to receive nothing of value in return.
- The request is compliant with this policy.

If the request is deemed complete, compliant and within budget and strategic plan, it will be sent to be reviewed and approved by Legal.

If the Donations Manager finds the request incomplete after attempting to obtain appropriate documentation, they will inform the requestor of the denial of the request.

Law, Patents and Compliance Review

LPC reviews all charitable contributions and for those requests that are with interactions with HCPs and HCOs, the Law, Patents and Compliance attorney participating on the Charitable Contribution Review Committee must verify that the letter of agreement contains a certification by the parties that the parties shall not violate the Anti-Kickback Statute for the performance or activities related to the contribution.

The attorney also evaluates whether the proposed arrangement satisfies the requirements of the Anti-Kickback Statute and assesses compliance with relevant Safe Harbor(s). The reviewing attorney must document that this review and assessment was conducted, their name, and the date it was conducted.

The attorney also confirms whether the contribution amount represents fair market value in that the proposed amount is fair and reasonable and represents support for necessary expenditures based on the nature and the extent of the event for which the contribution requestor seeks support. Any deviation from the fair market value methodology and the rationale for such deviation must be approved by the Vice President and Head, U.S. Office of Compliance, documented and maintained in the LPC Department. The charitable contribution amount may not depend upon or be based on the value or volume of referrals from the charitable contribution recipient.

Donations Manager Post-Approval Documentation

An email documenting the decision will be provided to the requesting organization.

// 21. Medical Education Grants (Including Continuing Medical Education)

The Physician Payments Sunshine Act requires that any transfer of value given to an HCP, teaching hospital and/or all employees of a teaching hospital must be reported to the Centers for Medicare & Medicaid Services (CMS). Employees, contractors, consultants, and agents are responsible for reporting accurate, complete, and timely data to applicable Bayer systems, as this is the data Bayer will report to CMS.

This Policy describes the appropriate use of grants to fund medical education activities that foster an increased understanding of scientific, clinical, or healthcare issues that contribute to improving patient care. Bayer's policy conforms to the HHS-OIG Compliance Program Guidance for Pharmaceutical Manufacturers, the AdvaMed Code of Ethics, the PhRMA Code, ACCME standards for commercial support, other accreditation agencies, and relevant industry guidance. Bayer prohibits offering a medical education grant to encourage recipients to prescribe, purchase, order, use or recommend Bayer pharmaceutical product(s). In addition, if medical education grants were to be provided as price terms or in place of a price concession, they could affect the accuracy of the prices reported to the government, which could potentially cause Bayer to violate the Medicaid Rebate Statute or the False Claims Act.

Definition of Medical Education Grant

Bayer may provide funding for activities associated with educational conferences, continuing education (CE), continuing medical education (CME) programs, or professional meetings if sponsored by an organization other than Bayer and will contribute to improving patient care. An accredited medical organization must sponsor all CE/CME programs. All medical education grants to the military must be provided through the Henry M. Jackson Foundation for the Advancement of Military Medicine (Jackson Foundation) or similar third-party organizations set up to receive grants on behalf of the Department of Defense.

Medical education grants may only be made to an organization, such as a hospital, medical professional society, conference sponsor or continuing medical education organization. Medical education grants may not be provided to individuals or private physician practice groups. The organization may use the grant funds for overall program expenses or specifically for speaker(s), meal(s), reception, etc. Grant funds cannot be used to offset the costs not directly related to the educational program (*e.g.,* routine office expenses), nor can they be used for expenses of attendees. A grant must never be made if one purpose of the grant is to provide a financial inducement for dispensing, recommending or ordering Bayer's pharmaceutical products, to encourage off-label use or to reward referrals for Bayer pharmaceutical products.

Bayer may not directly offer financial assistance to permit medical students, residents, fellows, and other healthcare professionals in training to attend major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations. The CE/CME provider or training institution may include such expenses in its request for financial support, and only the CE/CME provider or the training institution selects the individuals to attend the program.

It is essential to determine whether a request for support is a charitable contribution, corporate sponsorship, or medical education grant. The terminology used by the entity requesting the funding (*e.g.,* "charitable contribution," "grant") is not the determining factor because organizations may submit funding requests using inconsistent or incorrect terminology.

The key factors are the type of entity requesting the funding (*e.g.,* non-profit, patient organization, hospital) and the focus of the event or activity (*e.g.,* education, fundraising). For example:

- *Charitable contribution* is funding provided to a non-profit organization to support the organization's activities where Bayer does not receive anything of value in return.
- *Sponsorship* is funding provided to support the activities of a professional, medical or patient association or organization where Bayer receives something of value, such as banners or signage at a conference, an opportunity to advertise in the organization's publication, recognition of being a sponsor of the event or the primary purpose of the event/activity is fundraising/charity with a tangible benefit (*e.g.,* seats at a gala, tickets to an event). The sponsorship opportunity is offered to other similarly situated industry members, not just Bayer.
- *Medical education grant* is funding to support an event whose primary focus is educating the HCP participants/attendees.

Key Characteristics:

Charitable Contributions vs. Corporate Sponsorships vs. Education Grants

Characteristics	Charitable Contributions	Sponsorships	Education Grants
Promotional in nature	No	Maybe	No
Payee must be a 501(c)(3) or other tax-exempt organization	Yes	No	No
Bayer receives something of value in return	No	Yes	No
Payment can be made to an individual HCP or private practice group	No	No	No
Tickets or invitations received as a result can be offered to physicians or other customers	No	No	No
Sales and Marketing Involvement	No	Maybe	No

Exclusion of Sales and Marketing Personnel

Under no circumstances may Sales or Marketing personnel engage in discussions, negotiations or unsolicited requests with a grantee, including a CME provider, for the support, design or development of a medical education program supported by Bayer or in any way seek to influence the program's content. The Grant Review Committee is responsible for the review and approval of all medical education grants (including CME) within Bayer. In addition, Sales and Marketing may not be included in any communication regarding the status of a request. If Sales or Marketing is approached by a customer regarding a medical education grant, they are to direct the customer to the grants and contributions website or the customer service telephone number (1-888-84-Bayer or 1-888-842-2937).

Accredited CE/CME Programs Supported by Bayer

Continuing Medical Education (CME) programs are peer-to-peer educational activities sponsored by independent, third-party organizations accredited by the Accreditation Council for Continuing Medical Education (ACCME). Continuing Education (CE) programs may be accredited through other third-party accreditation organizations such as the American Commission on Pharmacy Education (ACPE pharmacy continuing education accreditation) or the American Nurse Credentialing Center's Commission on Accreditations. The purpose of CE/CME is to enhance the healthcare professional's ability to care for patients, and such programs must be independent, objective, balanced, and reflect scientific rigor in content development. Examples of programs that can be accredited for CE/CME include:

- Medical society meetings
- Medical school symposia
- Speaker programs sponsored by an institution or other appropriate third-party intermediary
- Audio conferences
- Webcasts and CD-ROMs containing CE/CME programs

To remain independent, the sponsoring organization must retain sole responsibility for and control over the selection of content, faculty, attendees, educational methods and materials for the CME program or scientific meeting. Accreditation for CME credit adds additional evidence that the program is independent of commercial influence. Bayer-supported educational events must conform to the ACCME and/or other applicable accreditation entities' guidelines (such as the ACPE).

Under an approved and signed contract (or letter agreement), Bayer may provide a medical education grant to support CME programs sponsored by accredited medical providers (*e.g.,* ACCME). The contract must require that the CME provider disclose the following information to all program participants:

- Bayer's program funding and any significant relationships between the vendor and Bayer;
- Financial or other relationships between individual presenters or moderators and Bayer;
- Any limitations on the information presented at the programs, such as data representing ongoing research, interim analysis, preliminary data or unsupported opinion;
- When a Bayer pharmaceutical product or a competitor's product is to be the subject of substantial discussion, the data must be objectively selected and presented. Both favorable and unfavorable information about the product must be fairly represented and any discussion of the prevailing body of scientific information on the product and of reasonable, alternative treatment options must be balanced; and
- Any unapproved uses of Bayer pharmaceutical product(s).

The following criteria also apply to CE/CME programs:

- Funds from Bayer will be provided in the form of a medical education grant made payable to the accredited provider or joint sponsor to support the programming.
- Bayer representatives may not distribute invitations to a Bayer-supported CME event to healthcare professionals on their own. If the CME provider requests Bayer's help in writing (*e.g.,* by letter) to distribute supplemental invitations either by digital or personal delivery, Bayer may distribute these invitations on the CME provider's behalf. Product detailing of any kind is not permitted during the distribution of these invitations. For a digital version of the invitation, you must use Veeva iRep email, and neither you nor anyone else on your team can send a promotional email on the same day. Furthermore, once the email has been sent, you are not permitted to access Veeva iRep to determine whether or not the email has been opened. Such invitations may only be distributed to healthcare professionals who can reasonably prescribe or otherwise use the product for an approved use.

- The focus of any CME program supported by Bayer must be the scientific and medical program. Meals provided with the program must always be modest, reasonable, and secondary to the educational activity. They must not be used to influence attendance. Bayer may not provide meals directly at a CME event. At its discretion, the CME provider may apply the financial support Bayer provides to offer meals to all program participants.
- Speakers at a Bayer-supported CME program must disclose any current or previous relationship with Bayer (*e.g.,* consultant, paid investigator, Bayer Speaker's Bureau member, etc.).
- Commercial exhibits may not interfere with the CME activities. No promotional materials may be displayed or distributed in the same room as the CME program before, during or after the program. No promotional activities may occur in the CME room, and no promotional materials may be displayed, or sales activities conducted within the "obligate path" that attendees must use to enter or exit the room where the CME activity is taking place. Although not explicitly defined by regulation, Bayer U.S. Pharmaceuticals interprets "obligate path" to include paths from the main entry of a hotel to the meeting room or the way to a restroom.

Bayer will not directly provide compensation or reimbursement for registration, travel, lodging or personal expenses to attendees of any CME event. However, pursuant to the PhRMA and AdvaMed Codes, Bayer may provide support to the CME provider, which, at its own discretion, can use the funds to reduce the overall CME registration fee for all participants.

Bayer Involvement in Medical Education Grants

The following applies to any educational program including, but not limited to, CE and CME activities, which includes or is reasonably expected to include information on unapproved uses of Bayer pharmaceutical products, regardless of whether or not the event is sponsored in whole or in part by Bayer.

1. Bayer Attendance

Medical Science Liaisons may attend such programs. Sales and Marketing personnel may not participate in such programs unless the request has been approved, in advance of the program, by their manager to ensure the topics of sessions are appropriate for the employee's position. Approval is based on the identified need for medical education.

Bayer representative's attendance is for educational purposes only. No discussion of any Bayer products is permitted during, immediately before, or after the educational event. These educational events are NOT opportunities for marketing or customer development. Bayer representatives attending such programs may not ask or "plant" questions in the audience, which will likely lead to off-label discussion.

2. Bayer Independence

Bayer U.S. Pharmaceuticals employees may NOT be involved in the following activities associated with any program supported, even partially, by medical education grants from Bayer:

- Selecting or recommending the audience; or
- Selecting or recommending the content, faculty, educational methods, materials, or venue.

3. Promoting Bayer's pharmaceutical products

- Bayer employees permitted to attend an educational program may not engage in formal or informal promotional activities inside or outside the meeting room(s).
- Bayer employees who are not attending the program may conduct appropriate promotional activities outside program meeting rooms, such as at an adjacent exhibit, provided that exhibit and display opportunities at the event have also been provided by the event sponsor to pharmaceutical companies other than Bayer.
- If the program includes events related to an approved use of a Bayer pharmaceutical product and the Event sponsor has provided the opportunity to multiple pharmaceutical companies to display at the event, Bayer employees may display or exhibit at the program. For more information, see Policy and Procedure, "Displays and Exhibits."

Acceptable Medical Education Grants

In summary, a grant is permitted only if:

- The grant is provided to foster an increased understanding of scientific, clinical, or healthcare issues that contribute to the improvement of patient care;
- It will be used solely for legitimate expenses related to the education or training of healthcare professionals or patients in connection with the improvement of patient care;
- It is awarded to an organization and not an individual or private practice group;
- The organization, not Bayer, controls the disbursement of the funds;
- The responsibility for and control over the selection of content, faculty, educational methods, materials, and venues belongs to the organizers of the conference per their guidelines; and
- The grant is provided in response to an unsolicited request that:
    - Describes the purpose/intended use of the grant or reference other documents attached, such as a brochure, pamphlet, flyer, agenda, or memo that describes the purpose/intended use of the grant;
    - Confirms that the grant will be used for educational purposes;
    - Confirms that the grant will not be used for general overhead or the expenses of attendees;
    - Acknowledges that Bayer may audit or review the use of the grant;
    - Provides a detailed budget describing the planned usage of the requested grant; and
    - Confirms that Bayer funding and relationship with program provider, presenters, or moderator will be disclosed to attendees.

Unacceptable Medical Education Grants

A grant is not permitted if it is any one of the following:

- Intended as a price term or offered in place of a price concession;
- Meant to encourage off-label use;
- Contingent on the purchase of or recommendation to purchase Bayer products;
- Intended to encourage the recipient to order, prescribe, or recommend Bayer products or reward or compensate the recipient for so doing;
- Made at the request of a healthcare professional in their individual capacity (*e.g.,* a request to fund their "pet project"); however, a healthcare professional may request a grant in their official capacity, such as the head of a hospital department;
- Made in return for anything of value provided to Bayer by the recipient, with the exception of disclosure in program materials that Bayer funds the program;
- Provided for the purchase of equipment, educational books, or other items of value;

- Provided to fund salaries of hospital nurses, residents, or other healthcare professionals, or any other routine administrative costs of a healthcare professional (except for specific fellowship programs);
- Provided to pay for activities that should be covered by fee-for-service contracts as described in Policy and Procedure, “Fee-For Service Arrangements”;
- Conditioned on the receipt of exhibit or display opportunities; or
- Not submitted through the Bayer website.

Invitations for Display Space at the Educational Event

For displays involving customer payment, the display and medical education grant must be processed as separate transactions to ensure that appropriate Focus Arrangements Procedures are followed. For displays not involving customers (such as those at medical society meetings), there may be limited situations where an organization submits a request for a medical education grant that also offers Bayer the opportunity to display at the event. These activities must be processed as separate transactions by the requesting entity. However, there may be limited occasions where it may not be possible to separate the product display fee in the documentation submitted by the requesting organization. In these situations, the Bayer Grant Review Committee will make the appropriate determination regarding whether the grant will be approved and/or whether Bayer may display at the event.

Procedures

All medical education grant (including CE/CME) requests must be submitted to the Bayer medical education grants website.

The initial request must:

- Describe the purpose/intended use of the grant or reference other documents attached, such as a brochure, pamphlet, flyer, budget, agenda, study protocol, or memo that describes the purpose/intended use of the grant. It is not acceptable to list only a generic description (*e.g.,* “medical education grant”) as the purpose of the expense;
- Confirm that the grant will be used for educational purposes or to support a medical education program; and
- Confirm that the grant will not be used for general overhead or the expenses of attendees.

Requestor

All medical education grant requests will be received electronically from the requestor through the Bayer website. The requestor (or institution-designated staff member) must input all required medical education grant information electronically. Additional backup documentation is also required (*e.g.,* agenda, budget, learning objectives). The requestor is responsible for providing all medical education grants-related documentation. Upon approval of the grant request from the Grant Review Committee, a signed letter of agreement is required to distribute funds.

Under **NO** circumstances will a medical education grant request be accepted or reviewed after the event has occurred.

Grant Manager Initial Review

The Grant Manager will review all grant requests submitted to the Bayer website and determine whether the proposed grant request is a potential interaction with HCPs and HCOs.

A grant request should be considered an interaction with HCPS and HCOs if the potential recipient of the grant is a customer or other source of sales or referrals of Government Reimbursed Products.

Questions regarding whether a grant request may constitute an Interaction with HCPs and HCOs (Focus Arrangement) must be directed to the LPC Department, which makes the final determination whether the grant is an Interaction with HCPs and HCOs (Focus Arrangement).

If the grant request is deemed complete, within budget and brand plan, it will be placed on the agenda for review by the Grant Review Committee at the next scheduled meeting.

If the Manager finds the request incomplete after attempting to obtain appropriate documentation, they will inform the requestor that the request is denied due to insufficient documentation.

Grant Review Committee

The Grant Review Committee is comprised of members from Medical Affairs, Medical Education, Field Medical Affairs, and LPC. Sales and Marketing personnel do not participate in the Grant Review Committee; however, they may provide a brand plan for the subject matter of grants to be considered.

The Grant Review Committee generally meets monthly to review medical education grant requests from a scientific, educational, regulatory and legal perspective. At the Grant Review Committee meeting, members review grant requests consistent with the following:

- Each Committee member certifies that, to the best of his/her knowledge, there are no legal or compliance issues prohibiting Bayer's approval of the grant request (*e.g.,* no conflict with government or industry guidelines or Compliance Policies and Procedures).
- The grant will support medical research, patient education, or other activities that foster an increased understanding of scientific, clinical or healthcare issues that contribute to improving patient care.
- The request is within the budget for each business area.
- The request is aligned with Bayer U.S. Pharmaceutical's business strategy.
- The funds will be used solely for legitimate expenses related to educating or training healthcare professionals or patients to improve patient care.

If the Grant Review Committee needs additional information to determine whether to approve the grant request, it will approve, reject, or table the request in anticipation of receipt of further clarification or information in conformance with these Policies and Procedures. Approval of the request requires consensus among the voting members present at the Grant Review Committee meeting.

Law, Patents and Compliance Review of Focus Arrangements (Interactions with HCPs and HCOs)

For all grant requests that are Interactions with HCPS and HCOs, the LPC attorney participating on the Grant Review Committee must verify that the agreement contains a certification by the parties that the parties shall not violate the Anti-Kickback Statute concerning the performance or activities related to the grant. The attorney also evaluates whether the proposed arrangement satisfies the requirements of the Anti-Kickback Statute and assesses compliance with relevant Safe Harbor(s). The reviewing attorney must document that this review and assessment was conducted, their name, and the date it was conducted.

