2017 Bayer U.S. Pharmaceuticals Policies & Procedures

Pharma Policies and Procedures August 2017

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INTRODUCTION

The Bayer U.S. Pharmaceuticals Compliance Policies and Procedures, includes, but is not limited to products that fall within a therapeutic area of the Bayer U.S., LLC Pharmaceuticals division (Dermatology, Hematology, Neurology, Oncology, Pulmonology, Radiology, Women's Health). You are required to understand and follow these policies which are part of the Bayer U.S. Compliance Program. The Bayer U.S. Compliance Program includes these Policies and Procedures, the Bayer Code of Conduct, and U.S. Compliance Training. The 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 Government reimbursed products, as well as interactions between Bayer employees, contractors, consultants, agents, healthcare professionals and healthcare organizations (HCOs). Any reference to Bayer employees, contractors, consultants, healthcare professionals (HCPs) and agents within this document refers to individuals affiliated with the aforementioned therapeutic areas of the Bayer U.S., LLC Pharmaceuticals division or corporate functions supporting such divisions.

"Healthcare Professionals (HCP)" is a very broad term and includes individuals who directly interact with patients and/or have a role in the diagnosis or treatment of patients and includes entities which are involved in the provision of healthcare services and/or items to patients and which may purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Bayer's pharmaceutical products in the U.S. Generally, this definition includes physicians, nurses, nurse practitioners, physician assistants, medical assistants who treat patients, and other allied healthcare professionals, such as pharmacists, radiology technologists, and therapists. However, the definition is not limited to these individuals alone; the term includes any person in a position to recommend or influence the purchase or prescribing of Bayer's pharmaceutical products. In some instances, this may include individuals who do not work directly with patients but who have influence over the recommendation, purchase, or prescribing of Bayer's pharmaceutical products—such as a purchasing agents at hospitals, physician practice managers, management personnel within group purchasing organizations (GPOs), managed care organizations (MCOs), pharmacy benefit managers (PBMs), health plan administrators, wholesalers, distributors, pharmacies, Pharmacy & Therapeutics Committee members, Formulary Committee members, or other customers who do not see patients. Some positions and titles within the industry are not considered healthcare professionals such as, Original Equipment Manufacturers (OEMs) or retail managers. Accordingly, such persons are not considered healthcare professionals under the program.

The Bayer U.S. Compliance Program Documents (e.g., Policies and Procedures, Forms) are accessible via the intranet at URL: **http://us.bayernet.cnb/en/organization/us-corporate-departments/compliance-operations/library.aspx#policies-and-procedures**

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 and the Department of Veterans Affairs. Bayer is committed to complying with all applicable laws, regulations and industry codes (including the PhRMA Code on Interactions with healthcare professionals, the AdvaMed Code of Ethics and Medical Device Manufacturers Association (MDMA)) governing the sale and marketing of pharmaceutical and biological products as well as laws and regulations governing the reporting of prices and reimbursement information for government reimbursed products. Failure to comply with federal regulations and Bayer's U.S. Pharmaceuticals Compliance Policies and Procedures can have direct and severe consequences both to you and to Bayer.

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

termination of employment. Each Bayer employee, contractor, consultant, and agent will be required to include a Compliance objective that is relevant and meaningful to his/her job responsibilities in his or her Performance Management Process or similar performance practices. Performance on that compliance objective will be evaluated by the manager of each employee, contractor or consultant. Said objective shall include the timely completion of any assigned Compliance certification or training. Failure to adhere to these Compliance Policies and Procedures will be considered in connection with performance evaluations for all Bayer U.S. Pharmaceuticals Compliance Program Participants.

Employees, contractors, consultants, and agents are required to report suspected violations of these Compliance Policies and Procedures to their supervisor, the Law, Patents and Compliance 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 a toll free number (Bayer Compliance Hotline), 1-888-765-3846 or at **www.expolink.co.uk/bayercompliance**. Any employee, contractor, consultant, or agent who in good faith reports a suspected violation, or raises any compliance matter, will not be subject to any retaliation or adverse actions based upon such reports.

Anti-Kickback Statute

Bayer U.S. Pharmaceuticals puts 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 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. One of the primary concerns about kickbacks is that they encourage the healthcare professional to make decisions based on personal financial gain and not necessarily on what is best for the patient.

Who is a U.S. Compliance Program Participant?

Bayer's Compliance Program covers all employees, contractors, consultants, and agents in the Pharmaceuticals, Consumer Health and Crop Science businesses. Among other things, the U.S. Compliance Program covers all employees, contractors, consultants, and agents who perform any of the following functions on behalf of Bayer U.S., LLC, or any Bayer Affiliate (1) the promotion, advertising, distribution, marketing, and sale of Government Reimbursed Products; or (2) the development or dissemination of materials or information about, or the provision of services relating to, Government Reimbursed Products; or (3) involved with the initiation, negotiation, proposal, development, approval, implementation, management, oversight (including accounting functions), or review of arrangements or transactions that involve, directly or indirectly, the offer, payment, solicitation or receipt of anything of value between Bayer U.S., LLC or any Bayer Affiliate and any actual or potential source of referrals or sales of Government Reimbursed Products.

Bayer Corporate Compliance Policy

In addition to Bayer's Compliance Program described above, the Bayer Corporate Compliance Policy published covers the various Bayer businesses on a global basis. This policy provides guidance regarding important areas of corporate responsibility, including the laws of various countries that impose obligations on Bayer and its employees, contractors, consultants and agents. Although the scope of the compliance programs differ, the concepts reflecting the Company's commitment to ethical behavior are consistent, and Bayer employees, contractors, consultants, and agents are required to comply with all applicable Bayer U.S. Pharmaceuticals Compliance Policies and Procedures. The Bayer Corporate Compliance Policy may be found at: **http://www.bayernet.com/corp/policies/policies_detail.cfm?fileid=333**. In addition, the global Integrated Compliance Management @Bayer (ICM@Bayer) provides a process (e.g., policies, monitoring, and training) relative to identified substantive risk areas, including such topics as anti-corruption, conflict of interest, and antitrust.