The LPC Department also confirms whether the grant amount represents fair market value in that the proposed amount is fair, reasonable and represents support for necessary expenditures based on the nature and the extent of the event for which the grant requestor seeks support. Any deviation from the fair market value methodology and the rationale for such deviation must be approved by the Vice President and Head, U.S. Office of Compliance (or designee) and documented and maintained in the LPC Department.

The grant amount may not depend upon or be based on the value or volume of referrals or expected referrals from the grant recipient.

If the reviewing attorney is absent at the Grant Review Committee meeting, the attorney may conduct the required review later. However, this review must be completed before the grant is approved and payment is made.

Grant Manager Post-Meeting Documentation

The Meeting Summary will be prepared for each Grant Review Committee meeting. The Meeting Summary will include whether or not the grant request was 1) approved (indicating amount), 2) rejected, or 3) tabled for receipt of further clarification or information or further discussion.

Following the meeting, the Grant Manager will provide a letter documenting the Grant Review Committee's decision to the grant requestor (or institution-designated staff member). The Grant Manager is responsible for updating the electronic system with the decision.

Grant Approval of Interactions with HCPs and HCOs

For approved grant requests that are interactions with HCPs and HCOs, the Grant Manager must send the grant recipient the approved Letter of Agreement, with a copy of Bayer's Code of Conduct and the attached Anti-Kickback Statute Policies and Procedures. These documents may be sent electronically or by hard copy and can be included as an exhibit to the Letter of Agreement or sent as separate documents. The Letter of Agreement must include a certification by the parties that the parties shall not violate the Anti-Kickback Statute concerning the performance of activities related to the grant. The Grant Manager must document that the documents were sent.

Proof of Service

The Grant Manager or other Bayer employee must be able to confirm the services or deliverables of the grant. Acceptable proof of performance includes a completed budget reconciled with the proposed budget, program evaluations, or a certification from the grant recipient that the program occurred or the grant funds were otherwise used for their intended purpose. The Letter of Agreement must permit Bayer to observe the services rendered or obtain proof of service.

Grant Approval of Arrangements

If the approved grant request is not a Focus Arrangement as determined by the LPC Department, the Grant Manager will send a Letter of Agreement to the requestor (or institution-designated staff member). The Requestor is responsible for returning a signed agreement to the Grant Manager.

// 22. Providing Samples and Device Evaluations at No Charge

Providing Samples

Bayer may offer product samples of Bayer pharmaceutical products to customers at no charge. The quantities of product samples provided must not exceed an amount reasonably necessary for the intended use of the samples. Providing product samples in violation of this policy is strictly prohibited.

The provision of product samples to customers must be documented in the program's system of record, either electronically or on paper. Such documentation must contain, at a minimum, the number of samples provided to each healthcare professional, lot numbers, the date the samples were provided and the healthcare professional's signature confirming the samples were requested and received, a valid state license number of the healthcare professional, name of the product and dosage strength. Sample requests mailed directly to a healthcare professional require a signed Acknowledgment of Content confirming receipt of the requested samples. Bayer's third-party vendor conducts annual physical inventories of drug samples in control of each representative and maintains records of such inventories. In addition, the third-party vendor performs signature verification to ensure accuracy. Therefore, the provision of samples must be recorded accurately. Guidelines (REGS-US03-SOP-000328) for dispensing product samples are available from the Sample Accountability Department.

Under **NO** circumstances is a sample to be given to a healthcare professional for personal use ("professional courtesy units" are prohibited). For immediate family and office staff, samples are only allowed if under medical care and they are a current patient of the HCP. Offering free samples to healthcare professionals for personal use potentially implicates the Anti-Kickback Statute if the offer aims to induce the professional to order or prescribe Bayer pharmaceutical products.
Recipients of product samples must be advised in writing that no product sample may be charged to any patient and that the entity may not submit a claim for reimbursement to Medicare, Medicaid, or any other public or private insurer for that sample. The packaging on all samples will read either: sample only-not for resale, sample only, sample not for sale or sample not for resale.

Product samples are not the same as charitable product donations. Samples are provided for patient or provider evaluation purposes only. Products provided as part of a patient assistance program or otherwise donated for a charitable purpose are considered a product donation, and the request must be processed as a request for a charitable product donation. For more information on product donations, refer to Policy and Procedure, "Providing Free Product for Charitable Purposes."

Federal Reporting Requirements

The Prescription Drug Sample Transparency Provision of the Patient Protection and Affordable Care Act of 2010 (PPACA) requires every pharmaceutical manufacturer and authorized distributor of record of an applicable drug to submit to the Department of Health and Human Services (HHS) for the preceding calendar year:

- The identity and quantity of drug samples requested.
- The identity and quantity of drug samples distributed.

Information submitted to HHS must be aggregated by:

- Name, address, professional designation, and signature of the practitioner requesting samples (or of any individual who makes or signs for the request on behalf of the practitioner).
- Any other information deemed appropriate by HHS.

Evaluation of Devices

Bayer's Radiology business may make a device product available without charge for evaluation for a standard 60-day period to a healthcare professional or facility to permit an evaluation of its use and functionality to determine whether to use or buy the product. Evaluations may not exceed 90 days without LPC's approval unless LPC has previously approved a specific evaluation program.

Device products may be made available for evaluation to healthcare professionals or facilities who do not currently use the specific product being evaluated or who use a prior version. If a department within a facility already uses a certain product and a different department expresses interest in evaluating that same product, the interested department may evaluate that product so long as all other evaluation requirements are met.

If the product is not purchased by the end of the evaluation period, it must be removed or deactivated immediately upon the conclusion of the evaluation. It is always the responsibility of the Bayer representative to track the location and status of evaluation equipment and remove or deactivate any equipment upon immediate conclusion of the evaluation.

Equipment – Equipment, such as injectors, may be provided for evaluation without transferring title only for a standard 30-day period or for a limited number of uses that are reasonable to permit an adequate evaluation of the equipment. The terms of the evaluation (including duration) must be in writing and include clear notice to the healthcare professional and/or facility that it may not seek reimbursement from or charge Medicare, Medicaid, any other health program, any insurer or patient for equipment and/or supplies provided at no charge by Bayer and that the person or facility using the evaluation equipment may have an obligation to notify government or private payors that the evaluation equipment was provided free of charge. The terms of the evaluation must be reflected in a written notification provided to the professional before or when the evaluation equipment is provided. The Bayer representative assigned to the account must make arrangements for promptly removing the equipment after the limited evaluation period unless the healthcare professional has agreed to purchase/lease the equipment. Equipment provided as a loaner or replacement for equipment that is not performing correctly or broken does not fall under the definition of "evaluation equipment."

Single Use/Consumables/Disposables – The number of single-use disposable products provided at no charge should be limited to a small number reasonably necessary for the healthcare professional's adequate evaluation of the disposables and related equipment. The procedures described above for a written notification must be followed.

At the time of publishing, Vermont and Oregon have established state laws regarding the reporting of samples provided. Please contact a member of LPC for more information and to find out whether any additional states have required such reporting since the publication of these policies.

// 23. Patient Protection and Affordable Care Act (PPACA) Transparency Requirement

Legislative, regulatory, and enforcement authorities aggressively pursue greater disclosure and transparency of financial relationships between HCPs, HCOs and pharmaceutical, biotech, medical device, and diagnostic companies. The Patient Protection Affordable Care Act (PPACA) sets forth the following transparency requirements applicable to Bayer:

- Pharmaceutical and device manufacturers must track payments and other transfers of value to "physicians" and "teaching hospitals"' and report this information to the federal government. This requirement is often called the "Physician Payment Sunshine Act" or the "Sunshine Act." Disclosures are due annually on the 90th day of each year, covering payments made in the prior calendar year and will be made available to the public through a searchable database.
- Pharmaceutical manufacturers also must track prescription drug samples distributed to practitioners. This requirement is called the "Prescription Drug Sample Transparency" provision in this policy. Under the Prescription Drug Sample Transparency provision, Bayer's disclosure report is due to the federal government no later than April 1. It covers prescription drug samples distributed during the preceding calendar year.

For U.S. government reporting requirements, an HCP is defined as a person who prescribes, purchases, supplies, recommends, administers or provides information about drugs or devices. In this context, this term has a broad application and includes, but is not limited to, licensed physicians, nurses, midwives, technologists, pharmacists, etc.

Each Bayer employee is responsible for accurately and completely capturing any transfers of value from HCP and HCO interactions to the Company in a timely manner. These steps are critical so that the Company can meet its obligations to submit accurate, complete and timely reports to the Federal government. Please consult your business's State Law Policies and Procedures governing payments to physicians and other healthcare professionals and entities, among other topics, to determine what payment information must also be disclosed in certain states.

Sunshine Act

The Sunshine Act broadly requires disclosure of payments and other transfers of value to "covered recipients" or to an entity or individual at the request of or designated on behalf of a "covered recipient" unless one of a limited number of narrow exceptions applies. Additionally, ownership and investment interests in the manufacturer held by physicians or their immediate family members must be disclosed unless the ownership or investment interest is in a publicly traded security and mutual fund. Furthermore, the Sunshine Act requires Bayer to report payments made to a covered recipient as part of an acquisition. The Aggregate disclosure to the federal Government is made annually on March 31. The information disclosed is publicly available on a searchable website on June 30 each year.

Covered recipients are defined under the Sunshine Act to mean certain U.S. teaching hospitals, U.S. licensed physicians, U.S licensed physician assistants, advanced practice registered nurses, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives unless the physician or other healthcare professional is a Bayer employee. The following information must be disclosed in connection with a reportable payment to a covered recipient:

- Name of the covered recipient
- Primary business address of the covered recipient
- For non-teaching hospital-covered recipients:
    - Specialty.
    - National Provider Identifier (NPI).
    - State professional license number(s) (for at least one state where the non-teaching hospital-covered recipient maintains a license) and the State where the license is held.
- Amount of the payment or other transfer of value.
- Date that payment or other transfer of value was provided.
- Form of payment or transfer of value (*e.g.,* cash or cash equivalent, in-kind items or
- services, stock, stock option, or any other ownership interest, dividend, profit or other return on investment).
- Nature of Payment or transfer of value, including but not limited to:
    - Consulting fee.
    - Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program. Examples of such other transfers of value include payments for:
        - Fees for services
        - Educational items
        - Food and beverages
        - Travel and lodging
        - Educational grants
        - Research and clinical trials
        - Royalties or licenses
        - Honoraria
        - Current or prospective ownership or an investment interest
        - Compensation for services as faculty or as a speaker for an unaccredited and non-certified continuing education program
        - Compensation for services as faculty or as a speaker for an accredited and certified continuing education program
        - Space rental or facility fees
    - Acquisitions.
- Product to which payment or other transfer of value relates (including whether it is related to marketing, education, or research specific to a product or disease).
- For drugs and biologics, applicable manufacturers must report the name under which the drug is or was marketed and the relevant National Drug Code(s) (NDC).

A limited number of transactions are excluded from the definition of a covered “payment or other transfer of value.” These are individual transfers of value generally under approximately $10 that cumulatively do not exceed approximately $100 during a calendar year. Bayer tracks all payments (transfers of value), and these cumulative amounts will determine if the spending on this individual or institution is reportable. CMS annually adjusts the allowable limit for individual transfers of value annually based on inflation.

Additional items tracked include:

- Product samples for patient use that are not intended to be sold;
- Educational materials (*e.g.,* clinical reprints) that directly benefit patients or are intended for patient use; and
- Short-term loans for a covered device unless the trial period exceeds 90 days.

Prescription Drug Sample Transparency Provision

The Prescription Drug Sample Transparency provision requires Bayer to disclose the quantity of drug samples by product name requested by and distributed to practitioners. The information is aggregated by name, address, professional designation, and signature of the practitioner requesting samples (or of any individual who makes or signs for the request on behalf of the practitioner). Disclosures are made annually to FDA on or before April 1st.

Please refer to Policy and Procedure “Providing Samples and Device Evaluations at No Charge” for more information on sample distribution. Also, guidelines for dispensing product samples may be obtained from the Sales Operations Department.

// 24. State Laws – Overview

Important Notice

Bayer policies must be followed. However, when state law is more restrictive than Bayer policies (*e.g.,* gift bans), Bayer employees must follow the more stringent state law requirements.

Key Abbreviations

- "HHS-OIG": United States Department of Health and Human Services - Office of Inspector General
- "OIG Compliance Guidance": HHS-OIG "Compliance Program Guidance for Pharmaceutical Manufacturers
- "PhRMA Code": Pharmaceutical Research and Manufacturers of America "Code on Interactions with Healthcare Professionals"
- "AdvaMed Code": Advanced Medical Technology Association Code of Ethics

// 25. State Laws – Data Collection

How Data is Collected

To capture the relevant data for federal, state and global reporting purposes, Bayer employees in pharmaceuticals must internally report all payments made to HCPs and HCOs.

Data is collected in a Data Repository System based on transactions recorded in SAP, Concur, Veeva, FA Upload, CyberGrants and other Bayer systems. Data from CROs, third-party vendors, and Bayer meeting planners are also uploaded into this repository.

It is the responsibility of each Bayer Pharmaceutical employee, contractor, consultant and agent to accurately and completely capture any transfers of value from HCP and HCO interactions to the Company promptly. These steps are critical so that the Company can meet its obligations to submit accurate, complete and timely reports to the Federal and State governments.

This section provides an overview of State Law Policies and Procedures governing payments to physicians and other healthcare professionals and entities, among other topics.

Compliance monitors and reviews all data to determine the payment information to be disclosed to each state.

Bayer Sponsored Meetings Planned through Third-Party Vendors or the Bayer Meeting Planners

The Bayer representatives responsible for planning a company-sponsored meeting must work with the third-party vendor to ensure that the vendor reports the required data to the Bayer representative. If data cannot be collected and reported, the Bayer representative is responsible for excluding from the invitee list all reportable healthcare professionals licensed in D.C. or any State with similar reporting requirements or spending limits.

Bayer representatives contracting with a third-party vendor for meeting planning services must also ensure that the vendor contract clearly states either that:

- Within one month (30 days) from the date of the payment, meal, travel or gift to a healthcare professional, the vendor will provide the required data to the Bayer representative or
- The vendor will exclude healthcare professionals licensed in D.C. or any State with similar reporting requirements or payment limits.

Physician Payments Sunshine Act Pre-emption

In light of the federal Physician Payments Sunshine Act's pre-emption of state law, payments reported under the federal Physician Payments Sunshine Act (such as those to physicians and teaching hospitals) are excluded from the state reporting requirements. However, payments to healthcare practitioners and healthcare organizations not covered by the federal Physician Payments Sunshine Act may be reportable under state law.

// 26. State Laws

// California

Compliance Program and Spending Limits

The State of California requires pharmaceutical companies to adopt a comprehensive compliance program (CCP) following the OIG Compliance Guidance. Pharmaceutical companies must include in their CCP policies for compliance with the PhRMA Code and the AdvaMed Code.

A manufacturer's compliance program must include annual dollar limits on business meals, gifts, and other items of value provided to medical or healthcare professionals licensed to practice in California following the PhRMA Code and OIG Compliance Guidance.

California law defines *medical or healthcare professional* as:

- A person licensed by state law prescribes drugs or medical devices for human patients;
- A medical student; or
- A member of a drug formulary committee.

Bayer has established an annual dollar limit of $2,500.

Exempt from this annual dollar limit are:

- Drug and device samples provided free of charge to physicians and healthcare professionals for free distribution to patients;
- Financial support for CME programs;
- Financial support for health education scholarships; and
- Fair market value payments for legitimate professional services a healthcare or medical professional provides. These include, but are not limited to, consulting fees, advisory board fees, and speaker fees.

Annual Declaration

Bayer must annually declare, in writing, compliance with its CCP and the CA state law.

Publication of Compliance Program and Declaration

California requires Bayer to make its CCP and written acknowledgment of compliance available to the public on its website and to provide a toll-free telephone number where a copy of the CCP and written declaration of compliance may be obtained (Bayer's number is 1-877-256-3562).

// Colorado

Drug Cost Disclosures & State Employee Gift Limitations

Drug Cost Disclosures

When providing information about a prescription drug to a licensed prescriber of controlled substances or prescription drugs in Colorado, a sales representative must provide that prescriber in writing the wholesale acquisition cost (WAC) of the prescription drug. If available, the sales representative must also provide the prescriber with the names of at least three generic prescription drugs in the same therapeutic class. If three generic prescription drugs are unavailable, the sales representative must provide the names of all generics available for prescriptive use. Bayer communicates these disclosures through an approved addition to iRep emails and approved forms made available to Bayer sales representatives in Colorado.

State Employee Gift Limitations

Colorado bans all state employees from accepting gifts and things of value that have a fair market value or aggregate actual cost of more than $75 per calendar year (as of 2023; this limit is re-evaluated every four years and is due to be re-evaluated in 2027). The prohibited items include “gifts, loans, rewards, promises or negotiations of future employment, favors or services, honoraria, travel, entertainment, or special discounts, from a person, without the person receiving lawful consideration of equal or greater value in return.” The ban is spelled out in Amendment 41 to the Colorado State Constitution, as are exceptions, which include, among other items, “unsolicited informational material, publications, or subscriptions related to the recipient's performance of official duties;” reasonable expenses for speakers; and the cost of admission, food, or beverages at an organization’s meeting, meal, or reception before which the recipient is a speaker in a scheduled program.

The $75 annual limit is for Bayer as an entity. Because of this, you must confirm whether a healthcare practitioner and that individual’s staff are employed by the State of Colorado before providing any meals or other items of value.

// Connecticut

Compliance Program, Manufacturer Registration, and Individual Sales Representative Disclosures

Compliance Program

Connecticut requires pharmaceutical and medical device manufacturers to adopt and implement a compliance program that is consistent with and contains, at a minimum, all the requirements prescribed in the PhRMA and AdvaMed Codes, as such codes were in effect on January 1, 2010. Additionally, pharmaceutical manufacturers' comprehensive compliance programs must follow the OIG Compliance Guidance.

Manufacturers are also required to conduct training and regular compliance program audits.

Failure to abide by these requirements could result in civil fines of up to $5,000.

Manufacturers Must Register with the State and Report All Pharmaceutical Sales Representatives

Effective October 1, 2023, Connecticut requires that all pharmaceutical manufacturers ("manufacturers") that employ pharmaceutical sales representatives register annually with the Connecticut Department of Consumer Protection and pay a $150 (as of 2023) annual fee.

Pharmaceutical sales representative is defined as any person, including but not limited to a sales representative who markets, promotes or provides information regarding a legend drug for human use to a prescribing practitioner (physician, APRN, physician assistant, etc.) and is employed or compensated by a pharmaceutical manufacturer.

Registrations expire annually on June 30th. On the original registration date and every year after that, the manufacturer must give the Connecticut Department of Consumer Protection a list of all individuals it employs as pharmaceutical sales representatives. Within two weeks of hiring a new pharmaceutical sales representative or leaving the manufacturer's employment, the manufacturer must report that personnel change to the Department of Consumer Protection. The Department of Consumer Protection will post each manufacturer's list on its website.

Beginning on July 1, 2024, manufacturers must annually report the following information for each registered employee:

- The aggregate number of contacts a pharmaceutical sales representative had with prescribing practitioners and pharmacists;
- The specialty of each prescribing practitioner and pharmacist with whom such pharmaceutical sales representative made contact;
- Whether product samples, materials, or gifts of any value were provided to a prescribing practitioner or such practitioner's staff in a prescribing practitioner's office or to a pharmacist; and
- An aggregate report of all free samples by drug name and strength.

Pharmaceutical Sales Representative Disclosures to Prescribers

At the time of each contact with a prescribing practitioner or pharmacist, every pharmaceutical sales representative marketing a drug for which a prescription is required must disclose, in writing,

- The list price of the drug at the time based on the dose and quantity of such the drug as described in the medication package insert and

- Information on the variation efficacy of the drug marketed to different racial and ethnic groups, if such information is available.

Bayer communicates these disclosures through an approved addition to iRep emails and approved forms made available to Bayer sales representatives in Connecticut.

Penalties for Failure to Properly Register or Disclose

Manufacturers who fail to register with the Department of Consumer Protection properly or whose pharmaceutical sales representatives fail to make the required disclosures to prescribers may be barred, suspended, or have conditions placed on their registration to operate in Connecticut and may be assessed a civil penalty of up to $1,000 for each violation.

// District of Columbia

Promotional Cost Reporting, Gift and Remuneration Prohibition, and Individual Licensure of Sales Representatives

Promotional Cost Reporting

Title III of the District of Columbia AccessRx Act of 2004 (the "Act") requires manufacturers of prescription drugs dispensed in the District of Columbia ("D.C.") that employ or use sales consultants in D.C. to report, on an annual basis (by July 1st of each year), the costs of marketing directed towards D.C. residents and persons and entities licensed to provide healthcare in D.C.

Reporting Requirements

Marketing to D.C. Residents

Each annual report must disclose the value, nature, purpose and recipient of advertising, marketing and direct promotion of prescription drugs to D.C. residents. For each reportable advertising expense, the report must specify, among other things, (1) the target audience (*e.g.,* the general public or prescribers); (2) the type of medium used (*e.g.,* radio, television, video, internet, magazine, newspaper, medical journal, direct mail, email, telephone, conference or other event), patient materials, or other printed material; and (3) the type of activity, (*e.g.,* advertising including direct-to-consumer and other advertisement production and placement), marketing, direct promotion, market research (including surveys), patient education (including materials such as disease management information), or materials/consulting to promote new uses of drugs; and (4) the dates of activity.

Marketing to D.C. Healthcare Professionals and Entities

The report must also disclose the value, nature of payment, form of payment, purpose and recipient, among other information, of the following expenditures (referred to as "gifts" by D.C.) on individuals and entities licensed to provide healthcare in D.C. (including healthcare professionals and persons employed by them in D.C., carriers, health plans and benefits managers, pharmacies, hospitals, nursing facilities, clinics, and other entities licensed to provide healthcare in D.C.):

- Educational or informational programs, including (i) support for medical education, (ii) printing costs and, if designed specifically for D.C. users, design costs of patient education and disease management materials, (iii) consulting fees and related expenses, (iv) fees, honoraria, and other payments for participation in speakers' bureaus and time speaking at or attending meetings, lectures, or conferences, (v) payments for writing articles or publications, (vi) charitable grants, and (vii) payments related to market research surveys and other activities in support of developing advertising and/or marketing strategies. Food, entertainment and gifts valued at more than $25, and anything provided at less than fair market value.
- Trips and travel.
- Product samples, except those intended for free distribution to patients.

Gifts to "physicians" and "teaching hospitals" must be reported to the federal Open Payments system and are, therefore, not required to be reported to the D.C. For Open Payments, a *physician* is defined as a Doctor of Medicine or Osteopathy, a Doctor of Dental Surgery or Dental Medicine, a Doctor of Podiatric Medicine, a Doctor of Optometry, or a Chiropractor. *Teaching hospitals* are defined as hospitals that received payment for Medicare direct graduate medical education (GME), inpatient prospective payment system (IPPS), indirect medical education (IME), or psychiatric hospital IME programs during the last calendar year for which such information is available.

Cost of Employees

The annual report must also disclose the aggregate cost of employees who engage in these advertising and promotional activities within D.C.

Exemptions for D.C. Reporting

The following expenses are exempt from these disclosure requirements:

- Marketing expenses of $25 or less per day and per healthcare provider or entity.
- Reasonable payments related to bona fide clinical trials.
- Scholarships and reimbursement of expenses for attendance at a significant educational, scientific or policy-making conference or seminar if the recipient is selected by the association sponsoring the conference or seminar.
- Expenses associated with advertising and promotional activities purchased for a regional or national market include advertising in D.C. if the portion of the costs pertaining to or directed at D.C. cannot be reasonably allocated, distinguished, determined or otherwise separated out.
- Payments made to healthcare practitioners for participation in market research if: (i) an independent survey research organization conducts the market research; (ii) Bayer does not know the identity of the practitioners who participate in the research; and (iii) the payments are determined and made directly by the survey research organization.

An *independent survey research organization* is defined as a survey research organization, marketing research organization, or similar entity that is not owned or affiliated, directly or indirectly, with a pharmaceutical company, manufacturer, or labeler and which does not share employees or independent contractors with a pharmaceutical company, manufacturer, or labeler.

Deadline for Submitting Information

Reports covering the previous calendar year are due annually on July 1.
Reports must be submitted in the electronic format specified by the D.C. Department of Health. Each annual report must include (i) the name and contact information of the individual responsible for the company's compliance with the D.C. law and the accuracy of the annual report and (ii) the name and position of the individual submitting the report. Bayer must also separately submit a "wet signature certification" regarding the truthfulness and completeness of the submission, as specified by the regulations. The regulations further require manufacturers to submit a $5,000 filing fee payable to "D.C. Treasurer."

Prohibition on Gifts and Remuneration to Medication Advisory Committee Members

The District of Columbia SafeRx Amendment Act of 2008 prohibits pharmaceutical companies and their representatives from offering any gifts or remuneration of any kind to a member of a "medication advisory committee" responsible for making recommendations or decisions regarding the formularies of District-administered health programs. Similarly, medication advisory committee members are prohibited from accepting gifts or remuneration from pharmaceutical companies. The sole exception to this prohibition is that pharmaceutical companies may offer, and licensed physician advisory committee members may accept patient samples. The *medication advisory committee* is "any committee or panel responsible for making recommendations or decisions regarding a formulary to be used by a health program administered by [D.C]." The terms *gift* and *remuneration* are not defined in the Act. The statutory prohibition on offering any gifts or remuneration to medication advisory committee members has been incorporated into a code of ethics established by the District's Department of Health.

Pharmaceutical employees and representatives who are required to obtain a license before interacting with District healthcare professionals (as described in further detail below) must comply with the code of ethics restrictions. Violators of this prohibition are subject to a $1,000 fine per violation.

Licensure of Pharmaceutical Manufacturer Representatives

The District of Columbia SafeRx Amendment Act of 2008 requires pharmaceutical employees and representatives engaged in certain interactions with healthcare professionals in the jurisdiction, defined in the Act as the "practice of pharmaceutical detailing," to obtain a license prior to engaging in those interactions. Those interactions are defined as "the practice by a representative of a pharmaceutical manufacturer or labeler of communicating in person with a licensed health professional, or an employee or representative of a licensed health professional, located in the District of Columbia, for the purposes of selling, providing Information about, or promoting a pharmaceutical product." This definition potentially reaches activities undertaken by a broad array of Bayer employees, including those traditionally undertaken by medical education personnel and physician consultants. However, individuals engaged in pharmaceutical detailing for a single period of less than thirty (30) consecutive days per calendar year are not subject to the licensure requirements. This exception allows individuals, such as speakers at a conference who come to D.C. once a year or others who come once a year for a short duration of less than thirty (30) consecutive days, to avoid licensure. This provision does not allow someone who comes to D.C. for a few days a month to avoid licensure if the person returns to D.C. again within the same calendar year to engage in pharmaceutical detailing.

Individuals who engage in activities covered by the Act without a license may be subject to a fine of up to $10,000, in addition to other penalties and sanctions. This includes individuals engaging in activities covered by the Act temporarily or in emergencies. The Act does not impose penalties directly on pharmaceutical manufacturers whose personnel have violated the Act.

Applying for a New License

New license application instructions and forms are posted on the District of Columbia website and are summarized below.

All applicants must submit the information specified in the application instructions and forms, including the following:

- A completed online DC application form
- One (1) recent passport photo (2"x2")
- One (1) clear photocopy of a U.S. Government issued photo
- A non-refundable application fee of $175
- ID, Social Security Number, or a sworn affidavit and proof that the applicant is legally authorized to work in the United States
- Name change documents (marriage certificate, divorce decree or court order), if applicable
- Official college/university transcript in a sealed envelope (from an institution of higher learning recognized by an accrediting body approved by the Secretary of the United States Department of Education)
- Notarized Affidavit to Abide by Code of Ethics Form
- Criminal background check (FBI & State)

The DC Board of Pharmacy has sixty (60) days after receipt of a complete application package to approve or deny the application. If an application is incomplete or otherwise deficient, this will significantly delay the process and can result in the return of your application materials to you. You

will be issued a license to interact with healthcare professionals in the District of Columbia upon final approval. If your license is denied, you will receive a “Notice of Intent to Deny Licensure” document in the mail, stating the basis for the proposed denial and advising you of your right to request a hearing and the procedures for doing so.

License Renewal Activities

All pharmaceutical detailer licenses will expire at midnight on the last day of February of each even-numbered year. Each initial license is valid for the balance of the then-current renewal cycle. Licensees will receive a renewal notice from the Board approved three months before the expiration of a license. It is the employee’s responsibility to complete all renewal requirements. A licensee must submit a renewal application by the license expiration date or be subject to late fees and additional renewal requirements.

An applicant for renewal of licensure must:

- Complete a minimum of fifteen (15) credit hours of approved continuing education during the two years preceding the date the license expires. These credits must include at least two hours of continuing education focused on cultural competency or specialized clinical training focusing on patients or clients who identify as lesbian, gay, bisexual, transgender, gender nonconforming, queer, or question their sexual orientation or gender identity and expression, and at least 10 percent of the total required continuing education must be in subjects classified as public health priorities, which will be disseminated to licensees via electronic communication and through publication on the Board of Health’s website.
- Attest to completing the required continuing education credits on the renewal application form.
- Be available for audit inquiries, which will be conducted at random.

After each renewal period, the Board will conduct a random audit. Those licensees selected in the random audit must submit proof of completing the required fifteen hours of continuing education.

Proof of completion of required continuing education credits includes the following information for each program:

- Name and address of the sponsor of the program;
- Name of the program, its location, a description of the subject matter covered, and the names of the instructors;
- Dates on which the applicant attended the program;
- Hours of credit claimed; and
- Verification by the sponsor of completion, by signature or stamp.

Licensees are responsible for obtaining completion certificates immediately after qualifying training programs. You must retain these certificates to submit them to D.C. as proof of completing your required continuing education credits.

Continuing Education Courses

The Board of Pharmacy must approve training courses before they can be applied to the 15 credit hours of continuing education requirement. The applicant must verify whether the Board approves a program before attending the program. Licensees may contact the Board at 877-672-2174 to confirm that a program will be acceptable before attending the course.

To qualify for approval by the Board, a continuing education program must cover specific subjects as listed in 17 DCMR 8307.2.

These educational programs may be given at a conference, a lecture, seminar, course of instruction, workshop, or on the Internet and be prepared, offered or administered by one of the following:

- A nationally or locally accredited program provider,
- A governmental unit,
- A healthcare facility,
- A pharmaceutical company, or
- A U.S. Department of Education-recognized institution of higher learning.

Bayer will apply for approval from the Board for many of its mandatory training courses, such as HealthCare Compliance, Ethics, and Sales Training Courses. Once these courses are approved, instructions on how to obtain your signed certificate of completion will be published on the Sales intranet site.

Record Requests from the DC Board of Pharmacy

The DC SafeRx Act allows the Board of Pharmacy to collect information from licensed individuals relating to their communications with healthcare professionals or employees or representatives of licensed health professionals located in the district. Licensees only have only ten (10) business days to reply to the Board.

If you receive such a request, you must immediately contact the Vice President and Head, U.S. Office of Compliance or the LPC Department. They will work with you to coordinate your response. The documentation that needs to be maintained must include whom the detailer visited, the date and time of the visit, the products discussed, whether samples were provided, and the type of materials supplied to the healthcare professional. Sales consultants need to maintain this information in the Bayer Veeva system. Those not on the Veeva system must develop a comparable documentation and retention process to capture the required information. A form is provided at the end of this Policy and Procedure. For five (5) years, you must retain documents and information relating to your communications with healthcare professionals and those who work for them.

Upon Leaving Bayer

Upon leaving Bayer, you must provide your documentation files to your immediate supervisor for ongoing record retention.

A licensed individual must also notify the Board within ten (10) calendar days of leaving the employ of a pharmaceutical company. This notification must be written and include the name, address, email, and telephone number of the person within the company who may be contacted to retrieve the records required to be maintained under this chapter (this is your immediate supervisor). The notification must be sent to the following address, with a copy provided to your supervisor:

District of Columbia Department of Health
Health Professional Licensing Administration
ATTN: Processing Department – Address/Name Change 899 North Capitol Street, NE, First Floor
Washington DC 20002

Supervisors of licensed employees leaving Bayer must be vigilant about obtaining the employee's records relating to communications with healthcare professionals in the District and remind the employee of this 10-day written notification requirement.

Change in Information

The Board of Pharmacy requires licensees to report all changes of business or residence address to the Board in writing within 30 days after the change at the following address:

District of Columbia Department of Health
Health Professional Licensing Administration
ATTN: Processing Department – Address/Name Change 899 North Capitol Street, NE, First Floor
Washington DC 20002

Licensees who fail to update their addresses may not receive renewal notices promptly.

Record of Communication Within the District of Columbia

The DC SafeRx Act allows the Board of Pharmacy to collect information from licensed individuals regarding communications with healthcare professionals or with employees or representatives of licensed health professionals located in D.C. If you are not on the Bayer Veeva system, you must use this form to document these interactions and retain it for five years to meet the requirements of this DC law.

Date of visit: _____

Time of visit: _____

Name of facility or entity: _____

Name(s) of individual(s) visited: _____

Product discussed: _____ Sample provided: YES or NO

Product discussed: _____ Sample provided: YES or NO

Product discussed: _____ Sample provided: YES or NO

Materials provided to the healthcare professional: _____

This documentation must be retained for a period of five (5) years.

// Florida

Miami Dade County – Sales Representatives Registration as Lobbyists May Be Required

Lobbyist Regulation Includes Certain Sales Representatives

Miami Dade County regulates lobbyists, a category that includes sales representatives who "appear before a Public Health Trust ("PHT") board or employees of Jackson Memorial Hospital/PHT to encourage the board or individual to purchase the product the vendor represents or who seek approval for a clinical trial of new products and services."

Registration Requirements & Fee

Among other things, lobbyists in Miami-Dade County must register within five days of being retained as a lobbyist or before engaging in lobbying activities, whichever comes first. To register, each lobbyist must submit a form prepared by the Clerk of the Board of County Commissioners, pay a registration and training fee of $490, and complete required ethics training. Lobbyists must register annually, and registration renewal is due by January 15th of each year. Anyone who withdraws as a lobbyist must file a notice of withdrawal. On July 1st of each year, lobbyists must submit annual expense reports for expenditures that exceed $25.

Failure to register can cause a lobbyist to be suspended from lobbying, the contract in question to be voidable, and individual penalties, including fines. Failure to file an expenditure report will result in a fine of $50 per day, and if the report is not filed by September 1st, the lobbyist will be suspended from lobbying until the fines are paid.

Although lobbyists are banned from receiving contingency fees, there is an exception for "traditional sales commission payments for sales representatives."

Public Health Trust/Jackson Memorial Hospital Vendors

If a sales representative qualifies as a lobbyist under the definition above, then the PHT/JMH vendor rules and requirements also apply.

If you call upon any identified entities or think you may be subject to these requirements, please contact the Compliance Department for further instructions.

// Illinois

City of Chicago – Individual Sales Representative Licensure and Reporting Requirements

Licensure of Company Representatives

The City of Chicago requires all pharmaceutical representatives who market or promote pharmaceuticals to healthcare professionals while both are in the City of Chicago for fifteen (15) or more days per calendar year to obtain a license, on an annual basis, from the Commissioner of Business Affairs and Consumer Protection. The term "pharmaceutical representative" excludes medical science liaisons and similar individuals (*e.g.,* those who have a doctoral degree in science or medicine and engage in non-promotional scientific exchange with healthcare professionals), as well as pharmaceutical representative managers or supervisors who do not interact directly with healthcare professionals while in the City of Chicago.