Bayer AG Anti-Corruption Compliance Manual

The principles set forth in the Bayer AG Anti-Corruption Compliance Manual also represent a broad outline of the minimum standards of business conduct that Bayer AG expects each of its employees, globally, to follow. These minimum standards are derived from globally applicable laws, industry codes and internal regulations, and 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' Compliance Policies and Procedures, such stricter Policies and Procedures always take precedence.
The Bayer AG Anti-Corruption Compliance Manual may be found at
http://www.bayernet.com/corp/policies/policies_detail.cfm?fileid=225

The Foreign Corrupt Practices Act

Bayer conducts its business with the highest legal and ethical standards and will not tolerate corruption. 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 in order to obtain or retain business; or
- Secure an improper advantage.

Each Bayer employee, contractor, consultant, and agent has the responsibility to ensure that his/her dealings with non-U.S. government officials —including state-employed healthcare professionals—comply with the FCPA. Likewise, each employee, contractor, consultant, and agent is prohibited from making payments to any third party who the employee, contractor, consultant, or agent knows will, or believes is likely to, make an unlawful payment related to Bayer's pharmaceutical business.

Third Party Due Diligence (TPDD)

Bayer developed its group-wide, Third Party Due Diligence process to not only comply with strict legal standards across the globe, but also to 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 using the COMPASS Tool (a web-based application available here: **https://compass.intranet.cnb/sage/nui/home?0**) 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 outside of the US.

Questions

It is expected that every employee, contractor, consultant, and agent will have a working knowledge of the laws affecting his/her responsibilities and the scope of permissible activities involved in his/her work, and will seek guidance from a supervisor or the Law, Patents and Compliance Department for any questions.

1. OPERATING THE CONFIDENTIAL DISCLOSURE PROGRAM

The Bayer Confidential Disclosure Program allows employees, contractors, consultants, and agents to disclose, 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 1-888-765-3846 or at **www.expolink.co.uk/bayercompliance**, 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. Each report is assigned a unique case number, which is provided to the caller. Callers may be provided a date to make a follow-up call for the purpose of receiving a response from Bayer or for the caller to provide additional information. The reports are transmitted to the Vice President and Head, U.S. Office of Compliance (or designee) within 24 hours of receipt.

To ensure complete confidentiality, the third party vendor will mark any reports that name a designated report recipient or investigator (the Bayer U.S. Compliance Officer or designee) for "Special Handling." Reports marked for "Special Handling" will therefore not be distributed to the designated report recipient or investigator named in the report. If all designated report recipients or investigators are named within the report, the report will be sent to the Special Handling Report Recipient, who is the Global Compliance Officer for Bayer.

Publication 0f Confidential Disclosure Program

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 his/her identity.
- The fact that the Bayer Compliance Hotline should be used to report issues or questions associated with Bayer's policies, practices, procedures, or with 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 Confidential Disclosure Log

The third party vendor provides two reports to the Law, Patents and Compliance Department each month; one summarizes reporting activity from the prior month and the other lists all open reports. The third party vendor assigns the case number to each report which is recorded on all documents that are added to the disclosure file, as well as those that are maintained in Human Resources and/or the Law, Patents and Compliance Department. This allows the status of any subsequent investigation to be tracked. The reports from the third party include all disclosures made to the Bayer Compliance Hotline. Reports involving federal healthcare programs and/or Bayer U.S. Pharmaceuticals Compliance Policies and Procedures will be processed as described below. Reports that do not involve 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 Law, Patents and Compliance Department or the Human Resources Department within the related Bayer business.

Procedure upon receipt of disclosure report involving federal healthcare programs

Upon receipt of a disclosure report, involving federal healthcare programs and/or Bayer's U.S. 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 set forth in the disclosure to ensure that he or she has obtained the information necessary to determine whether further review must be conducted.

An internal review is initiated to investigate any disclosure that is sufficiently specific 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 Law, Patents and Compliance Department and/or the applicable Human Resource Department, as appropriate.

After a reasonable period of investigation 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. Once all necessary information is obtained and the investigation is finalized, the disclosure report will be documented as closed by the third party vendor.

A final written report is maintained in the Law, Patents and Compliance Department and will include, as appropriate, the results of the investigation 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, up to and including termination.

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

2. Determining ineligible persons

Scope

This Bayer U.S. Pharmaceuticals Compliance Policy and Procedures document applies to all Bayer employees, contractors, consultants, and agents as well as additional Bayer personnel as identified.

Procedures

New Hire Self-Disclosure and check against Government websites.

1. Prior to hiring a Bayer employee, contractor, consultant or agent or permitting internal job transfers and changes, the appropriate Human Resource Department Recruiter, Contingent Labor or Bayer Sponsor, must ensure that the applicant signs a Self-Disclosure form that certifies that he or she:

   - Is eligible to participate in federal healthcare programs and procurement and non-procurement programs.
   - Has not been convicted of a criminal offense involving a state or federal healthcare program.
   - Is not excluded, debarred or suspended from participating in any other government programs.
   - Will disclose immediately to the Law, Patents and Compliance Department if he/she becomes an Ineligible Person.

The Self-Disclosure form also contains the applicant's certification that he or she has received, read, understood, and agrees to abide by the Bayer Code of Conduct. The Human Resources Department must provide the Bayer Code of Conduct to the applicant as part of the onboarding process (electronically or manually) before the applicant completes the paper certification.

1. Prior to hiring, internal transfers or to approving job changes involving a Bayer employee, contractor, consultant, or agent, Human Resources, Contingent Labor or Bayer Sponsor will provide the Self-Disclosure form and the Bayer Code of Conduct to the prospective Bayer employee, contractor, consultant, or agent. In addition, Human Resources, Contingent Labor or Bayer Sponsor will arrange with the contracted consumer reporting agency to complete the government exclusion checks for each prospective Bayer employee, contractor, consultant or agent. The government exclusion checks involve checking the prospective employee's, contractor's, consultant's, or agent's name against two government exclusion lists: the Department of Health and Human Services/Office of Inspector General's List of Excluded Individuals/ Entities at **https://oig.hhs.gov/**, the General Services Administration's List of Parties Excluded from Federal Programs at **http://www.sam.gov** and the U.S. Food and Drug Administration (FDA) Debartment List at **https://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList/default.htm**. Bayer's consumer reporting agency conducts the required government screenings and maintains the reports permanently.
2. The exclusion check and the Self-Disclosure form must be completed, scanned and emailed to the Law, Patents and Compliance Department at: **bayeruscompliance@bayer.com** before the hiring process is complete and before the applicant's first day in the position. If a Bayer employee, contractor, consultant, or agent is listed on either of the government websites, you must follow procedures detailed in the following section entitled "Change in Eligibility Status of a Bayer Employee, Contractor, Consultant, or Agent."

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 original Self-Disclosure form and results of the government screenings and exclusion checks are retained by the Human Resources Department, Contingent Labor or Bayer Sponsor. The Law, Patents and Compliance Department retains the fax or electronic copy of the Self-Disclosure form along with the Exclusion Check search documentation online in the Law, Patents and Compliance Department. The certifications will be retained for a period of 10 years from the date they are completed

Annual check against government websites for all employees, contractors, consultants, and agents

The Law, Patents and Compliance Department will make a request to the Human Resources Department (myServices) and the Global User Management System-GUMS (BBTS Service Center to arrange for the annual government exclusion checks to be conducted for all Bayer employees, contractors, consultants, and agents. myServices and GUMS (BBTS Service Center) prepares a report of all active and inactive Bayer employees, contractors, consultants, and agents and submits the report to the Law, Patents and Compliance Department to utilize in conducting the government screenings. The Law, Patents and Compliance Department will create a list of all contractors, consultants and agents, by comparing the reports received from myServices and GUMS (BBTS Service Center), as well as data from Bayer's internal Learning Management System (LMS) My Learning powered by Plateau,TM Contingent Labor Program databases, along with manual records. The list will then be compared to the government exclusion lists identified above. Additional information will be used in a more refined comparison and research performed for any returned possible or exact match. Written records will be generated and retained to show why/how the individual was determined not to be ineligible. The Law, Patents and Compliance Department will complete the annual exclusion process by March 1st of each year for all Bayer employees, contractors, consultants, and agents.

If it is determined that the Bayer employee, contractor, consultant, or agent is listed as ineligible, written notice records will be forwarded to the Human Resource Department, Contingent Labor or Bayer Sponsor by the Vice President and Head, U.S. Office of Compliance (or designee). For any confirmed match, see section "Change in Eligibility Status of a Bayer Employee, Contractor, Consultant or Agent" of this procedure.

Documents used in completing the annual check against government websites will be retained by the Law, Patents and Compliance Department for a period of 10 years.

Change in eligibility status of a Bayer employee, contractor, consultant or agent

The Vice President and Head, U.S. Office of Compliance (or designee) and the appropriate Human Resource Representative must be notified immediately if a Bayer employee, contractor, consultant, or agent

- Becomes an Ineligible Person;
- Is proposed to be included on the exclusion list of either the General Services Administration or the Department of Health and Human Services/ Office of Inspector General; or
- Has been charged with a criminal offense related to a federal healthcare program.

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 his/her 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 not paid in whole or part, directly or indirectly, by federal healthcare programs or otherwise with federal funds.

SELF DISCLOSURE FORM

Bayer employees, contractors, consultants and agents

I, _____represent that I:_____

- have never been convicted of a crime under Section 306(a) or 306(b) of the Generic Drug Enforcement Act of 1992 or as defined or included within 42 U.S.C. section 1320a-7(a) or (b), or
- am not currently excluded, debarred, suspended, or otherwise ineligible to participate in any Federal health care programs, including Medicare and Medicaid, or in Federal procurement or non-procurement programs.
- agree to report immediately to my Human Resources Department any change in my status as an individual eligible to participate in federal health care programs or in federal procurement or non-procurement programs.

Code of Conduct Certification

- I hereby recognize and acknowledge that I have received a Compliance Code of Conduct booklet and certify that I have read, understand, and agree to abide by this code.

_____ _____
Signature Date

_____
Print Name Clearly

Please print and ensure all sections are completed with the new hires information before sending via email to Compliance.

Title:_____	Supervisor_____
Division: _____	Site Location/Mailing Address_____
	_____
	_____
Cost Center:_____	New Hire Date:_____
	Rehire
	CWID _____
Exclusions Check Date:_____	Email: _____
Signature of person completing this section:_____	
Print Name of person completing this section:	

This form along with the Exclusion Check search results must be completed, scanned and emailed to the Bayer Compliance Department at: **bayeruscompliance@bayer.com** before the hiring process is complete and before the applicant's first day in the position. Original is to be maintained by HR/CLP/ Bayer Sponsor with the Exclusion Check search results documentation.

SELF DISCLOSURE FORM 080814A.doc
Printed: December 2016

3. SUPERVISOR RESPONSIBILITY

The process described in this procedure is for immediate supervisors of new employees, transferring employees, or employees with changes in responsibilities (includes contractors, consultants or agents) resulting in a new role or position that qualifies the employee, contractor, consultant and agent as a participant in the Bayer U.S. Compliance Program. Supervisors must follow this procedure to ensure that Bayer meets all the Bayer U.S. Compliance Program requirements for participants. The supervisor who has hired a contractor, consultant or agent is referred to as a Bayer Sponsor. Immediate supervisors are primarily responsible for ensuring that training and certification occurs on schedule, as well as for appropriate and timely communication with the Human Resources Department and the Law, Patents and Compliance Department.

If an employee, contractor, consultant, or agent who is not a current Bayer U.S Compliance Program participant is transferred or promoted into a participant position, the employee, contractor, consultant, or agent must meet the same Compliance training and certification requirements as that of a New Hire participant.

Communication from the Supervisor is relied upon to ensure the Bayer U.S Compliance Program requirements are met for transferred and promoted employees, contractors, consultants or agents

Procedures

PRIOR to the Effective Date of Becoming a Participant in the Bayer U.S. Compliance Program

Once the employee, contractor, consultant or agent accepts his/her new position, and prior to his/her effective date of hire, transfer or promotion, the immediate supervisor is required to notify the Bayer Human Resources Department and the Law, Patents and Compliance Department prior to the effective date of hire or transfer or change in responsibilities.