To become initially licensed, a pharmaceutical representative must complete an online Business License application and an online professional education course to which an applicant is directed as part of the licensing process. The course provides instruction on the pharmaceutical representative license and an overview of ethical standards and disclosure requirements. Pharmaceutical representatives must submit their Certificate of Completion from that course and pay the $750 license application fee to complete the application.

Licensed pharmaceutical representatives must complete five hours of continuing professional education each year. The Chicago Department of Public Health ("CDPH") provides a list of approved continuing education courses offered by CDPH-approved institutions on its website (as of January 2024). Upon completion of a course, a pharmaceutical representative should receive a signed certificate of course completion. Pharmaceutical representatives must maintain these certificates and information regarding their completed courses for at least five years.

Each pharmaceutical representative license is valid for one year, and the renewal deadline is based on the individual license's expiration date. When applying for a license renewal, a pharmaceutical representative must affirm that they have completed the required 5 hours of continuing education during the previous year and pay the license application fee. The CDPH will audit a subset of renewal applications each year to confirm compliance with the continuing education requirement. Upon request, sales representatives must provide information on courses completed, including:

- Title and date of each course,
- Number of credit hours completed,
- Name of the education provider(s), and
- Signed certificate(s) of completion.

Disclosure of Certain Interactions with Healthcare Professionals

CDPH maintains a list of pharmaceutical products for which pharmaceutical representatives may be required to disclose information related to marketing and promotional activities. As of January 2024, the list is limited to Schedule II medications, as that term is defined by the Controlled Substances Act, found at Title 21 of the United States Code. As of January 2024, Bayer does not sell, market, or promote such medications, so as of January 2024, these disclosure requirements do not apply to Bayer sales representatives.

If a pharmaceutical representative markets or promotes pharmaceuticals, pharmacological classes, or categories of pharmaceuticals listed at www.cityofchicago.org/health during the month the representative obtains or renews a license. They should begin tracking interactions with healthcare

professionals using the available spreadsheet, which requires reporting the following:

- A list of healthcare professionals within the City of Chicago contacted;
- The number of times healthcare professionals were contacted;
- The location and duration of contact;
- The pharmaceuticals promoted;
- Whether product samples, materials, or gifts of any value were provided to the healthcare profession and the value of the products, materials, or gifts; and
- Whether and how the healthcare professional was compensated for contact with the pharmaceutical representative.

Pharmaceutical representatives are not required to disclose information related to activities (1) during which either the healthcare professional or the representative is not in the City or (2) that take place at large conferences, symposia, conventions, or like gatherings that are expected to be attended by a regional, national, or international audience and where representatives from at least three unrelated pharmaceutical companies (*e.g.,* not subsidiaries or affiliates of the same company or parent company) are marketing products. The second exemption does not apply to activities that occur concurrently with the conference, symposium, convention, or other event but are not officially part of the event.

Please contact LPC if you have any questions, including whether you need to track your interactions with healthcare professionals.

Ethical Standards

The City of Chicago's Municipal Code and its associated rules set out ethical standards to which pharmaceutical representatives must adhere. Under the ethical standards, a pharmaceutical representative must (1) comply with the applicable policies and procedures of the healthcare facilities and healthcare professional offices they visit and (2) provide healthcare professionals with information that is truthful, accurate, and non-misleading, consistent with federal Food and Drug Administration laws and regulations.

In addition, pharmaceutical representatives shall not:

- Engage in any illegal, fraudulent, misleading, or other deceptive marketing of a pharmaceutical product, including the knowing concealment, suppression, omission, misleading representation, or misstatement of any material fact.
- Use a title or designation that could reasonably lead a licensed healthcare professional, or an employee or representative of a licensed healthcare professional, to believe that the pharmaceutical detailer is licensed to practice medicine, nursing, dentistry, optometry, pharmacy, or other similar health occupation, in the City of Chicago, unless the pharmaceutical detailer currently holds an active license to practice that health occupation.
- Attend patient examinations without the express, written consent of the patient.
- Enter an area meant primarily for healthcare providers and patients, other than a designated waiting area, unless invited by a healthcare provider working on site.
- Harass, intimidate, or coerce a healthcare professional, employee, or representative of a healthcare professional through any form of communication.
- Stop making sales calls to a healthcare professional or an employee or representative of a healthcare professional if the healthcare professional requests it in writing or verbally to the pharmaceutical representative or the representative's employer.
- Make any misleading statements to gain access to a healthcare professional.

Proof of Licensure

Upon request by a healthcare professional, a pharmaceutical representative must show their license or an exact copy thereof (*e.g.,* a photocopy or image saved on an electronic device). Healthcare professionals and patients may file complaints about a pharmaceutical representative's failure to comply with the requirements of the Code or its associated rules. Pharmaceutical representatives can respond to such complaints and provide relevant information.

Complaints, Violations, & Penalties

Pharmaceutical representatives who violate the Code or its associated rules are subject to suspension or revocation of the license and/or a fine of no less than $1,000 and no more than $3,000 per day of violation. No license will be reinstated until all code violations related to the suspension or revocation have been remedied and all assessed penalties and fees have been paid. No person whose pharmaceutical license is revoked for any cause will be granted a license sooner than two years from the revocation date.

// Louisiana

Restrictions on Interactions with State Executive Branch Officials (Including Healthcare Professionals)

Prohibition on Gifts to Public Servants & Public Employees

Louisiana's Code of Government Ethics prohibits HCPs who are public employees or public servants from accepting most gifts and other items of value. The code defines a "public employee" as anyone, whether compensated or not, who is an administrative officer or official of a government entity, a person who was appointed as a member or employee of an agency, a person engaged in the performance of a governmental function, or a person under the supervision or authority of an elected official or another government employee. It defines a "public servant" as a public employee or an elected official.

Meals and Gifts

The only items of value that public employees and public servants are permitted to accept are "promotional items"[1] that have no substantial resale value and "food and drink" valued at $77 (as of July 1, 2023, this amount is adjusted annually) or less at a single event.

Accordingly, they **may not accept medically related gifts, textbooks, etc**.

You must assume that healthcare professionals working at state facilities, such as state hospitals, universities, clinics, and prisons, are public employees or public servants. Under Louisiana law, they remain public employees or public servants even when they are not physically located at a state facility (*e.g.,* on their days off or when working at a civilian facility). You must determine whether a Louisiana healthcare professional is a public employee or public servant before offering or providing a meal in compliance with Bayer policies.

Fee for Service Arrangements

Louisiana significantly restricts a pharmaceutical manufacturer's fee-for-service arrangements with Louisiana public employees or public servants. The Louisiana statutory provisions are very complex and often amended by the legislature or subject to new interpretations by the Louisiana Board of Ethics. Because of this, **you must consult the LPC Department before Bayer Pharmaceuticals enters into a financial arrangement with, reimburses travel expenses for, and/or engages any Louisiana healthcare professional as a consultant, advisor, or speaker.**

Namely, Louisiana's Code of Governmental Ethics prohibits a public employee or public servant from receiving compensation for services rendered by the public employee or public servant if such services are compensated for by an entity from which the public employee or public servant may not receive a gift under Louisiana law. Louisiana law does, however, provide limited exceptions to this prohibition.

For example, HCPs who are public employees or public servants are prohibited from performing certain compensated services, including payment of travel expenses or a speaker's fee from a pharmaceutical company for speaking at a seminar or other engagement.

[1] Because Bayer's "Educational Items for Healthcare Professionals" policy prohibits the provision of promotional items, regardless of value, to any healthcare professional, Bayer prohibits you from providing any promotional items to public employees or public servants in Louisiana.

Public employee/public servant HCPs, however, may serve as paid consultants to pharmaceutical companies to assist in product development or to advise on issues particular to the practice of medicine that are related to their academic discipline or area of expertise as long as they obtain written approval from the management of their institution. Similarly, a public employee/public servant HCP may not receive travel expenses reimbursement from a pharmaceutical company sponsoring a clinical trial or a study unless there is a contract between the HCP's employer and the pharmaceutical company that obligates the sponsor to pay all reasonable travel expenses. See Louisiana Ethics Advisory Opinion Nos. 2006-247 (April 18, 2006) and 2006-654 (Sept. 14, 2006) (analyzing fee-for-service arrangements between pharmaceutical companies and employees of Louisiana public universities).

Louisiana law also prohibits hospital employees from providing consulting services to help design new products to manufacturers from which the hospital purchased products for resale at a retail establishment owned and operated by the hospital. Louisiana Ethics Advisory Opinion No. 2013-1560 (January 23, 2014) (analyzing a fee-for-service consulting arrangement between a parish district hospital employee (a director of therapy services) and a manufacturer of medical equipment).

Gift restrictions also apply to members of the Louisiana Medicaid P&T Committee. As a result, the members are barred from receiving compensation for serving on scientific advisory boards and speakers' bureaus, on the faculty of a national council supported by a grant from a pharmaceutical company, and as a consultant and co-principal investigator on a clinical trial. They are also barred from receiving research grants from pharmaceutical companies to support research. See Louisiana Ethics Advisory Opinion No. 2008-424 (May 13, 2008) (analyzing fee-for-service arrangements between pharmaceutical companies and members of the Louisiana Medicaid P&T Committee).

Pharmaceutical Samples

Bayer may give state-affiliated healthcare professionals free pharmaceutical samples for distribution to patients free of charge, so long as the provision of such samples complies with applicable federal law and Bayer policy. Specifically, Louisiana law specifies that pharmaceutical samples that comply with the Federal Food, Drug, and Cosmetic Act and the Prescription Drug Marketing Act and that are provided to a physician, healthcare professional, or appropriate public employee for the administration or dispensation to a patient at no cost to the patient are not considered to be items of value.

Lobbying Registration and Disclosure

The Louisiana Lobbying Disclosure Act requires those who entertain or present before "executive branch officials" (defined below) with the intent to influence executive branch action to register as lobbyists.

Because of the stringent reporting requirements and additional legal ramifications, under no circumstances should a Bayer employee entertain or appear before an executive branch official without contacting U.S. Government Relations well before the contemplated activity.

To that end, NO BAYER SALES FORCE EMPLOYEE SHOULD BE REGISTERED AS A LOBBYIST IN LOUISIANA. (Note that U.S. Government Relations employees must register as lobbyists as a job requirement.)

"Executive Branch Action" and "Executive Branch Officials" are Broadly Defined

The term *executive branch action* includes efforts to influence the conduct of the Medicaid Pharmaceutical and Therapeutics (P&T) Committee.

Thus, any Bayer employee who entertains (*e.g.,* provides a business meal) or appears before Medicaid P&T Committee members or state healthcare practitioners who interact with the P&T Committee may be required to register with the Louisiana Board of Ethics as an executive branch lobbyist.

Executive branch officials include HCPs practicing or affiliated with public hospitals. Therefore, when pharmaceutical industry employees' education and detailing are conducted to educate the HCPs practicing or affiliated with public hospitals or other public entities about available pharmaceutical products and the risks and benefits associated with drugs to enable practitioners better to make appropriate patient treatment choices, it is considered "lobbying." Because of this, pharmaceutical industry employees who make $500 or more expenditures on HCPs who are practicing or affiliated with public hospitals must register as lobbyists.

A list of executive branch departments and agencies can be found on the State of Louisiana website. The list is not all-inclusive, and it is your responsibility to exercise due diligence to determine if your interaction is with a member of a governmental body. If in doubt, ask the healthcare professional whether they are an executive branch official before providing any meal, speaker fee, or other fee-for-service payment.

// Maine

Manufacturer Registration and Ban on Gifts to Practitioners

Registration Required by Manufacturers – But Not Employees of the Manufacturers

Maine requires all prescription drug manufacturers whose products are distributed within Maine in any manner to register with the Maine Board of Pharmacy. Individuals whom the manufacturer employs are not required to obtain separate licensure. As of January 2024, the fee for an initial license for a manufacturer is $200, and the annual license renewal fee is $200. Licenses both renew and expire on December 31 of each year. A late fee of $50 is imposed for licenses renewed within 90 days after the expiration date. If a renewal application is submitted more than 90 days after the license expiration date, that renewal is subject to all requirements governing new applicants and the applicant is required to reapply with an original license application, documentation and fees. Maine's licensing information for pharmaceutical manufacturers is available on their website under Establishments/Manufacturer.

Any changes in the manufacturer's ownership or location must be reported to the Board of Pharmacy within seven days, and any other changes to information provided on the manufacturer's licensure application must be reported within ten days.

Gift Restrictions

Maine prohibits a prescription drug manufacturer licensed in the state from offering or giving a practitioner (1) a cash gift in any amount or (2) a gift for which reciprocity is expected or implied.

The following items are exceptions to the gift ban and may be given to Maine practitioners without violating the law:

- Noncash items of minimal value that will directly benefit the practitioner's patients, including:
  - Prescription drug samples for distribution to patients;
  - Educational materials; and
  - "Modest meals and refreshments" that are provided to a practitioner in connection with a meeting or presentation about the benefits, risks, and appropriate uses of prescription drugs or medical devices, disease states or other scientific information, as long as the meeting or presentation occurs in a venue and manner conducive to informational communication.
    - *Modest meals and refreshments* mean food and beverages of minimal value of the type and quantity typically provided for attendees at the meeting or presentation venue. *Minimal value* means cost similar to that which a practitioner would pay when dining at their own expense as judged by local standards where the event is held.
- Providing funding to academic institutions and residency and fellowship programs to support the participation of medical, nursing, physician assistant, veterinarian and pharmacy students, residents and fellows in professional meetings, including educational meetings, as long as the program identifies such funding recipients based on independent institutional criteria and the funds are distributed to recipients without specific attribution to sponsors.
- Giving reasonable honoraria to a practitioner and paying reasonable expenses for a practitioner at a professional or educational conference or meeting.
  - *Reasonable honoraria* means cash, gratuity and/or a gift given to a practitioner in recognition of that practitioner speaking at a professional or educational conference sponsored by a manufacturer or wholesaler.

- The aggregate value of all cash and gifts received by a practitioner for a particular speaking engagement may not exceed an annual limit of $500 in retail value. The requirement for reasonable honoraria does not include or apply to:
    - The fee-for-service paid to the practitioner for the presentation, travel or lodging reimbursement, or other expenses incurred or
    - Where the manufacturer or wholesaler sponsoring the event does not participate in or influence the selection of the practitioner chosen for the speaking engagement or payment for the services rendered by the practitioner.
- For the “reasonable honoraria” exception, pharmacists are not included in the definition of practitioners.
- *Reasonable expenses* are the reasonable and actual expenses for travel, lodging, and meals incurred by a practitioner that are necessary for the practitioner to speak at a professional or educational conference sponsored by a manufacturer or wholesaler.

// Massachusetts

Marketing Code of Conduct and Meal and Gift Regulations

Massachusetts law requires pharmaceutical and medical device manufacturing companies that participate in a Massachusetts healthcare program and employ a person to sell or market in Massachusetts to (1) adopt a marketing code of conduct as developed by the Massachusetts Department of Public Health (the "Department") and (2) annually report payments and other economic benefits of $50 or more.

In addition, Massachusetts code and regulations require manufacturers to file quarterly reports detailing all non-CME educational presentations at which modest meals and refreshments are provided to healthcare practitioners outside of the office or hospital setting, which are not otherwise subject to federal reporting in Open Payments.

Key Definitions Regarding the Massachusetts' Pharmaceutical and Medical Device Manufacturer Conduct Law and Regulations

The law and its implementing regulations provide the following key definitions:

- *Covered recipient* is authorized to prescribe, dispense, or purchase prescription drugs or medical devices in Massachusetts, including a hospital, nursing home, pharmacist, health benefit plan administrator, or healthcare practitioner. A person who otherwise meets this definition but is a bona fide employee of a pharmaceutical or medical device manufacturing company shall not be a covered recipient for payments by that company. Additionally, consumers who purchase prescription drugs or medical devices are not covered recipients.
- *Health Care Practitioner* is a person who prescribes prescription drugs for any person and is licensed to provide healthcare in Massachusetts, or a partnership or corporation comprised of such persons or an officer, employee, agent or contractor of such person acting in the course and scope of their employment, agency or contract related to or in support of the provision of healthcare to individuals. The following are not included in the definition of "healthcare practitioners": hospitals and full-time employees and board members of pharmaceutical or medical device manufacturers.
- *Physician* is licensed to practice medicine by the Board of Registration in Medicine who prescribes prescription drugs or medical devices or is an employee or agent of such a licensed practitioner.
- *Modest Meals and Refreshments* are food and/or drinks provided by or paid for by a pharmaceutical or medical device manufacturing company or agent to a healthcare practitioner that, as judged by local standards, are similar to what a healthcare practitioner might purchase when dining at their own expense.

Marketing Code of Conduct

The marketing code of conduct to be adopted by each company is required to be no less restrictive than the most recent versions of the PhRMA and AdvaMed Codes on interactions with healthcare professionals, and the regulations governing codes of conduct are required to be updated by the Massachusetts Department of Public Health no less than every two years. To be compliant with Massachusetts' law and regulations, every company must affirmatively, among other things, adopt a program of regular training for employees, including, but not limited to, all sales and marketing staff; report certain monetary transactions with Massachusetts healthcare providers; conduct annual audits to monitor compliance with Massachusetts' law and regulations; annually register with the Department of Public Health and pay an, as of 2024, $2,000 annual registration fee; and have a compliance officer certify that the company complies with Massachusetts' law and regulations.