Following the effective date of hire, transfer or promotion, the Law, Patents and Compliance Department electronically and/ or manually sends to the new or existing participant a training package that includes training materials, training instructions, the Compliance Helpline telephone number, the Bayer U.S. Pharmaceuticals Compliance Policy and Procedures booklet, and the Bayer Compliance Hotline materials.

The Law, Patents and Compliance Department will monitor training progress and send weekly reminders to the new participant and their supervisor if training and certifications are not completed.

Notification is also sent to the Human Resources Department or Contingent Labor, which will communicate deadlines and consequences to the employee, contractor, consultant or agent, as well as to the supervisor.

All employees, contractors, consultants, or agents who do not complete training by the deadline requirement will be notified by their supervisor and the Human Resources Department or Contingent Labor. Appropriate corrective action will be taken which may include a monetary penalty, suspension without pay, ineligibility from receiving “fully meets” under the LIFE performance management program (PMP) objective or termination of employment

Changes in Employment Status of Bayer U.S. Compliance Program Participants

Supervisors must report immediately any leave of absence (e.g., short-term or long- term medical leave, personal leave) or termination to the Human Resources Department and report to the Human Resources and the Law, Patents and Compliance Department when the participant returns to work after a leave of absence.

Changes in Employment Status of Compliance Program Participants

Agencies must ensure that the Bayer U.S. Compliance Program requirements are met for all contractors, consultants, and agents placed with Bayer Sponsors (supervisors) and the Human Resources Department Representative or Contingent Labor responsible for temporary staffing must communicate with the agency or vendor, as well as the Law, Patents and Compliance Department, to assure the Bayer U.S. Compliance Program requirements are met.

The Bayer Sponsor (supervisor)/Human Resources representative or Contingent Labor must:

- Inform the agency or vendor that the position to be filled is a participant position.
- Inform the Law, Patents and Compliance Department immediately (prior to the first work day) upon placing a contractor, consultant or agent in a participant position.
- Inform the Law, Patents and Compliance Department immediately (the same day) upon a contractor, consultant or agent leaving a participant position.

4. Compliance Training

Within 30 days of becoming a Bayer employee, contractor, consultant, or agent Business Ethics and Compliance eLearning must be completed. This training includes topics such as: (a) The seven elements of an effective Compliance Program (b) U.S. Laws and Industry Guidance (c) Overview of State Laws, The Patient Protection and Affordable Care Act (PPACA) and government reporting requirements.

Throughout the year, additional Compliance Training will be distributed on topics such as Anti-Corruption, Anti-Trust, Conflict of Interest, Data Privacy, Travel, Gifts and Entertainment policies; and/or new laws or regulations within the industry. All Compliance Training must be completed within 30 days from the training assignment date. Failure to complete Compliance Training by the deadline may result in a monetary penalty, implications for employee performance evaluations (PMP), and/or disciplinary action for each late or incomplete training/certification.

5. 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 Bayer Code of Conduct and the Bayer U.S. Pharmaceuticals Compliance Policies and Procedures. Disciplinary action up to and including termination of employment may be taken against any Bayer employee, contractor, consultant, or agent who violates applicable federal, state or local laws or regulations, industry guidelines, the Bayer Code of Conduct, or the Bayer U.S. Pharmaceuticals Compliance Policies and Procedures.

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

Bayer compliance program participants subject to disciplinary action

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 the Vice President and Head, U.S. Office of Compliance or the Law, Patents and Compliance Department.

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

Any disciplinary action taken by Bayer in response to a violation of the Bayer U.S. Pharmaceuticals Compliance Policies and Procedures 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.

6. FOCUS ARRANGEMENTS (Interactions with HCPs and HCOs)

When interacting with HCPs and HCOs, Bayer Compliance 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 drugs or devices for Bayer's pharmaceutical products. This Policy defines those interactions with HCPs and HCOs and outlines the policies and procedures that Bayer U.S. Pharmaceuticals must follow when entering into 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 - also referred to as interactions with an HCP or HCO - 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. While the term "HCP" has many definitions in our industry and across the organization, an HCP for Compliance reporting purposes is defined as: a person who may prescribe, purchase, supply, recommend, administer or provide information about drugs 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.

Source of Sales or Referrals The term "source of sales or referrals" means 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, as a general rule, you should treat potential sources of sales or referrals as actual sources.

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

Third Party Personnel are defined as 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 to the extent the other party is an actual or potential source of referrals or sales of Government Reimbursed Products:

- Speaker agreements
- Medical education grants
- Consultant agreements

- Advisory board agreements
- Disease management speaker programs
- Exhibit or display fees
- Clinical research or clinical trial grants
- 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 Arrangements/Interaction with HCPs and HCOs. If you have any questions about whether a potential activity or transaction may constitute an interaction with HCPs and HCOs or reportable interaction with a healthcare professional, you must consult the Law, Patents and Compliance Department.

Procedures for Focus Arrangements/Interactions with HCPs and HCOs

Bayer has established a written review and approval process for Focus Arrangements /Interactions with HCPs and HCOs of a contractual nature. If you are unsure whether a transaction, contract, program, or other activity constitutes a Focus Arrangement/Interaction with HCPs and HCOs you must consult with the Law, Patents and Compliance 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:

1. Set forth in writing prior to the services being performed.
2. Agreement must be signed by Bayer U.S., LLC and the HCP/HCO parties to the arrangement prior to the services being performed.
3. 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.
4. 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 entity that is a party to the arrangement 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 can be included as an exhibit to the contract or sent as separate documents.

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

The Law, Patents and Compliance Department evaluates whether each proposed interaction 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, his/her name, and the date it was conducted.

The Law, Patents and Compliance Department 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. The methodology used to determine individual fair market value calculations is available on the Law, Patents and Compliance website. Any exception from the fair market value methodology and the rationale for such exception must be approved by the Vice President and Head, U.S. Office of Compliance (or designee) and documented and maintained in the Law, Patents and Compliance 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, time sheets, or exhibit booth attendance forms). Proof of service must be retained by the Requestor of the arrangement owner 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 are requested. Failure to associate such fees with the correct contract number is a violation of this policy and can result in inaccurate reporting to the government.