Meal Regulations

Massachusetts allows pharmaceutical or medical device manufacturing companies or their agents to provide healthcare practitioners with" modest meals and refreshments":

- In the healthcare practitioner's office or hospital setting in connection with informational or educational meetings or presentations and
- Outside of the healthcare practitioner's office or hospital setting to educate and inform healthcare practitioners about the benefits, risks and appropriate uses of prescription drugs or medical devices, disease states or other scientific information, provided that such presentations occur in a venue and manner conducive to informational communication. The information provided may not include the promotion of off-label uses.

Massachusetts expressly prohibits the provision of or payment for meals for healthcare practitioners that are:

- Part of an entertainment or recreational event.
- Offered without an informational presentation made by the sales consultant or without the sales consultant being present.
- Provided to HCP's spouse or another guest.

The following payments and gifts are prohibited:

- Providing entertainment or recreational items of any value.
- Payments of any kind, including cash, cash equivalents, equity, "in kind" or tangible items, including any "complimentary" items such as pens, coffee mugs, gift cards, etc., to healthcare practitioners either directly or indirectly, except as compensation for bona fide services.
- Sponsorship or payment for CME that does not meet ACCME standards or provides payment directly to an HCP.
- Payment of travel related expenses for attendees of CME, third-party scientific or educational conference, or professional meetings, either directly to the attendees or indirectly to the event's sponsor.
- Compensation for the time spent with attendees of CME, third-party scientific or educational conference, or professional meetings.
- Payment for meals directly at any CME event, third-party scientific or educational conference, or professional meetings.
- Providing anything – including, but not limited to grants, scholarships, subsidies, or consulting contracts – in exchange for prescribing prescription drugs or using devices or for a commitment to continue prescribing prescription drugs or using medical devices.

Additional specific limitations are outlined in the Massachusetts Code of Conduct regulations.

// Minnesota

Promotional Spending Limits, Cost Reporting, and Licensing/Registrations

Minnesota has a $50 per person per year spending limit for gifts and business meals and a reporting requirement for all cumulative payments exceeding $100 per year to certain practitioners licensed in Minnesota.

Definition of "Practitioner"

- For purposes of the Minnesota law, *practitioner* means any licensed:
  - Doctor of Medicine;
  - Doctor of Osteopathic Medicine;
  - Dentist;
  - Doctor of Optometry;
  - Podiatrist;
  - Veterinarian;
  - Physician assistant;
  - Advanced practice nurse;
  - Dental Therapist; or
  - Pharmacist who is licensed by the state of Minnesota and prescribe self-administered hormonal contraceptives, nicotine replacement medications, or opiate antagonists.

Promotional Spending Limits

The total value of gifts or business meals that all Bayer employees and agents can provide to any Minnesota-licensed practitioner in a calendar year cannot exceed $50. The $50 annual limit applies to practitioners licensed in Minnesota, regardless of where the meal occurs or the gift is presented. Thus, you cannot invite a Minnesota-licensed physician to a dinner and speaker program in another state to avoid the $50 limit.

Exceptions to the $50 Annual Spending Limit

The following expenditures do not count toward the $50 annual spending limit:

- Free samples of a drug provided to a prescriber for free distribution to patients;
- Payments to the sponsor of a medical conference, professional meeting, or other educational program, provided the payment is not made directly to a practitioner and the payment is used solely for bona fide educational purposes;
- Payment of a reasonable speaker fee and reasonable expenses to a practitioner who serves on the faculty at a professional or educational conference or meeting;
- Compensation for a practitioner's professional or consulting services in connection with a genuine research project;
- Product or company publications and educational materials; and
- Salaries or other benefits paid to employees.

This limit applies to all Bayer business groups combined, not individual Bayer employees.

Cost Reporting

Minnesota requires drug manufacturers to file annual reports identifying the nature and value of any payments totaling $100 or more to a particular practitioner during the year and identifying the practitioner, where the Federal Sunshine Act does not otherwise require the reporting. This includes all payments, honoraria, reimbursement, and other compensation permitted by Minnesota law.

To capture the relevant data for cumulative reporting purposes, Bayer employees must internally report all payments, regardless of dollar amount, to Minnesota practitioners (as defined above). This internal reporting requirement applies to all payments made to practitioners licensed in Minnesota, regardless of where the services were rendered.

Licensing and Annual Registration

Minnesota requires that, as of June 1, 2020, all drug manufacturers apply for and obtain a license from the Board of Pharmacy. After that, the manufacturers must apply for the renewal of that license and pay an annual registration fee, which in 2024 is $5,260 (for non-opiate facilities). To obtain a new license or renew an existing license, the manufacturer must, among other things, agree to operate in a manner prescribed by federal and state law and according to Minnesota Rules.

// Nevada

Marketing Code of Conduct; Company Licensure; Sales Representative Reporting & Compliance Requirements

Marketing Code of Conduct and Company Licensure

Nevada requires each manufacturer that sells prescription drugs or medical devices in the state to obtain a license from the Nevada State Board of Pharmacy and "adopt a written code of conduct which establishes the practices and standards that govern the marketing and sale of its products." Nevada sets out parameters for each company's code, including that the company's activities must be "intended to benefit patients, enhance the practice of medicine and not interfere with the independent judgment of healthcare professionals." Adopting the most recent version of the PhRMA Code and the AdvaMed Code of Ethics explicitly satisfies Nevada's requirements. In addition, each company must adopt a training program for appropriate employees on its Marketing Code of Conduct ("Code"), annually audit for compliance with its Code, adopt procedures for the investigation of non-compliance, and designate a compliance officer who will be responsible for "developing, operating, and monitoring" the code of conduct. A certification of compliance with Nevada's requirements is due annually between May 1 and June 1. It uses a form that is periodically updated and is available on the Board of Pharmacy web page.

Sales Representative Reporting & Compliance Requirements

Reporting for pharmaceutical representatives is the responsibility of **BOTH** the individual and the manufacturer.

Manufacturers' Reporting

Manufacturers must provide a list of all pharmaceutical sales representatives who market prescription drugs on their behalf to "providers of healthcare licensed, certified or registered in the State of Nevada, pharmacies and employees thereof, operators and employees of medical facilities and persons licensed or certified under the provisions of the Nevada Insurance Code" (hereinafter referred to as "Covered Individuals and Entities"). The term *provider of health care* covers an array of approximately thirty healthcare professionals, including physicians, physician assistants, pharmacists, dentists, and nurses. The term *medical facility* is similarly broad and covers sixteen entity types, including hospitals, surgical centers for ambulatory patients, and skilled nursing centers. If a person is not included on a manufacturer's list of pharmaceutical sales representatives, he or she may not market prescription drugs on behalf of the manufacturer (i) to Covered Individuals and Entities or (ii) for sale to any Nevada resident. Manufacturers must also notify the Nevada Department of Health and Human Services promptly when new sales representatives are hired or upon a sales representative's ceasing work for the company.

This list must be updated by the manufacturer "at least annually." Covered Individuals and Entities have electronic access to each manufacturer's list of pharmaceutical sales representatives. By March 1 of each year, each person who was included on a list of pharmaceutical sales representatives must submit a report that includes the following information:

- A list of Covered Individuals and Entities to whom the pharmaceutical sales representative provided:
    - any compensation with a value that exceeds $10; or
    - total compensation with a value that exceeds $100 in the aggregate; and

- The name and manufacturer of each prescription drug for which the pharmaceutical sales representative provided a free sample to a Covered Individual or Entity and the name of each person to whom a free sample was provided.

While the law requires the individual to submit the annual report, manufacturers are permitted to submit the reports on behalf of pharmaceutical representatives in their employment.

Penalties for Non-Compliance

Administrative penalties can range up to $5,000 per day of noncompliance for manufacturers and up to $500 per day for pharmaceutical sales representatives.

// New Jersey

Prescriber Limits on Accepting Value from Pharmaceutical Manufacturers

New Jersey limits the types and amount of value that may be accepted by "prescribers" from pharmaceutical manufacturers related to prescription drugs. Although the rule does not directly apply to manufacturer activity, Bayer follows the limits outlined in the New Jersey rule and strives not to cause a Prescriber to violate the rule.

Key Definitions:

- *Prescribers*: Physicians, podiatrists, physician assistants, advanced practice nurses, dentists, and optometrists. Who holds an active New Jersey license and practice in New Jersey or have New Jersey patients, regardless of the prescriber's practice site.
- *Bona Fide Services*: Services provided by a prescriber pursuant to a written agreement (that includes certain required information) including, but not limited to, presentations as speakers at promotional activities and education events, participation on advisory boards, and consulting arrangements. This does not include services a prescriber provides in connection with research activities.
- *Education Event*: A meeting or gathering held in a venue that is appropriate and conducive to informational communication and training about healthcare information, including information about disease states and treatment approaches, where the gathering is primarily dedicated to promoting objective scientific and educational activities and discourse and the main purpose of the gathering is to bring attendees together to further their knowledge on the topic(s) being presented. The NJ definition includes events that fall within the NJ definition, even if they are classified as promotional by the FDA. An "Education Event" is interpreted by Bayer to include Lunch and Learns and Speaker Bureau programs.
- *Research*: Any pre-market or post-market study assessing the safety or efficacy of prescribed products administered alone or in combination with other prescribed products or other therapies, or assessing the relative safety or efficacy of prescribed products in comparison with other prescribed products or other therapies, or any systematic investigation, including scientific advising on the development, testing, and evaluation, that is designed to develop or contribute to general knowledge, or reasonably can be considered to be of significant interest or value to scientists or prescribers working in a particular field.

Prohibited gifts and payments to providers and members of their immediate families[2]

- Financial or in-kind benefits, such as payments, stock, stock options, grants, scholarships, subsidies, and charitable contributions;
- Entertainment and recreational items, such as theater or sporting event tickets and leisure or vacation trips;
- Items of value that do not advance disease or treatment education (certain exceptions are below), such as promotional items, items for the personal benefit of the prescriber or staff, flowers, artwork, sporting equipment, and items that could be used in both professional and non-professional settings; and
- Payments in cash or cash equivalents and subsidies for non-faculty attendance at educational events or promotional activities.

Permitted Items

[2] The prohibitions do not apply to an immediate family member of a prescriber who is employed by a pharmaceutical manufacturer and receives, as part of the usual and customary employment relationship, compensation, financial benefit, or other item of value.

- Educational items with minimal or no value to the prescriber outside their professional responsibilities. For example:
    - Anatomical models for use in an examination room;
    - Other information and materials directly related to patient care or prescriber education; or
    - Electronic devices used by patients and remain in a common area of the prescriber's office.
- Subsidized registration fee at an education event, where the subsidy is available to all event participants.
- Compensation, based on fair market value, for providing bona fide services and reasonable payment or remuneration for travel, lodging, and other personal expenses in connection with such services:
    - Serving as a speaker, faculty organizer or academic program consultant for an education event; and
    - Participation in advisory bodies or under consulting arrangements.
- Reasonable payment or remuneration for travel, lodging, and other personal expenses in connection with research activities.
- Reasonable payment or remuneration to prospective applicants for travel, lodging, and other personal expenses associated with employment recruitment.
- Royalties and licensing fees paid in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the prescriber holds an ownership right.
- Sample medications or devices intended to be used exclusively for the benefit of the prescriber's patients, provided the prescriber does not charge patients for such samples, and all dispensing standards, as applicable, are satisfied in the prescriber's licensing board rules.

$10,000 Maximum Payment Per Prescriber for Bona Fide Services

New Jersey imposes a Bona Fide Services Cap under which a prescriber may not accept more than $10,000 in the aggregate from all pharmaceutical manufacturers in any calendar year for the bona fide services of presentations as speakers at promotional activities, participation on advisory boards, and consulting arrangements.

The cap does not include payments for (a) speaking at Education Events (including Lunch and Learns and Bayer Speaker Bureau programs), (b) research activities, or (c) royalties and licensing fees. In light of these exclusions, Bayer interprets the Bona Fide Services Cap as only applying to advisory boards and prescriber consultation agreements entered into after January 15, 2018.

Required Disclosure by Prescriber

A prescriber serving as a speaker at an education event or for a promotional activity must directly disclose to attendees orally or in writing at the beginning of the presentation that the prescriber has accepted payment for bona fide services from the sponsoring pharmaceutical manufacturer within the preceding five years.

// New York

Public Employee Gift Ban

New York prohibits all employees of public authorities, paid officers and employees of state departments, boards, and commissions, and other public employees and elected officials from accepting gifts.

Gifts are defined as “anything of more than Nominal Value in any form including, but not limited to money; service; loan; travel; lodging; meals; refreshments; entertainment; discount; or a forbearance of an obligation or a promise that has a monetary value.”

Nominal value refers to an item or service with a “fair market value of fifteen dollars or less.”

While exceptions exist to this ban, you must confirm whether a healthcare practitioner and that individual’s staff are employed by the State of New York before providing any meals or other items of value.

// Oregon

Pharmaceutical Representative Licensing

Oregon requires every pharmaceutical representative who markets or promotes pharmaceutical products to healthcare providers within Oregon to acquire a license from the Department of Consumer and Business Services ("DCBS"). The licensing requirement does not apply to pharmaceutical representatives who engage in marketing or promotion activities in Oregon for less than fifteen days in a calendar year.

Key Definitions

Pharmaceutical representative: A person that markets or promotes pharmaceutical products to healthcare providers.

Health Care Provider: A person that is licensed, certified or otherwise authorized under Oregon law to prescribe, provide or dispense pharmaceutical products to patients for diagnosis, treatment or care of disease, injury or congenital conditions including, but not limited to, a person who is: (A) a physician or physician's assistant; (B) a nurse practitioner; (C) a psychiatrist; (D) a pharmacist; or (E) a hospital, clinic or pharmacy.

Licensure Requirements

To obtain/renew a license, a pharmaceutical representative must complete an initial or renewal application that requires:

- The applicant's full name, social security number, email address, residence address, personal telephone number, business address, and business telephone number.
- A description of the business activities in which the applicant will engage.
- Documentation that shows the applicant has completed the professional education requirement:
    - For an initial pharmaceutical representative license, at least 10 hours of approved course(s) is required.
    - For renewal, 5 hours of approved continuing education is required.
- Payment of an annual licensing fee of $750.
- For each annual renewal, the licensee must document that they:
    - Reported to DCBS, in writing and a form specified by DCBS, any changes to the information submitted in an initial or renewal license application, including any material changes made in the licensee's business operations.
    - Maintained a disclosure log documenting their interactions with healthcare providers using a reporting spreadsheet available as of January 2024 on the State of Oregon's website.
    - Submitted the disclosure log to the DCBS no later than April 1.

The required disclosures that must be memorialized in the Disclosure Log include:

- A list of healthcare providers within Oregon that the licensee contacted during the preceding calendar year;
- The number of times the licensee contacted each healthcare provider during the preceding calendar year;
- The location and duration of the licensee's contact with each healthcare provider;
- Which pharmaceutical products the licensee promoted;
- Whether the licensee provided the healthcare provider with any product samples,

materials or gifts, and, if so, the monetary value of the samples, materials or gifts; and
- Whether and how the licensee otherwise compensated the healthcare provider for contact with the licensee.

Licenses are valid until the end of the calendar year in which the license was issued and are not transferable.

A pharmaceutical representative must show their license or an exact copy when a healthcare provider asks to see it. An exact copy may include a legible reproduction, such as a photocopy or an image saved or produced on an electronic device.

Prohibited Conduct

In Oregon, licensees are prohibited from:

- Engaging in any deceptive or misleading marketing of a pharmaceutical product, including knowingly concealing, suppressing, omitting, misrepresenting, or misstating material facts concerning or related to a pharmaceutical product;
- Using a title or designation that could reasonably lead a healthcare provider or an employee of a healthcare provider to believe that the licensee is a healthcare provider if the licensee is not licensed as a healthcare provider or otherwise authorized to provide healthcare services;
- Attending an examination of a patient without the patient's consent; or
- Making or filing, or causing to be made or filed, to or with the Director of the Department of Consumer and Business Services, any statement, report or document known to be false in any material respect or matter.

Violations of Pharmaceutical Representative Licensing Requirements

Penalties may be imposed for violations of Oregon's pharmaceutical representative licensing requirements, including:

- Suspension or revocation of a license.
    - A license may not be reinstated until all violations have been remedied and all fees and civil penalties have been paid.
    - If a license is revoked, it cannot be reinstated or renewed, nor can a new license be issued to the licensee whose license was revoked for two years after revocation.
- A civil penalty of not less than $1,000 and not more than $3,000 for each violation, and each day during which a violation continues constitutes a separate violation.

// Vermont

Gift Ban, Disclosures, and Fees on Manufacturers

Vermont bans most gifts by manufacturers of pharmaceutical products, biological products, and medical devices ("Manufacturers") to healthcare providers. It also requires Manufacturers to register with the state and report their permitted expenditures and gifts to Vermont healthcare providers, including expenditures for samples (including vouchers) and clinical trials.

Marketing Disclosure Law

Overview

Vermont law regulates expenditures from manufacturers to the following:

- Vermont healthcare providers (defined below), including healthcare professionals (defined below) (collectively, "HCPs");
- Academic institutions located in or providing services in Vermont;
- Nonprofit hospital foundations located in or providing services in Vermont;
- Professional, educational, and patient organizations representing or serving healthcare providers or consumers located in or providing services in Vermont; and
- Members of the Green Mountain Care Board.

All expenditures to Vermont HCPs are regulated, regardless of where they occur: a Vermont HCP is a Vermont HCP whether or not the expenditure or sampling took place in Vermont.

There are four types of regulated expenditures:

- Banned gifts (including, *e.g.,* food, compensation for marketing research)
- Permitted gifts
- Allowable expenditures
- Samples

A detailed annual guide to the prescribed products gift ban and reporting requirements is available in the "Updates" subsection under the "Disclosure of Expenditures for Prescribed Products" section.

Particularly relevant to Bayer, under Vermont law, if a company has multiple divisions, some of which market-prescribed products to Vermont healthcare providers and institutions and others that do not, the entire company is bound by the Vermont gift ban. It must report allowable expenditures and permitted gifts.

Additionally, if the manufacturer of prescribed products markets those products through a subsidiary, the expenditures must be reported in the name of the manufacturer, and the Compliance Officer Form (discussed below) must also be submitted in the name of the manufacturer.

Key Definitions:

Healthcare professional:

- a person who is authorized by law to prescribe or to recommend prescribed products, who "regularly practices"[3] in Vermont, and who either is licensed by Vermont to provide or is otherwise lawfully providing healthcare in Vermont;
- a partnership or corporation made up of such persons; or

[3] "Regularly practices" means to practice at least periodically under contract with, as an employee of, or as the owner of, a medical practice, health care facility, nursing home, hospital, or university located in Vermont.

- an officer, employee, agent, contractor of such person acting in the course and scope of employment, of an agency, or of a contract related to or supportive of healthcare provision to individuals. This includes nursing and office staff.

Healthcare provider:

- A healthcare professional, a hospital or nursing home, a pharmacist, health benefit plan administrator or any other person authorized to dispense or purchase for distribution prescribed products in Vermont. A hospital foundation organized as a nonprofit entity separate from a hospital is not a "healthcare provider."

Banned Gifts

Vermont broadly bans Manufacturers from giving gifts to HCPs. A "gift" is defined as:

- Anything of value provided for free to a healthcare provider or a member of the Green Mountain Care Board;
- Any payment, food, entertainment, travel, subscription, advance, or service provided to a healthcare provider or board member (except for the allowable expenditures of meals and food for participants at (a) permitted significant educational, medical, scientific, or policy-making conferences or seminars and (b) educational programs offered by medical device manufacturers); or
- Anything of value provided for free to a healthcare provider or board member unless the healthcare provider or Board member reimburses the cost at fair market value.

Examples of banned gifts include:

- Monetary donations to a doctor or clinic
- Charitable donations to a hospital
- Sponsoring a fellowship, even if the company does not select the recipient
- Meals, drinks, or snacks in the doctor's office with Vermont HCPs (the definition of which includes provider's staff)
- Marketing surveys
- Dinner at a seminar or conference at which the meal is organized and paid for by the manufacturer
- Food provided at a manufacturer's display in Vermont other than at a conference or seminar
- Dinner provided in another state to a Vermont-licensed physician whose primary office is in Vermont
- Driving a Vermont physician to an event in another state

Note that this is **not** an all-inclusive list of banned activities. For further information, including guidance regarding common errors that may result in enforcement action, please review the Vermont state link in this policy or contact the LPC Department.

Permitted Gifts

The following are gifts that are permitted under Vermont law:

- The loan of a medical device for a short-term trial period, not to exceed 120 days, permits evaluation of a medical device by a healthcare provider or patient.
- The provision of reasonable quantities of medical device demonstration or evaluation units to a healthcare provider to assess the appropriate use and function of the product and determine whether and when to use or recommend the product in the future.
- The provision, distribution, dissemination, or receipt of peer-reviewed academic, scientific, or clinical articles or journals and other items that serve a genuine educational function
- provided to a healthcare provider for the benefit of patients.

- Scholarship or other support for medical students, residents, and fellows to attend a professional association's significant educational, scientific, or policy-making conference or seminar[2] if the association selects the recipient.
- Rebates and discounts for prescribed products provided in the normal course of business.
- Labels approved by the federal Food and Drug Administration for prescribed products. The provision to a free clinic of financial donations or free prescription drugs, OTC drugs, medical devices, biological products, combination products, medical food, infant formula, or medical equipment or supplies.
- Prescribed products distributed free of charge or at a discounted price under a manufacturer-sponsored or manufacturer-funded patient assistance program.
- Coffee, snacks and refreshments at a conference or seminar booth.
- Fellowship salary support provided to fellows through grants from manufacturers of prescribed products, provided (a) an academic institution or hospital applies for the grants; (b) the institution or hospital selects the recipient fellows; (c) the manufacturer imposes no further demands or limits on the institution's, hospital's, or fellow's use of the funds; and (d) fellowships are not named for a manufacturer and no individual recipient's fellowship is attributed to a particular manufacturer of prescribed products.

Allowable Expenditures

Certain expenditures are allowed, including the following items:

- Payment to the sponsor of a "significant educational, medical, scientific, or policy-making conference or seminar"[4] provided:
    - the payment is not made directly to a healthcare professional or pharmacist;
    - funding is used solely for bona fide educational purposes, except that the sponsor may, at the sponsor's discretion, apply some or all of the funding to provide meals and other food for all conference participants; and
    - all program content is objective, free from industry control, and does not promote specific products.
- Honoraria and payment of the expenses of a healthcare professional who serves on the faculty at a bona fide significant educational, medical, scientific, or policy-making conference or seminar, provided:
    - there is an explicit contract with specific deliverables that are restricted to medical issues, not marketing activities; and
    - consistent with federal law, the healthcare professional determines the presentation's content, including slides and written materials.
- For a "bona fide clinical trial," (an FDA-reviewed clinical trial that constitutes "research" as that term is defined in 45 C.F.R. § 46.102 and reasonably can be considered to be of interest to scientists or healthcare professionals working in a particular field of inquiry):
    - gross compensation for the Vermont location or locations involved;
    - direct salary support per principal investigator and other healthcare professionals per year; and

[4] A *significant educational, scientific, or policy-making conference or seminar* means an educational, scientific, or policy-making conference or seminar that (1) is accredited by the Accreditation Council for Continuing Medical Education or a comparable organization or is presented by an approved sponsor of continuing education, provided that the sponsor is not a manufacturer of prescribed products; and (2) offers continuing education credit, features multiple presenters on scientific research, or is authorized by the sponsor to recommend or make policy.

    - expenses paid on behalf of investigators or other healthcare professionals paid to review the clinical trial.
- For a research project that constitutes a systematic investigation, is designed to develop or contribute to general knowledge, and reasonably can be considered to be of significant interest or value to scientists or healthcare professionals working in the particular field of inquiry:
    - gross compensation;
    - direct salary support per healthcare professional; and
    - expenses paid on behalf of each healthcare professional.
- Payment or reimbursement for the reasonable expenses, including travel and lodging-related expenses, necessary for technical training of individual healthcare professionals on the use of a medical device if the commitment to provide such expenses and the amounts or categories of reasonable expenses to be paid are described in a written agreement between the healthcare provider and the manufacturer.
- Royalties and licensing fees paid to healthcare providers in return for contractual rights to use or purchase a patented or otherwise legally recognized discovery for which the healthcare provider holds an ownership right.
- The payment of the reasonable expenses of an individual related to the interview of the individual by a manufacturer of prescribed products in connection with a bona fide employment opportunity or for healthcare services on behalf of an employee of the manufacturer.
- Sponsorship of an educational program offered by a medical device manufacturer at a national or regional professional society meeting at which programs accredited by the Accreditation Council for Continuing Medical Education or a comparable professional accrediting entity are also offered, provided:
    - no payment is made directly to a healthcare professional or pharmacist; and
    - the funding is used solely for bona fide educational purposes, except that the manufacturer may provide meals and other food for program participants.
    - Other reasonable fees, payments, subsidies, or other economic benefits provided by a manufacturer of prescribed products at fair market value.

Samples

Vermont permits manufacturers to provide samples of a prescribed product or reasonable quantities of an OTC drug, non-prescription medical device, an item of non-prescription durable medical equipment, an item of medical food, or infant formula to a healthcare provider for free distribution to patients.

A “sample” is defined 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 an individual to receive a prescribed product for free or at a discounted price. The term does not include prescribed products distributed free of charge or at a discounted price according to a manufacturer-sponsored or manufacturer-funded patient assistance program.

Disclosure of Permitted Gifts and Allowable Expenditures

On or before April 1 of every year, every manufacturer must submit a detailed annual disclosure of value, nature, purpose and recipient of any allowable expenditures or permitted gifts made to healthcare providers, to a member of the Green Mountain Care board, or an academic institution, or a professional, educational or patient organization representing or serving healthcare providers or consumers during the previous year.

Bayer must report all expenditures for actively licensed Vermont prescribers, even if the expense was not incurred in Vermont and if the prescriber's primary practice is outside Vermont. All Bayer employees are responsible for tracking expenditures on healthcare professionals in the appropriate tracking systems (Concur, Veeva, etc.).

Disclosure of Samples and Other Items Provided to a HealthCare Provider for Free Distribution

On or before April 1 of every year, manufacturers must disclose all samples provided to Vermont HCPs during the preceding calendar year by identifying the product, recipient, number of units, and dosage for each sample.

When manufacturers are otherwise required to report under Vermont's Marketing Disclosure Law, as part of their sample disclosures, manufacturers must also report certain information relating to non-prescription medical devices, non-prescription durable medical equipment, medical food, infant formula, and OTC products provided to Vermont healthcare providers for free distribution to patients during the preceding calendar year.

Compliance Officer Form

Bayer must complete and submit a Compliance Officer Form by January 1 each year. A form identifying the compliance officer is on the Attorney General's website.

Penalties

Civil penalties for violating Vermont's gift ban and reporting requirements may be imposed up to $10,000.00 per violation. Each unlawful gift or failure to disclose constitutes a separate violation.

Registration Fee

Manufacturers with expenditures above $0 must pay an annual $500.00 registration fee by the first day of each annual reporting period (April 1).

Manufacturer Fee

Vermont also imposes an annual fee on manufacturers of prescription drugs paid for by the Department of Vermont Health Access (DVHA) for individuals participating in Medicaid or related Vermont programs. Specifically, the annual fee is 1.5 percent of the DVHA's prescription drug spending from the previous year, payable to the Vermont Agency of Human Services, for which the DVHA annually invoices each manufacturer.

// 27. Restrictions on Interactions with Certain State and Local Executive and Legislative Officials/Employees

Most states and municipalities use state lobbying and/or ethics reform statutes to regulate the activities of persons doing business with state officials or employees. Some states and municipalities require vendors and/or their representatives to register as lobbyists. Some states prohibit receiving state or municipal contracts if certain campaign contributions have been made to state or local candidates. Some states prohibit vendors from offering anything of value to certain state executive or legislative officials or state employees, and virtually all states restrict providing anything of value to any official in return for an official act.

The categories of state or local officials or employees that may trigger state lobbying, pay-to-play, procurement or ethics statutes, or similar laws include:

- State employees, including employees of state hospitals;
- Clinicians with privileges at state-owned hospitals, even if not employed by the state-owned hospital;
- State hospital formulary committee members;
- State Medicaid P&T Committee members;
- State executive branch members and their immediate family members;
- Members of the state legislature and their immediate family members; and
- Other public officials, potentially including local officials and employees.

The lobbying and ethics laws are often complex and vary from state to state. At Bayer, lobbying is also covered by the Code of Conduct for Responsible Lobbying. Therefore, sales consultants must, in advance of detailing, providing educational items or meals to, or otherwise interacting with any of the above categories of individuals, contact the Government Relations & Policy Department to determine whether the contemplated activity triggers any lobbying, procurement or ethics laws in the state or locality in which the activity will occur. If the activity potentially implicates a state lobbying, procurement or ethics law, the sales consultant must receive written approval from the Government Relations & Policy Department before proceeding with the activity.

If the contemplated activity involves a Louisiana individual who falls into one of the above-referenced categories, please review the Policy and Procedure, “State Laws: LOUISIANA – Restrictions on Interactions with State Executive Branch Officials (Including Healthcare Professionals).”

// 28. Promotion and Government Reimbursement

Bayer recognizes that each customer is solely responsible for the accuracy of any billing and coding information used by that customer in obtaining reimbursement.

Bayer U.S. Pharmaceuticals employees, contractors, consultants and agents may provide insurance coding, coverage or reimbursement information for Bayer's pharmaceutical products only if it satisfies the following requirements:

- The coding, coverage or reimbursement information has been prepared and approved by the Promotional Review Team and relates to FDA-approved uses of Bayer pharmaceutical products.
- Bayer provides equal access to the same reimbursement information to all purchasers or potential purchasers of Bayer pharmaceutical products.

Bayer employees may not create their own materials or provide information not contained in the official materials prepared and approved by the Corporate Government Accounts Department. Subject to the requirements above, only Field Reimbursement Managers may provide the customer with authoritative information regarding billing codes (CPT and HCPCS) to use when submitting claims to third-party payers for approved uses of Bayer pharmaceutical products. The information may relate to published dollar reimbursement amounts assigned to a code from the current Medicare Durable Medical Equipment for Prosthetics, Orthotics and Supplies and/or Clinical Laboratory Fee Schedule.

Written materials must not direct any customer how to bill but may collate and report information relating to procedural and product coding, billing and reimbursement obtained from authoritative sources, such as the websites of American Medical Association, the Centers for Medicare & Medicaid Services (CMS), regional and local public contractors (carriers, fiscal intermediaries, and durable medical equipment regional carriers) or private insurance contractors. Such written documents also must clearly reference the source for any such information. Any materials provided to customers must be informational only to assist the customer in understanding and complying with CMS and other insurers' billing, coding and reimbursement policies and requirements. Bayer does not add to, delete, or modify third-party information and must include a conspicuous disclaimer that the information was obtained from a third party, is not advice from Bayer, and that Bayer cannot guarantee reimbursement from any third party.

Bayer employees may not discuss the reimbursement a customer may receive for a Bayer pharmaceutical product or procedure from Medicare, Medicaid, or any other third-party payer. Bayer employees may not provide personal opinions or interpretations of coding, coverage or reimbursement information. Bayer employees are also prohibited from advising customers regarding how to use the coding process to maximize financial benefit to the customer and from suggesting codes that a customer should use based on patient-specific information.

Bayer employees should not disclose an Average Wholesaler Price (AWP) and/or Wholesale Acquisition Costs (WAC) to customers or other prices such as Average Sales Price (ASP) on which government reimbursement is based, unless required to do so by law and disclosure is made in a pre-approved manner (please review the Policies and Procedures on State Law for further detail). If a customer requests that information, you must suggest the customer consult the CMS website, the state Medicaid office, or other publicly available source (such as First Databank) where the information may be obtained and/or direct the customer to the Market Access Department. Bayer shall strictly limit any communications relating to billing, coding and reimbursement to communications that comply with this policy.

Bayer's policy is to promote products based solely on their efficacy, safety and cost. You must not encourage customers to prescribe or purchase Bayer's pharmaceutical products based on reimbursement levels or any "spread" that is the difference between the price the customer paid for the product and the amount the customer may receive in reimbursement from a third-party payer, including Medicare or Medicaid.

The federal Anti-Kickback Statute (AKS) prohibits offering remuneration to induce someone to purchase your product, and the government could view attempts to market product based on the "spread" as an improper inducement in violation of the AKS.

If you have any questions regarding the promotion of products that Medicare or Medicaid reimburses or what constitutes proper promotional activity, contact your supervisor or the LPC Department.

// 29. Appropriate Target Audience for Promotional Activities

The promotion of Bayer's pharmaceutical products must be directed to healthcare professionals who can prescribe, influence the prescribing of, order, or otherwise use the product for an approved use. Bayer sales representatives may make sales calls or present product information only in situations in which the audience is comprised, to a reasonable degree, of healthcare professionals who would have reason to prescribe, administer or dispense the Bayer pharmaceuticals product in question for an approved use.

Healthcare Professionals (HCP) is a very broad term and includes individuals who directly interact with patients and/or have a role in diagnosing or treating patients. This includes individuals who work for entities that provide healthcare services and/or items to patients. These individuals may purchase, lease, recommend, give information on, use, arrange for the purchase or lease of, or prescribe Bayer's pharmaceutical, biologics or device products in the US. Generally, this definition includes physicians, nurses, nurse practitioners, physician assistants, and medical assistants. In addition, those closely connected to the patient experience, such as pharmacists, radiology technologists, and therapists, also fit into Bayer's definition. However, this definition is not limited to these individuals alone; the term includes any person, whether licensed or not, who is in a position to recommend, influence, or provide information about the purchasing or prescribing of Bayer's pharmaceutical, biologics, or device products. In some instances, this may include individuals who do not work directly with patients but have influence over or provide information about the recommendation, purchase, or prescribing of Bayer's pharmaceutical products, such as billing or office managers, agents at hospitals, physician practice managers, management personnel within group purchasing organizations (GPOs), managed care organizations (MCOs), pharmacy benefit managers (PBMs), specialty pharmacies (SPs), health plan administrators, wholesalers, distributors, pharmacies, Pharmacy & Therapeutics Committee members, Formulary Committee members, or other customers who do not see patients. In addition, some positions and titles within the industry are not considered healthcare professionals, such as Original Equipment Manufacturers (OEMs), retail managers or back-office staff. Accordingly, such persons are not considered HCPs under Bayer's policy. Bayer's HCP definition differs from a "covered recipient" used for reporting purposes under the Sunshine Act. As a reminder, as of January 2023, HCPs with the following credentials are reportable under the federal Sunshine Law: APRN, CNM, CNS, DO, MD, DO, NPP, and PA. They must always be documented as an HCP, including capturing their license number, regardless of the state where they practice or where you interact with them.

In addition, specific states require reporting interactions with certain, locally defined HCP credentials (*e.g.,* RNs, LPNs, pharmacists. The chart below lists HCP credentials for whom payments and exchanges of goods or services, otherwise referred to as "transfers of value" (ToVs), are reportable.

Reportable Healthcare Professional Credentials by State

Healthcare Professional	Credential	Connecticut	Massachusetts	Minnesota	Nevada	Washington, DC
Registered Nurse	RN				✓	✓
Licensed Practical Nurse	LPN		✓		✓	✓
Pharmacist	PHAR	✓	✓	✓	✓	✓
Registered Pharmacist	RPh	✓	✓	✓	✓	✓
Doctor of Pharmacy	PharmD	✓	✓	✓	✓	✓

When conducting an event that includes an HCP attendee with a credential in one of these identified states, you must record this attendee as an HCP and include the state license information; otherwise, the attendee should be recorded as a Business Guest.