Focus Arrangements Database

Bayer maintains a compliance database tracking all interactions with Focus Arrangements (Interaction with HCPs and HCOs) which also ensures the interactions 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:

1. Name of each party involved;
2. Type of interaction (e.g., medical education grant, clinical research agreement, fee for service);
3. Compensation to be paid and any related expenses;
4. Source system (e.g., SAP, GIFTS, FA Upload) from which Bayer compensation is paid (e.g., check, product, periodic payments);
5. Verification of payments made by Bayer;
6. Itemized detail of expense payments provided in conjunction with the contractual agreement, (e.g., lodging, air, ground, meals, and the city and state where the travel to took place);
7. Fair market value documentation;

8. Bayer product associated with HCP/HCO interaction;
9. The date of any deliverable or services that have been provided; and
10. Name and title of attorney who reviewed or assessed whether the Focus Arrangement satisfies the requirements of an Anti-Kickback Safe Harbor, dates, etc. the assessment was made.

7. Interactions with Government Investigators

General Rule

Bayer may be contacted by or receive requests for information from various government agencies such as, for example, the Food and Drug Administration (FDA), the Department of Health and Human Services (including the Office of Inspector General (OIG)), the Federal Bureau of Investigation (FBI), or other regulatory agencies. It is Bayer policy to cooperate fully with federal and/or state government officials or agents who conduct an inquiry, audit or otherwise investigate Bayer. Bayer expects all employee, contractor, consultant, or agent to extend the same cooperation within the guidelines of this Policy.

Reporting Government inquiries or audits

All Bayer employees, contractors, consultants, or agents must immediately report to the Law, Patents and Compliance Department any notice of a government inquiry or audit with respect to Bayer related activities. Notice of a government inquiry may include, but is not limited to: (1) telephone calls or letters from government officials or agents to Bayer employees, (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 employees, contractors, consultants, and agents.

Contact by Government Investigator

In the event a Bayer employee, contractor, consultant, or agent is contacted by a federal or state investigator with respect to Bayer related activities, the employee, contractor, consultant, or agent must obtain proper identification from the government investigator prior to answering questions. Bayer employees, contractors, consultants, and agents: (1) are not required to answer any questions asked by the government agent without the assistance of the Law, Patents and Compliance Department, (2) have the right to decide whether or not to consent to an interview, (3) have the right to consult legal counsel – either their own or Bayer counsel – before answering any questions and to have such counsel present during questioning by a government agent, and (4) may stop the interview at any time.

If a government investigator attempts to contact or interview a Bayer employee, contractor, consultant, or agent at his or her respective home and/or any location which is off Bayer premises with respect to Bayer related activities, the employee, contractor, consultant, or agent has the right to either: (1) talk to the government investigator, (2) not talk to the government investigator without representation by an attorney, or (3) request that an appointment be scheduled on Bayer's premises during regular business hours or at an alternate time and place that is otherwise convenient. If the Bayer employee wishes to have counsel present during questioning by the government agency please call Law, Patents and Compliance.

Government Interviews

If a Bayer employee, contractor, consultant, or agent decides to be interviewed or to respond to questions from a government investigator, with respect to Bayer related activities, the employee, contractor, consultant, or agent must answer all questions completely, accurately and truthfully. Bayer employees, contractors, consultants, or agents must not guess, speculate, or make-up answers to questions to which the answers are not known.

In addition, if the employee, contractor, consultant, or agent consents to an interview, the employee, contractor, consultant, or agent must obtain specific authorization from the Law, Patents and Compliance Department before discussing the company's privileged information. The employee, contractor, consultant, or agent must refuse to discuss any communications he or she may have had, or of which he or she may be aware, involving the Law, Patents and

Compliance Department or Bayer's outside legal counsel. If the employee contractor, consultant, or agent does not know whether the information he or she is being asked to discuss is privileged, the employee, contractor, consultant, or agent must consult with the Law, Patents and Compliance Department for a determination as to whether that information is privileged to ensure that no unauthorized disclosures of privileged information are made.

If you do not know with certainty the answer to any question, it is appropriate to say that you do not know the answer to the question. If an employee, contractor, consultant, or agent would like to consult with an attorney, the employee, contractor, consultant, or agent may request the presence of Bayer counsel. Alternatively, Bayer may recommend qualified counsel and, under appropriate circumstances, will pay for such counsel to represent the Bayer employee, contractor, consultant, or agent. If at any time, the employee contractors, consultants, and agents feels uncomfortable or uncertain about whether to proceed, or if at any time the employee, contractor, consultant or agent feels the need to consult with his/her own attorney or a Bayer attorney, the employee, contractor, consultant, or agent may stop the interview or tell the investigator that he/she wishes to consult with counsel.

Corporate Documents

Bayer employees, contractors, consultants, and agents must contact the Law, Patents and Compliance Department if asked by a government investigator or anyone outside the company for Bayer documents. 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, any (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, and (11) design documentation. Likewise, your computer, company issued cell phone, or tablet is Bayer property and is subject to this policy.

In addition, Bayer employees, contractors, consultants, and agents must not provide privileged Bayer documents to the government or anyone outside the company without specific authorization from the Law, Patents and Compliance Department. Privileged documents include, but are not limited to, any documents involving the Law, Patents and Compliance Department or Bayer's outside legal counsel. If the employee, contractor, consultant, or agent does not know whether the documents being requested are privileged, the employee, contractor, consultant, or agent must consult with the Law, Patents and Compliance Department for a determination as to whether that information is privileged to ensure that no unauthorized disclosures of privileged information are made.

Signing Documents

Bayer employees, contractors, consultants, and agents may be asked to sign an affidavit or other legal document as the company's representative during the course of an interview. Bayer does not authorize you to sign or initial any such documents or statements as a Bayer employee, contractor, consultant, or agent unless expressly authorized by the Law, Patents and Compliance Department. If a Bayer employee, contractor, consultant, or agent is asked to sign such a document, the employee, contractor, consultant, or agent must decline to do so and inform the government investigator of Bayer's policy.