Audiences for promotional activities should not be selected in such a way as to circumvent the prohibition of off-label promotion of Bayer pharmaceuticals products. For example, Bayer representatives may not:

- Make sales calls, present product information, or provide samples to physicians who specialize in disease states not aligned with the approved use of a Bayer pharmaceutical product.
- Display or hand out literature and/or free product samples at a convention or conference dealing primarily with off-label topics.
- Host a speaker program for healthcare professionals whose practice does not include any on-label uses of a Bayer pharmaceutical product.

Questions regarding the approved use of the products must be directed to Medical Affairs.

// 30. Promotional Practices Outside the United States

If Bayer pharmaceutical products are being promoted for use in the United States even if that promotional activity occurs outside the United States these Compliance Policies and Procedures and the Bayer Code of Conduct apply. This policy is consistent with the requirements of the PhRMA and AdvaMed Codes.

Additional Guidance

- You may not discuss off-label uses of a Bayer pharmaceutical product with a U.S. physician or offer prohibited remuneration simply because you are both attending a conference outside the United States. Use extra care in setting up courtesy suites or exhibit booths abroad. If the product is used in the United States, you are bound by United States promotional rules.
- Bayer employees cannot arrange for the attendance of U.S. healthcare professionals at medical education programs outside the U.S. to discuss uses unapproved in the U.S., even if those uses are approved in the country where the medical education program takes place.
- Policies related to unlawful remuneration or kickbacks apply when you are overseas interacting with U.S. customers and/or healthcare professionals.
- Bayer employees must adhere to applicable international industry guidelines (*e.g.,* European Federation of Pharmaceutical and Industry Associations (EFPIA) Code of Practice; Eucomed Code) when interacting with international healthcare professionals who may prescribe, recommend, purchase or lease Bayer pharmaceutical products.
- The U.S. meal and travel policies must be followed when interacting with a U.S. HCP outside the U.S. Please refer to Policy and Procedure “Business Meals with Healthcare Professionals.”

Bayer complies with the EFPIA Code of Practice requirements and the reporting obligations of the EFPIA Disclosure Code. This formal code of conduct requires all EFPIA member companies and companies that are members of EFPIA member associations to disclose transfers of value to healthcare professionals (HCPs) and healthcare organizations (HCOs). Please contact Compliance for assistance with EFPIA-related questions or activities.

// 31. Materials for External Use

Bayer employees, contractors, consultants and agents may only distribute promotional and non-promotional materials approved through the Promotional Review Team ("PRT") review process. Bayer employees, contractors, consultants and agents may conduct presentations to instruct healthcare professionals on the proper, on-label use of Bayer pharmaceutical products. However, you must neither solicit questions about nor provide presentations for unapproved uses. You may not make suggestions about or assist in specific prescribing decisions.

In cases where a full PRT review is not required under this policy, Legal can request a full PRT review if the Legal reviewer believes such review is warranted.

Advertising and Promotional Materials

Advertising and promotional materials include but are not limited to visual aids, "slim jims," file cards, journal article reprints, journal supplements, article abstracts, pilot study reports, letters to physicians, audiovisual materials, slide or computer presentations, displays, posters, monographs, press materials, consumer materials, computer programs and Internet or Internet-based programs, and websites as well as any materials (regardless of the media used) issued by or on behalf of the company to support or encourage the prescription, supply, sale, lease, license, administration, or consumption or use of its products.

Self-Created Materials ("Homemade Bread") are Prohibited

Creating your own promotional materials, known as "homemade bread," IS STRICTLY PROHIBITED. Self-created materials include detailing pieces, publicly available materials (websites, journals, press releases), and documents containing cost comparisons, reimbursement information, or other materials that have not been approved through the PRT process. Adding to, altering or modifying approved promotional or non-promotional materials, such as by highlighting, deleting, editing or adding notes or other material, makes those materials unacceptable for use.

Any changes to approved materials or changes in the contextual use of materials must be resubmitted for approval by the PRT review process.

Non-Promotional Customer Education Materials

Non-Promotional Customer Educational Materials include training materials issued by or on behalf of Bayer that are intended for education and use by a customer (end-user customers and any customer in the sales channel).

Educational or business materials used for advisory boards, investigator meetings, speaker training, etc., may not be distributed to healthcare professionals who do not attend the meeting. All such materials must be approved through PRT before distribution or use at these meetings.

Comparative Claims

You may not make comparative or superiority claims without substantial supporting clinical evidence provided in approved materials. Do not compare drug reactions/events from package inserts of other Bayer pharmaceutical products or of competitor's products.

// 32. Materials for Internal Use Only

Bayer permits the distribution of certain educational materials intended for education or to provide general business information among its employees, contractors, consultants, and agents. These materials may not, however, be used externally (*e.g.,* to promote, discuss or reference Bayer's pharmaceutical products), unless specifically approved for such use.

In cases where a full PRT review is not required under this policy, Legal can request a full PRT review if the Legal reviewer believes such review is warranted.

Communications and Materials to Sales Force

Educational or business materials to be used for internal purposes only must be clearly marked with language such as "STOP: For your educational use only, confidential and proprietary information, not to be distributed externally." It is the obligation of every Bayer employee, contractor, consultant or agent providing services to or on behalf of Bayer to ensure that any distributed material is clearly marked in this manner, including any material forwarded by electronic mail. Documents marked for internal use only are not to be distributed to or discussed with customers.

Radiology-Specific Training Materials

Non-Promotional Internal Training Materials mean any training materials for Bayer Radiology internal personnel issued by or on behalf of the company, provided that those materials do not support or encourage the prescription, supply, sale, lease, license, administration, or consumption or use of its products. Non-Promotional Internal Training Materials include but are not limited to training for internal personnel relating to 1) the service of our equipment, 2) the technical aspects of the equipment, 3) skills-based sales trainings and 4) internal procedures or protocols. Non-Promotional Internal Training materials do not require PRT review.

Sharing of Information Gathered from Publicly available sources for Educational Purposes (in Accordance with Copyright Restrictions)

Subject to the process below, information gathered from the public domain may be shared among Bayer employees, contractors, consultants, and agents (*e.g.,* within the sales force, from representative to representative, representative to manager, or manager to representative). Information gathered from the public domain must be forwarded for Legal, Medical, and Regulatory review before dissemination. Together, these departments will formulate appropriate educational materials for the field.

Examples of industry-related information gathered from the public domain include:

- Competitive intelligence (*e.g.,* revised package inserts for competitive products, press releases regarding new data or studies on competitive products);
- Industry or product-related news or information from the press (*e.g.,* newspapers, magazines, online news services, Pink Sheet, industry publications, medical journals, medical textbooks);
- Consumer advertisements (*e.g.,* newspaper ad); and
- Recall notices.

If a Bayer employee or manager shares information with other Bayer employees, contractors, consultants, or agents gathered from the public domain, the sharing employee/manager cannot interpret or analyze the information in any way. The party forwarding the information must include a disclaimer such as: "STOP: For your educational use only. Not to be used as a promotional item."

// 33. Inquiries About Off-Label Uses of Bayer Products

If anyone (such as a physician, pharmacist, healthcare professional or individual from a buying group or patient group) asks an unsolicited question about off-label uses of Bayer pharmaceuticals products, you must have that person complete a PIR or provide Medical Communications' phone number. You may neither answer these questions nor solicit this type of inquiry.

Procedures

If a discussion of, or question about, an unapproved ("off-label") use is initiated by anyone outside Bayer, the Bayer employee, contractor, consultant, or agent must advise the inquirer that Bayer policy prohibits them from discussing off-label uses. The employee, contractor, consultant, or agent must:

- Refer the inquiry to Medical Communications by providing to the requestor the telephone or telefax number of Medical Communications: 1-888-84BAYER (1-888-842-2937); or
- Complete a Professional Inquiry Request (PIR) form, either paper or electronic, including the name, address and signature of the requesting healthcare professional, a description of the information being requested and the method by which the healthcare professional wishes to receive the information, then transmit the PIR form to Medical Communications for processing of the request.

Sales/marketing personnel may not directly contact Medical Science Liaisons or Medical Directors regarding requests for information on unapproved uses of Bayer products. Medical Communications will provide information directly to the requestor or deploy a Medical Science Liaison following applicable Medical Affairs policies and procedures. No discussions can occur in a public forum about the unapproved uses of Bayer's pharmaceutical products.

Additional Guidance

Soliciting Discussion: It is against Bayer policy for a sales consultant to ask leading questions to encourage discussion of unapproved uses (*e.g.,* "What was new at ASCO?"). Bayer representatives may not promote or participate in "off-label" discussions at events such as physician speaker programs or "plant" questions in the audience that are likely to lead to off-label discussion.

Budgets or quotas: Budgets or quotas must not be designed or construed to encourage off-label promotion. Budgets and quotas can properly account for all physician use of a product, including off-label use. However, you cannot generate or try to generate such sales by off-label promotion.

Medical Science Liaisons (MSLs): MSLs may respond to unsolicited requests from healthcare professionals to discuss unapproved uses of Bayer products to the extent permitted by the Medical Affairs Guidelines. MSLs, however, may not promote Bayer products for unapproved uses, nor may MSLs serve as surrogates for sales consultant efforts to elicit "unsolicited" inquiries from healthcare professionals.

Requests for Non-Approved Materials: Requests from healthcare professionals or other Bayer customers for product samples for off-label uses, non-promotional materials, materials discussing off-label uses, or materials that are not approved for promotion must be directed to Medical Communications or a Medical Science Liaison. You may not solicit this type of request or inquiry nor provide such information.

Inquiries about Equipment Setup

Bayer representatives may receive inquiries from healthcare professionals regarding the setup and use of Bayer Radiology device equipment. Bayer personnel may provide instructions on setting up and using Bayer device equipment consistent with the equipment's labeled instructions for use. The representative cannot answer questions relating to technique or other questions that are not covered in the labeled instructions for use. They must be referred to Medical Communications by providing to the requestor the telephone or telefax number of Medical Communications: 1-888-84BAYER (1-888-842-2937).

The Clinical Science and Regulatory Affairs and Medical Affairs Department will provide appropriate information directly to the requestor. Bayer sales representatives must not provide instruction on or answer any questions concerning off-label uses of Bayer Radiology device equipment.

// 34. Adverse Events/Product Technical Complaints/Device Complaints Involving Bayer Products

All Bayer employees, contractors, consultants and agents are responsible for ensuring that any information relating to the safety of our products, regardless of the causality/relatedness or seriousness of the event to the product, is relayed to GPV-US within 24 hours after the employee, contractor, consultant or agent becomes aware of the information.

The following information should be reported:

- Adverse Event (AE): Any unintended medical occurrence in a patient, following the use of a Bayer Pharma or Consumer Health product, regardless of whether it is considered to be causally related (*e.g.,* associated) with the treatment (definition adapted from ICH E2D guidelines). This includes reports of suspected adverse (drug) reactions (also referred to as individual case safety report (ICSR), adverse events, invalid cases, medical device reports, serious undesirable effect (SUE) for cosmetic products and certain reports without an adverse event referring to special circumstances (*e.g.,* exposure via parent) lack of drug effect (LODE), medication errors, (intentional) product use issue, off-label use, overdose, abuse, misuse, drug dependency, product use issue, preexisting condition improved (in an unapproved indication) and occupational exposure.
- Product Technical Complaint (PTC) is any report received (written, electronic or verbal communication) about a potential or alleged failure of a Bayer product in its quality (including the identity, durability, reliability, safety, efficacy or performance) or a suspected counterfeit. The complaint may or may not represent a potential risk to the patient/customer/user/environment.
- Device Complaint (DC) - Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a Bayer device after it is released for distribution.

When reporting safety-related information, it is essential to obtain the following:

- Identifiable Patient Information (*e.g.,* gender, age or age range, DOB, patient initials, name, etc.);
- Description of the AE/PTC/DC (try to use the reporter's exact words as much as possible);
- Bayer product (including lot # if available); and
- Reporter information (*e.g.,* Patient, Nurse, Physician, etc.).

Within 24 hours, provide all AE/ADR/PTC-related information using any one of the following four methods:

Via SafeTrack with the web version: https://safetrack.bayer.com (OR via mobile App to be downloaded in the Bayer App Store or Apple App stores)

For AE:	For DC/PTC:
Phone: 1-888-842-2937	Phone: 1-888-842-2937
E-Mail: DrugSafety.GPV.US@bayer.com	E-Mail: MPS.Bayer@Bayer.com
Facsimile: 1-973-709-2185	Facsimile: 1-973-305-3565

For Radiology

For prescription drug products, information must be provided to the Medical Communications Department at 1-888-842-2937.

Reports involving device products should be directed to the Complaint Handling Department at 1-800-633-7231.

For both drug and medical device product reports, the information can also be emailed to the drug safety reporting email box: DrugSafety.GPV.US@bayer.com.

In addition, the employee, contractor, consultant, or agent should provide their contact information, including the date and time they were first notified about the report if GPV-US needs to follow up to obtain additional information.

// 35. Clinical Research and Clinical Study Support

The Physician Payments Sunshine Act requires that any transfer of value given to an HCP, teaching hospital and/or all employees of a teaching hospital must be reported to the Centers for Medicare & Medicaid Services (CMS). Each employee's, contractor's, consultant's, and agent's responsibility is to report accurate, complete and timely data to applicable Bayer systems, as this is the data Bayer will report to CMS.

All research and clinical studies supported by Bayer must promote legitimate research goals. Bayer may enter into an arrangement to sponsor or authorize clinical research or clinical studies to develop clinical information concerning Bayer pharmaceutical products and/or Bayer-supported research related to the diagnosis and treatment of conditions or diseases, provided that the clinical information sought is reasonably necessary to achieve a commercially reasonable business purpose. Support for any research or study cannot be provided with the requirement or expectation that Bayer's support will induce or encourage the prescription, purchase, order, referral, use, or recommendation of Bayer's pharmaceutical products. Any research or study supported by Bayer must be conducted according to a written agreement approved by the LPC Department that, at a minimum, includes:

- A statement of the research objectives;
- An outline of the research protocol;
- A written budget detailing the financial and other support to be provided by Bayer U.S. Pharmaceuticals; and
- Data must be provided periodically and, where applicable, a final written report.

Payments for clinical or research studies must represent fair market value. It is not appropriate for Bayer to pay a clinical investigator compensation based on, or related to, the past, present or future volume or value of business generated directly or indirectly for Bayer by that clinical investigator or their colleagues.

Agreements to fund clinical trials or research may constitute a Focus Arrangements (Interaction with HCPs and HCOs). For example, an agreement to fund clinical research or clinical studies must be considered a Focus Arrangement (Interaction with HCPs and HCOs) if the intended recipient of the funds, such as a hospital or research site, is an actual or potential source of sales or referrals of Bayer's pharmaceutical products.

Sales and Marketing may not be involved directly or indirectly in the selection of potential sites for clinical studies.

Law, Patents and Compliance Review of Focus Arrangements (Interaction with HCPs and HCOs)

For all requests for clinical research or study support that are interactions with HCPs and HCOs, the LPC department must verify that the agreement contains a certification by the parties that the parties shall not violate the Anti-Kickback Statute concerning the performance of activities related to the arrangement.

The LPC Department evaluates whether the proposed arrangement satisfies the requirements of the Anti-Kickback Statute and assesses compliance with relevant Safe Harbor(s). The reviewing attorney must document that this assessment was conducted, name, and the date the assessment was conducted.

The LPC Department also confirms that the proposed payment represents fair market value. The methodology used to determine fair market value will be based on information in a database of fair market values or other sources available to Bayer. Any deviation from the fair market value methodology and the rationale for such deviation must be approved by the Vice President and Head, U.S. Office of Compliance (or designee) and documented and maintained in the LPC Department. Bayer must provide each party to the arrangement a copy of Bayer Code of Conduct and Anti-Kickback Statute Policies and Procedures. These documents may be sent electronically or by hard copy and can be included as an exhibit to the agreement or sent as separate documents. Bayer must document that these documents were sent.

Law, Patents and Compliance Review

If the approved request for clinical research or clinical study support is not an interaction with HCPs and HCOs as determined by the LPC Department, the Department of Monitoring & Study Management will send the approved agreement to the fund's recipient (or designated staff member).

Third-Party Contracts

Bayer may work with third parties who contract with hospitals, research sites, or other entities on behalf of Bayer. To ensure that third-party contracts comply with the Anti-Kickback Statute and Bayer Pharmaceuticals Compliance Policies and Procedures, the LPC Department will provide a template contract for the contracting entities to use. The reviewing attorney must assess whether the proposed arrangement complies with the Anti-Kickback Statute and assess compliance with relevant Safe Harbor(s). This assessment, the date it was conducted, and their name must be documented.
The third-party contract must include a maximum value for the research or clinical studies support based on information from a database of fair market values or other relevant sources. The contract provided to the third party must contain a certification by the parties that the parties shall not violate the Anti-Kickback Statute for the performance of activities related to the grant.

The third party must send to each party the arrangement, a copy of the approved contract, a copy of the Bayer Code of Conduct and the Anti-Kickback Statute Policies and Procedures and document that these were sent.

When the executed contract is returned from each party to the contract specialist from the Department of Monitoring & Study Management, the contract specialist must complete the Focus Arrangement Upload Template. Refer to Policy and Procedure, Focus Arrangements (Interaction with HCPs and HCOs), for information regarding these Procedures.

Additional Guidance

- Bayer may not seek to further the pre-approval or off-label use of Bayer pharmaceutical drug products under the guise of a less-than-adequate clinical study.
- Recipients of Bayer's financial support for clinical research and clinical studies must be made aware, and the respective contract(s) reflect, that Bayer reserves the right to audit the use of such funds and will require documentation, such as progress reports, to show that its financial support has been used properly.
- "Investigators' Meetings," where researchers doing clinical research studies meet to discuss the status of their research, are not promotional events and must not be utilized for such purposes. Neither Sales nor Marketing personnel may attend these meetings.
- Sales Consultants and Marketing personnel are not permitted to approve the sponsorship of any clinical research or clinical study.

Proof of Service

The Department of Monitoring & Study Management or Medical Communications Department will retain documents confirming proof of the services provided, such as a report on the clinical trials, for ten years.

// 36. Investigator/Institution Initiated Research (IIR)

The Physician Payments Sunshine Act requires that any transfer of value given to an HCP, teaching hospital and/or all employees of a teaching hospital must be reported to the Centers for Medicare & Medicaid Services (CMS). Employees, contractors, consultants, and agents are responsible to report accurate, complete, and timely data to applicable Bayer systems, as this is the data Bayer will report to CMS.

This policy describes the appropriate use of grants to fund independent investigator/institution-initiated research that fosters increased understanding of scientific, clinical, or healthcare issues that contribute to improving patient care. Bayer's policy conforms to the HHS-OIG Compliance Program Guidance for Pharmaceutical Manufacturers, the PhRMA Code, the AdvaMed Code of Ethics, ACCME standards for commercial support and other relevant industry guidance.

Requirements of Investigator-Sponsored Study Grants

All grants for investigator/institution-initiated research provided by Bayer U.S. Pharmaceuticals must promote legitimate research goals. Investigators/institutions must be selected based solely on their credentials and the merits of their research proposals. Bayer may not provide an investigator/institution-initiated research grant to induce or reward an investigator for prescribing, recommending, or purchasing a Bayer product or to familiarize an investigator with a Bayer pharmaceutical product. Elements of a bona fide study include:

- Stated research goals are scientifically sound and can be achieved by clinical protocol;
- Investigator/institution and staff are qualified; and
- Bayer and/or the investigator/institution intend to publish the study or submit the results to the FDA.

Investigator/institution-initiated research grants must not be provided directly to the investigator or a private physician practice. Grants must be made only to an entity, such as a hospital or research facility. All grants to the military must be provided through the Henry M. Jackson Foundation for the Advancement of Military Medicine (Jackson Foundation) or similar third-party organizations set up to receive grants on behalf of the Department of Defense.

Involvement of Bayer Personnel

Protocols for Bayer-supported clinical studies must be written primarily by the investigator/institution. Bayer employees, contractors, consultants, and agents may not write a protocol for an independent investigator/institution. However, upon request by the investigator/institution, Bayer clinical or medical personnel may provide comments, advice and/or assistance with protocols (*e.g.,* Medical Affairs personnel may provide a protocol summary outline for use by the IIR Grant Review Committee, as described below.)

The Investigator/Institution Initiated Research ("IIR") Grant Review Committee is responsible for the review and approval of all investigator/institution-initiated research grants within Bayer. Sales and Marketing may not be included in any communication regarding the status of a grant request, nor may Sales and Marketing personnel be involved in the provision of a grant. Sales and marketing personnel must not:

- Select or recommend recipients;
- Discuss Bayer's provision of investigator/institution-initiated research with a customer or assure a customer about participation in a prospective study;

- Discuss ideas for potential research protocols with customers; or
- Assist in drafting a research protocol.

Sales and Marketing may not be involved directly or indirectly in selecting potential sites for investigator/institution-initiated research.

If Sales and Marketing personnel are approached by a customer or potential investigator/institution regarding a grant, they must direct the customer to the Investigator-Institution Initiated Research website and/or the customer service telephone number (1-888-84-Bayer or 1-888-842-2937).

Disclosure of Bayer Support

All publications that relate to or result from research supported in whole or in part by a grant or other financial support from Bayer must accurately disclose Bayer's financial support.

Unacceptable Investigator/Institution-Initiated Research Grants

A grant is **not permitted** if it is **any one** of the following:

- Intended as a price term, offered in place of a price concession; or
- Intended to encourage off-label use; or
- Contingent on the purchase or recommendation of Bayer products; or
- Intended to encourage the investigator/institution to order, prescribe, or recommend Bayer pharmaceutical products or reward or compensate the recipient for having done so; or
- Solely to fund salaries of hospital nurses, residents, or other healthcare professionals, or routine administrative costs; or
- Provided to pay for activities that should be covered by fee-for-service contracts as described in Policy and Procedure, "Fee-For-Service Arrangements;" or
- Not submitted through the Bayer website.

Grants for clinical trials or medical research initiated or controlled by Bayer are not considered "investigator/institution-initiated research" for purposes of this policy. Instead, they must comply with Policy and Procedure, "Clinical Research and Clinical Study Support."

Procedures

All requests for grant funds for investigator/institution-initiated research must be submitted to the Bayer website. The initial request must:

- Describe the purpose/intended use of the grant or reference other documents attached, such as a study protocol or concept that describes the purpose/intended use of the grant. It is not acceptable to list only a generic description (*e.g.,* "investigator-sponsored study") as the purpose of the expense;
- Include a budget; and
- Confirm that the grant will be used to support investigator/institution-initiated research.

Grant Requestor

The investigator/institution (or designated staff member) must input all required grant information electronically. The investigator/institution is responsible for providing any requested grant-related documentation.

Grant Manager Review

A Grant Manager initially reviews the grant request. If the grant request is deemed complete, within budget and brand plan, it will be placed on the agenda for review by the IIR Grant Review Committee at the next scheduled meeting.

If the Grant Manager finds the request incomplete after attempting to obtain appropriate documentation, they will inform the requestor that the request is being denied due to insufficient documentation.

Grant Review Committee

The Grant Review Committee comprises members from Medical Affairs, Field Medical Affairs, and LPC. Sales and Marketing personnel do not participate in the Grant Review Committee.
The Grant Review Committee reviews grant requests from a scientific, educational, regulatory and legal perspective consistent with the following:

- Each Committee member certifies that, to the best of his/her knowledge, there are no legal or compliance issues prohibiting Bayer's approval of the grant request (*e.g.,* no conflict with government or industry guidelines or Compliance Policies and Procedures);
- The grant will support medical research or other activities that foster increased understanding of scientific, clinical, or healthcare issues that contribute to improving patient care;
- The request is within the budget for each therapeutic area; and
- The request is aligned with Bayer's strategy and therapeutic focus.

If the Grant Review Committee needs additional information to determine whether to approve the grant request, it will approve, reject, or table the request in anticipation of receipt of further clarification or information in conformance with these Policies and Procedures. Approval of the request requires consensus among the voting members present at the Grant Review Committee meeting.

Law, Patents and Compliance Review of Arrangement

The LPC attorney participating on the Grant Review Committee must verify that the agreement contains a certification by the parties to the arrangement that the parties shall not violate the Anti-Kickback Statute concerning the performance of the interaction with HCPs and HCOs.
The attorney also evaluates whether the proposed arrangement satisfies the requirements of the Anti-Kickback Statute and assesses compliance with relevant Safe Harbor(s). This review/ assessment, its date, and who conducted it must be documented.

The LPC Department confirms that the proposed grant funds represent fair market value. The methodology used to determine fair market value will be based on information in a database of fair market values or other relevant sources available to Bayer. Any deviation from the fair market value methodology and the rationale for such deviation must be approved by the Vice President and Head, U.S. Office of Compliance (or designee) and documented and maintained in the LPC Department.
If the reviewing attorney is absent at the Grant Review Committee meeting, the attorney may conduct the required review later. However, this review must be completed before the grant is approved and payment is made.

Grant Manager Post-Meeting Documentation

The Meeting Summary will be prepared for each Grant Review Committee meeting. The Meeting Summary will include whether or not the grant request was 1) approved (indicating amount), 2) rejected, or 3) tabled for receipt of further clarification or information or further discussion.

If approved, the Grant Manager may provide a letter documenting the Grant Review Committee's decision to the requestor (or institution-designated staff member) following the meeting. The Grant Manager is responsible for updating the electronic system with the decision.

Proof of Service

The Grant Manager or other Bayer employee must confirm that the grant's services and/or deliverables were performed and/or delivered. Acceptable proof of performance includes enrolment logs, clinical data, a report of clinical trial results, or a publication containing such results. The agreement must permit Bayer to obtain proof of service.

// 37. Price Reporting

It is Bayer's policy to completely and accurately report cost, price and sales information about Bayer's pharmaceutical products in compliance with federal laws and regulations and to the extent requested by any federal and/or state government entity relating to a government healthcare program and, as appropriate, to any private price reporting entity. Bayer maintains detailed desktop standard operating procedures ("SOP") in the Government Contracting Department for calculating:

- Medicaid Best price ("BP")
- Medicaid Average Manufacturer Price ("AMP")
- Medicare Average Sales Price ("ASP")
- Non-Federal Average Manufacturer Price ("Non-FAMP")
- Federal Ceiling Price
- Public Health Service ("PHS") Price (340B Ceiling Price)

These desktop procedures are updated periodically to reflect changes in the statutes, regulations or guidance issued by the Centers for Medicare and Medicaid Services (CMS), the Department of Veterans Affairs or other relevant agencies. For further information on these SOPs, contact the LPC Department or Government Contracting Department.

Definitions

Government Healthcare Program – Any plan or program that provides health benefits and is funded, in whole or in part, by the federal government or the states. Examples include Centers for Medicare and Medicaid Services (CMS)'s Medicaid and Medicare Programs, Department of Veterans Affairs' Federal Supply Schedule Program, U.S. Department of Health and Human Services Pharmacy Affairs Branch, TRICARE, Department of Defense, Public Health Service (340B Program), and the U.S. Department of Labor programs.

Price Reporting Entity – A private publisher, such as Redbook or First Databank, collects pricing information and makes such information available to healthcare professionals and customers.

General Policy for Reporting Price Information

All information that Bayer must report or generate, directly or indirectly, about costs, prices and sales information for Bayer pharmaceutical products for submission to or use by a Government Healthcare Program or a Price Reporting Entity must be accurate, complete and per government laws and regulations.

The Government Contracting and Price Reporting department calculates and submits government price reports under each government program's reporting policies and procedures. The Government Contracting and Price Reporting department maintains and updates the policies and procedures following each government program's rules and regulations.

Procedures

Completion of Requests for Pricing Information and Submission Process

Any Bayer employee, contractor, consultant, or agent who receives a survey or request for pricing information from any Government Healthcare Program or a Price Reporting Entity must forward that request to the Director of Government Contracting and Price Reporting for completion. In addition, a copy of all such requests for pricing information must be sent to the LPC Department.

Only the Director of Government Contracting and Price Reporting may submit responses to such surveys or requests.

Questions

Any questions concerning a response to a request for pricing information from a government entity or a Price Reporting Entity must be directed to the Head of Contracting or the LPC Department.

// 38. Reviewing and Approving Customer Contracts

Bayer often sells its products according to written contracts that list all discounts and notify the recipient of its potential obligation to report the arrangement to the government. All discounts, rebates, and other price concessions must be provided to customers consistent with the discount Safe Harbor to the Anti-Kickback Statute, as determined by the LPC department. “Side deals” or price concessions offered outside written contracts, whether oral or written, are not allowed.

Scope

This policy sets forth the process for reviewing and approving contracts for purchasing Bayer pharmaceutical products and associated trade contracts, such as Wholesaler Fee for Services Agreements, Distributor Services Agreements and other trade agreements.

Discounts are typically provided at the time of invoice. Bayer must fully and accurately report discounts, if known, on the invoice or other statements submitted to the customer at the time the product is furnished and inform the customer of its potential obligation to report such discounts to payors and insurers.

Rebates The terms of any rebate must be fixed and disclosed in writing to the purchaser at the time of invoice. A rebate may only be furnished based upon products sold and purchased and may not be paid or earned before the provision and purchase of the Bayer products to which the rebate applies without the prior written approval of the Contract and Pricing Subcommittee (“CPS”) or Executive Pricing Committee (EPC). Each rebate paid must clearly indicate to the purchaser those Bayer Pharmaceutical products to which the rebate will be applied. A rebate on any Bayer Pharmaceutical product(s) may not exceed the total of the actual purchase price(s) for the Bayer Pharmaceutical product(s) to which the rebate is to be applied. Bayer must fully and accurately report rebates, if known, on the invoice or other statements submitted to the purchaser at the time the product is furnished and inform the customer of its potential obligation to report such rebate to payors and insurers, as appropriate, as a reduction in price on the Bayer Pharmaceutical products purchased. Bayer may only pay rebates to customers in the form of an electronic funds transfer, check or credit. If the value of the discount, rebate, or other price concession is unknown when the contract is signed, Bayer must disclose the existence of the price concession in the contract. For example, if Bayer offers tiered rebates, the purchase volume threshold and volume-based discount required to attain each tier must be disclosed in the contract.

Administrative and Service Fees It is Bayer’s policy to pay administrative and service fees only for bona fide services and at fair market value. To be excluded from prices reported to the government, administrative fees must be bona fide, as defined in the Medicaid Rebate Statute, and, in particular, must represent fair market value. To the extent Bayer cannot determine whether an administrative fee is bona fide, the value of that fee will be included as a price concession in prices reported to the government.

Bundled Goods The terms “bundled goods” and “bundling” refer to offering a discount on one product that is related to sales of another product or different product strength of the same product or making the price of one product contingent on the purchase or formulary placement of another product or different product strength of the same product. Any discount potentially involving “bundled goods” must be approved in advance and in writing by the Executive Pricing Committee. If Bayer offers bundled discounts, such bundled discounts will be unbundled per the guidance provided by CMS for price reporting purposes.

Free Product It is against Bayer policy to provide free product as a discount or price term (***e.g.,*** "buy 10, get one free").

Procedures

Approval Process

- The Bayer employee handling the account sends the proposed Request for Contract ("RFC") to Pricing and Contracting (Market Access) to review the RFC and confirm that:
    - A financial analysis has been performed;
    - The impact on Medicaid and 340B pricing has been considered;
    - Business justification has been made;
    - Competitive information has been included;
    - Past performance and contract compliance have been documented;
    - The proposal matches the potential of the customer; and
    - If required, a deviation form detailing the need to meet the competition or provide a Robinson-Patman defense has been filled out properly by the Account Manager.
- For contracts within "guidelines" previously established by the (EPC) once the above items have been reviewed, Pricing and Contracting presents the proposed custom contract to the Contract Generation, which will confirm that the above criteria are met.
- As determined by the Director of Pricing and Contracting, a "custom contract" is a proposed RFC that does one of the following:
    - Deviates from but does not exceed current contracting guideline discounts;
    - Requires a material change from Bayer's standard legal language (addition, revision, or deletion of standard language), as determined by the LPC Department;
    - Appears to conflict with product and/or approved market strategies; or
    - Significantly impacts or changes the intent of the approved strategy.
- The Director of Pricing and Contracting or designee function presents any custom contract with applicable justification to the CPS, which is composed of:
    - Business/Brand Finance Business Partner or designee;
    - Director of Contract Generation or designee; Director, Government Pricing and Contracting (Government) or designee; and
    - LPC Department.

The CPS reviews the custom contract and recommends revision, rejection, or approval of the custom contract. As part of considering a requested contract, the CPS representative from the LPC Department will consider the applicability of Robinson-Patman. Director of Pricing and Contracting or designee should provide the reviewing attorney documentation reflecting the basis and rationale for FMV. The CPS may act upon a custom contract by live meetings or e-mail. The Director of Contract Generation or the CPS representative from the LPC Department may request that the EPC review a custom contract proposal.

A custom contract requires additional approval by the EPC when it has the potential to exceed a previously approved Medicaid best price for a product if the value of the proposal exceeds $5 million, if there is not unanimous CPS approval, if a new contracting strategy is proposed or as otherwise required by the EPC. The EPC members include:

- Senior Vice President, LPC

- Vice President, Finance Business Partner
- Senior Vice President, Market Access

Requests that are approved by the EPC which impact Best Price, include a WAC increase or decrease, include a new Brand or Channel strategy (has never been approved), or include an annual discount or rebate value of $10 Million or more are subsequently forwarded to the Pharmaceutical Division President Region USA who may either approve the EPC's actions or return the proposed contract for the EPC's reconsideration.

Once a contract has been approved as outlined above, a copy is returned to the Bayer employee handling the contract to provide to LPC for review. The contract must contain:

- A certification by the parties that the parties shall not violate the Anti-Kickback Statute for the performance or activities related to the contract.
- Where applicable, Contracting must send the customer a copy of Bayer Code of Conduct and Anti-Kickback Statute Policies and Procedures or include a hyperlink to save in the contract.

Awarding the Contract

Bayer's general policy is not to backdate contracts. The effective date for a contract to purchase Bayer Pharmaceutical products may not be earlier than the day both parties agree upon all material business terms and are contemporaneously documented. Material business terms include product pricing and price concessions (including any rebate requirements), the value of administrative or service fees and the underlying services to be performed, or otherwise as may be relevant to the specific agreement. Bayer's agreement to any business term must be consistent with relevant contract guidelines and approval requirements that may be in effect.

On rare occasions generally related to extensive contract negotiations, Bayer, with the approval of LPC department, may determine that there is a need to have an effective date before the date of agreement as to all material business terms. Circumstances under which such an effective date may be permissible include amendments to correct an error in the original agreement or to avoid confusion about the parties' original intent, delays resulting from administrative processes, or the need to replace a damaged or missing document. Provided all material business terms are agreed upon by the parties and contemporaneously documented, further negotiations concerning legal and non-material items may continue before the final execution of the contract without delaying the effective date. Unless expressly approved in writing by the LPC Department, no contract may have an effective date more than ninety days before the date of execution by Bayer. Any deviations from this policy must be approved by the Vice President and Head, U.S. Office of Compliance (or designee) and documented and maintained in the LPC Department.

Under no circumstances may a contract be backdated to provide retroactive price concessions or other preferential terms not included in the original agreement.

Proof of Service

Commercial Operations maintains information confirming proof of product shipment and payment of rebates by Contract Administration and for price reporting purposes by the Government Contracting either in a database (*e.g.,* SAP, Vistex) or in hard copy, as appropriate. Contract Administration also maintains copies of proof of service related to dispensing data, administrative fees, inventory management agreements, or other service fees included in contacts for product purchase under laws and regulations and the Bayer Corporation Records Management Policy and Records Retention and Disposal Schedule.