8. False Claims 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 (3) times the amount the Government is defrauded plus penalties of $10,781 to $21,563 assessed after August 1, 2016 and $5,500 to $11,000 before August 2016 for each false claim submitted. 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 on which the overpayment is identified or the date any corresponding cost report is due, if applicable; and
- Knowingly reporting false or fraudulent pricing information to government agencies.

The FCA, and some state false claims acts, includes 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 suits.

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 False Claims Act to employees, contactors, 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 are required to 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 Law, Patents and Compliance Department. Third, you may file an anonymous report via the confidential disclosure process, the Bayer Compliance Hotline, at 1-888-765-3846 or at **www.expolink.co.uk/bayercompliance**.

9. Vendor Credentialing

Note: The Patient Protection and Affordable Care Act, Sunshine Law provision, 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). It is each employee's, contractor's, consultant's, and agent's responsibility to report accurate, complete and timely data as this is the data Bayer will report to CMS.

This policy describes the process for complying with vendor credentialing requirements. Many customers such as hospitals require manufacturing representatives to go through a credentialing process before obtaining access to a facility and pay a fee for registration. 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 as well as 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 Law, Patents and Compliance 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 is administered through a third party vendor who will guide the Bayer representatives through the process. In addition, upon hire all Sales Consultants will be assigned, via the LMS, an informative video outlining the process of vendor credentialing. 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 to non-customers are permitted only under the following circumstances:

- Registration fees must be reasonable and must not exceed $500 for an Individual Registration (valid for a single representative). Should you be presented with fees that exceed these amounts, you must contact the Law, Patents and Compliance 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 practice or paid to obtain access to a physician private practice group. Questions regarding whether the payment of registration fees constitutes an Interaction with HCOs must be directed to the Law, Patents and Compliance Department.

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

The Law, Patents and Compliance Department generates a written 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 written 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 with respect to the performance of activities related to the interaction with HCPs and HCOs.

The Law, Patents and Compliance 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, his/her name, and the date it was conducted.

The Law, Patents and Compliance 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 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 Law, Patents and Compliance Department.

The Requestor or other Bayer employee must provide each party to the Interactions with HCPs and HCOs two copies of the approved contract and a copy of (1) Bayer's Code of Conduct and (2) applicable Anti-Kickback Policies and Procedures and must document in Efilia that these were sent.

10. Prescriber Data

Bayer uses prescriber data for appropriate purposes such as conducting research, communicating important safety and risk information to prescribers regarding a particular drug or device, tracking adverse events, and focusing appropriate marketing activities on prescribers who may find such information useful. Prescriber data includes information such as the prescriber's name, address, and specialty, as well as the number of prescriptions for a particular product written by that prescriber. None of the prescriber data used by Bayer contains any identifiable patient information.

Bayer respects the confidential nature of prescriber data and is committed to using such data responsibly and in accordance with applicable law as well as the American Medical Association (AMA) PDRP (defined below) and the PhRMA and AdvaMed Codes.

Uses of Prescriber Data:

Bayer may use prescriber data for appropriate purposes only, including to:

- Impart important safety and risk information to prescribers of a particular drug or device;
- Conduct appropriate research such as, for example, evidence-based medical research;
- Comply with FDA mandated risk management plans that require drug companies to identify and interact with physicians who prescribe certain drugs;
- Track adverse events of marketed prescription drugs or devices; and
- Focus appropriate marketing activities on those healthcare professionals who have not "opted out" from receiving information and would most likely benefit from information on a particular drug or device.

Bayer does not use Drug Enforcement Administration (DEA) registration numbers (assigned to prescribers who have authority to prescribe controlled substances) for sales purposes. The disclosure of a practitioner's DEA registration number to entities other than those involved in the legal distribution of controlled substances or the enforcement of the laws governing their legal distribution may facilitate the diversion of controlled substances from the legal channels of distribution.

Restricting Access To Prescriber Data

Bayer respects a physician's choice in whether his or her prescribing data is used by complying with physician "no contact" requests and any applicable restrictions under state law. As described below, Bayer has adopted processes for restricting access to prescriber data following a physician "no contact" request that are in accordance with the AMA Physician Data Restriction Program (PDRP), applicable state laws, and the PhRMA and AdvaMed Codes.

AMA Physician Data Restriction Program (PDRP)

The PDRP is a large AMA database containing prescribing information on physicians throughout the United States. Health information organizations (HIOs), such as Wolters Kluwer or IMS, match the information from the AMA database (called the Physician Masterfile) to prescribing data from other sources such as pharmacy data clearinghouses, which have removed any identifiable patient information from the prescriber data before transferring it to HIOs or other third parties. The HIOs then license to pharmaceutical companies the combination of prescriber data from the clearinghouses with the information from the AMA Physician Masterfile.

Some physicians do not wish to be contacted by third parties that would otherwise have access to a physician's prescribing data through the HIO licensing arrangements. Physicians who do not wish to receive marketing communications from pharmaceutical companies or other third parties can opt-out of PDRP 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.

You must direct any prescriber wishing to opt-out of the AMA PDRP to: **http://www.ama-assn.org/ama/pub/about-ama/physician-data-resources/ama-database-licensing/amas-physician-data-restriction-program.page**. Pharmaceutical companies are required to review the PDRP opt-out list on at least a quarterly basis and have 90 days to comply with each new request.

State Laws

The Law, Patents and Compliance Department tracks federal and state legislation regarding 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 use of prescriber data for commercial purposes. A number of other states have introduced bills with similar provisions. For those states which have imposed limitations, Bayer has added PDRP opt-out flags to the relevant physician profiles in accordance with 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:

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

- On a monthly basis, the HIO data, including any PDRP opt-out flags related to specific physician profiles, is loaded into the Bayer Enterprise Data Warehouse (EDW).
- On a monthly basis, the HIO data, including any PDRP opt-out flags related to specific physician profiles, is also loaded into 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.

11. 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 presents the appearance of impropriety when conducting business with employees of the federal government.

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 while he or she 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 advocates who is employed by the DOD and providing 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 he or she is physically located at Johns Hopkins.

The following is NOT considered a government employee:

- An individual who works at a civilian facility that 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 in order to influence him or her 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 his or her 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, it is your responsibility to determine whether he or she is a federal government employee.

As a general rule, 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 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 that exceed $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 to an individual sales consultant.

In order to ensure that Bayer complies with the law, it is Bayer's policy that Bayer employees, contractors, consultants, and agents may not provide educational items (e.g., textbooks, anatomical models) or business meals to federal government employees, regardless of dollar value. Business meals may be provided to a federal government employee if there is a fee for service arrangement (consultant or speaker) with this employee.

Product samples are not considered "educational items" and may be provided to federal employees, if permitted by the government entity and in accordance with the Bayer U.S. Pharmaceuticals 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 providing such products.

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 there has been a determination that the government employee's attendance is in the interest of the agency because it will further agency programs and operations, Bayer may offer free attendance to the government employee, but 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 that are open to both government and civilian officials (e.g., AMA conference, ASCO). In order for the Bayer sponsored event to be considered a "widely attended gathering," the sponsored event must be open to all attendees of the conference or convention, (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 official free attendance at widely attended gatherings that are not sponsored by Bayer 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 Government Affairs Manager responsible for that state (if you are interested in contracting with a state employee) or the Law, Patents and Compliance Department (if you are interested in contracting with a federal government employee). Please refer to "Fee-for Service Arrangements" Policy for further details on this Policy.

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 Law, Patents and Compliance 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 that may result 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 for the purpose of accepting and disseminating 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. 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)."

Record Retention

The Accounting Department must maintain the payment request package for a period of 10 years.

Audit

Medical education grants are subject to auditing by Bayer Internal Audit and the Law, Patents and Compliance Department to ensure compliance with these policies. The government (e.g., IRS) may also request to audit/review grant payments at any time.

12. Business Meals with Healthcare Professionals

The Patient Protection and Affordable Care Act, Sunshine Law provision, 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 each employee's, contractor's, consultant's, and agent's responsibility 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 Code on Interactions with healthcare professionals published by the Pharmaceutical and Research Manufacturers of America ("PhRMA Code"), the Advanced Medical Technology Association ("AdvaMed Code of Ethics"), as well as guidance from the Department of Health and Human Services Office of Inspector General (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. You may find these policies at: **http://www.bayernet.com/corp/policies/policies_detail.cfm?fileid=348**.

Note that the definition of "Healthcare Professionals (HCP)" is a very broad term and includes individuals who directly interact with patients and/or have a role in the diagnosis or treatment of patients and includes entities which are involved in the provision of healthcare services and/or items to patients and which may purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Bayer's pharmaceutical products in the U.S. Generally, this definition includes physicians, nurses, nurse practitioners, physician assistants, medical assistants who treat patients, and other allied healthcare professionals, such as pharmacists, radiology technologists, and therapists. However, the definition is not limited to these individuals alone; the term includes any person in a position to recommend or influence the purchase or prescribing of Bayer's pharmaceutical products. In some instances, this may include individuals who do not work directly with patients but who have influence over the recommendation, purchase, or prescribing of Bayer's pharmaceutical products—such as a purchasing agents at hospitals, physician practice managers, management personnel within group purchasing organizations (GPOs), managed care organizations (MCOs), pharmacy benefit managers (PBMs), health plan administrators, wholesalers, distributors, pharmacies, Pharmacy & Therapeutics Committee members, Formulary Committee members, or other customers who do not see patients. Some positions and titles within the industry are not considered healthcare professionals such as, Original Equipment Manufacturers (OEMs) or retail managers.

General Rule

Meals may be provided to healthcare professionals if they are: (1) occasional; (2) modest; (3) 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; (4) take place in a setting conducive to such discussion; and (5) involve only individuals who are necessary for the conduct of Bayer business.

Providing a healthcare professional with a meal solely for "relationship building" is not acceptable. Further, it is not appropriate for Bayer employees, contractors, consultants and Agents of to pay for or reimburse healthcare professionals for personal meals. Offering meals in any location without a Bayer representative present, or providing "take-out" meals, is not allowed with the exception of virtual programs, meaning providing meals to healthcare professionals as the Bayer representative conducts a webcast through his/her iPad is acceptable only for

territories where the healthcare professional's office is in a remote area or otherwise would involve extensive travel for the Bayer representative. Even though attending remotely, 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.

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. In the event that alcohol is provided, it must accompany a meal, must not be excessive, and the cost must be included in the total cost of the meal. Providing alcoholic beverages in connection with an in-office or in-hospital meal is prohibited.

Setting for Business Meals

All business meals must be provided in a setting 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 According to Bayer policy and the PhRMA Code, pharmaceutical drug field sales representatives and immediate managers may provide business meals only in the healthcare professional's office or in the hospital during the healthcare professional's normal working hours. Appropriate places within a hospital include the cafeteria, coffee shop located within the hospital facility (e.g., Starbucks) or a meeting space conducive to an educational discussion (e.g., conference room). If a meal is being provided in connection with a promotional speaker program that fully complies with the requirements of the Compliance Policy and Procedure, "Fee- for-Service Arrangements," a sales consultant and/or immediate manager may attend and pay for the meal, as appropriate.

Device field sales representatives 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., meeting can only occur outside of normal 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. Alcoholic beverages must generally not be offered but, if provided, the cost must be included in the total cost of the meal.

Frequency of Business Meals

Consistent with PhRMA and AdvaMed Codes and OIG guidelines, business meals may be provided on an "occasional" basis. It is Bayer's policy that "occasional" should mean generally no more than twelve (12) meals to any one individual healthcare professional (including individual employees of retailers, wholesaler(s), distributors, and/or mail order suppliers) during the calendar year.

Spending Limits

Business meals must be "modest" in cost as judged by local standards. A modest business meal must cost no more than $125 per person when provided outside of an office environment (e.g., restaurant, hotel, conference center). Any food or drinks provided by Bayer personnel to healthcare professionals prior to and/or after a business meal must be included in the $125 per person limitation. The limit includes food, beverages, tax, and gratuity. 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 $25 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 his/her immediate manager as a meal setting.

For in-office or in-hospital meals, the amount to be spent must be based upon the number of healthcare professionals in attendance at the educational discussion who consumed the meal (e.g., if there are three healthcare professionals, the maximum to be spent is $75). Any food that is remaining after the in-office or in-hospital educational discussion with the healthcare professionals may be made available to the remainder of the office staff (e.g., clerical personnel).

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

State Spending Limits

Some states have laws regarding the provision of business meals and other promotional activities that are more restrictive than Bayer's general policy. 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

There are federal laws that restrict business meals 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 business meals or food/drinks (except for meals provided under a fee-for-service arrangement) 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, and therefore, 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., check, gift cards/certificates, reward points, your credit card, etc.) to purchase a meal. Under no circumstances can this Policy be circumvented by the use of the employee, contractor, consultants, or agent's own cash or personal credit card.

Additional Guidance

- It is not appropriate to pay or reimburse a healthcare professional for personal meals.
- Bayer may only pay for meals of healthcare professionals who actually attend a meeting at which Bayer is legitimately sponsoring a meal pursuant to this Policy.
- Meals are only provided to individuals who are necessary for conducting Bayer business. Leftovers may be provided to office staff at the end of the meal.
- It is not appropriate to pay for a meal where the Bayer representative is not present 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 accurately calculate the cost of the meal for the remaining attendees. The attendee should 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 Kovaltry
- Providing a physician with a meal in the hospital cafeteria to discuss a newly approved indication for Xofigo

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 his/ her office for a meal to discuss the use of Adempas (restaurant is not an appropriate venue)
- Catering a meal from a 5-star restaurant to a physician’s office or hospital for a product discussion on Betaseron (too expensive to be modest)

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

- 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 meal is consumed)
- Giving your credit card to a healthcare professional and telling him/her 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 prior to 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 and waiting outside of the meeting room while the meal is consumed (no Bayer employee present when meal is consumed)

Procedures

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 in either the healthcare professional's office or an appropriate hospital venue?
- Is the amount modest?
- Is a Bayer representative present when the meal is consumed?
- Is the frequency of meals provided to this healthcare professional occasional (it is Bayer's policy that "occasional" means generally no more than 12 meals per healthcare professional within a calendar year) and is the total value of meals modest?
- Am I reasonably certain that each of the participants in the meal is not a federal government employee?
- Am I reasonably certain that each of the participants in the meal does not practice in a state with special restrictions or reporting requirements?

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 $125 (including food, beverage, tax, and gratuity) per person.

For Bayer Speaker Bureau Events

Bayer policy strictly prohibits the purchase of alcoholic beverages beyond the two glasses of house wine or domestic beer that is authorized in the Speaker Bureau agreement with the venue. Orders at the event for any other type of alcoholic beverage for this program is prohibited. The Bayer representative at the event should intercede if this occurs since any alcoholic beverages beyond what is authorized will not be reimbursed. Alcoholic beverages prior to the official start of the program/event also count toward the two beverage maximum.

Documentation of Business Meals with Healthcare Professionals

Business meals with healthcare professionals including non-licensed HCP (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" or "Business Guest (Non-HCP)." All employees must document the details of business expenses according to IRS rules, Compliance Policies and Procedures, and the Corporate TG&E Policy. An accurate description describes what product you are discussing as well as the purpose for the visit to the HCP's office must be documented. Instructions on how to complete your T&E when providing a business meal to an HCP can be found on the intranet at: http://us.bayernet.cnb/en/organization/us-corporate-departments/compliance-operations/library.aspx.

Understanding how to set up a HCP Business Meal in Concur

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

Who is a healthcare professional?

A healthcare professional (HCP) is anyone licensed to prescribe or involved in the provision of healthcare services or products to patients. An HCP is anyone who has the ability to influence the usage of (e.g. refers, recommends, arranges for, orders, prescribes or purchases) Bayer products.

Who is a business guest?

A business guest is anyone who is not licensed to prescribe medicine, but may influence the buying or prescribing of Bayer products, including but not limited to:

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

If a licensed HCP has attended and consumed the meal, it is imperative they are 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.

Itemized (detailed) receipts and copies of the attendee sign-in sheet must be included with every HCP Business meal expense entered into Concur, regardless of the amount. These two requirements supersede the Corporate TG&E Policy.

The failure to submit for reimbursement for the business meal does not circumvent the business meal policy.

All business meals where healthcare professionals are in attendance, whether in- or out-of-office, regardless of amount, require an itemized (detailed) receipt and completed sign-in sheet which documents the attendance and meal consumption of each individual. If the Bayer employee pays for the meal on his/her 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. 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 in accordance with the Policy and Procedure "Focus Arrangements/ Interactions with HCPs and HCOs."

The Bayer employee who is hosting or on site at the event is responsible for ensuring the sign-in sheet is completed accurately and submitted appropriately. While a third party vendor assists with the logistics at the event, only the Bayer employee should handle and remains responsible for the accurate and timely completion of the sign-in sheet.

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 licensed HCPs and number of non-licensed HCPs (business guests) including Bayer employees as a total number of attendees Double-check the attendees' meal opt-ins/opt-outs, as this 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 attendees (licensed, non-licensed and also those who "opted-out" of or did not consume the meal) are required. Bayer employees should pre-populate information about meeting attendees but attendees must personally provide their signature on the sign-in sheet. Each HCP must sign for himself/herself. If you are unable to obtain a signature, please indicate on the sign-in sheet the reason.

Supervisor Review of Travel and Expenses (T&Es)

Complying with the expense reporting and approval policies is a critical responsibility for managerial employees within the company to ensure compliance with this policy and proper control of business expenses and accurate government reporting.

Immediate supervisors are responsible for reviewing all T&E submissions in its entirety for each employee or any contracted third party sales professional, they oversee to ensure that consistency with this Policy and Procedure and other applicable Bayer requirements. This includes a detailed review to ensure that:

- the limit per-person/per-meal is not exceeded;
- the correct number of attendees is reported;
- the attendees are appropriate for the event;

- the venue is appropriate;
- the total number and amount of business meals provided to any single healthcare professional are consistent with this Policy and Procedure.

If the review reveals potential divergence from Bayer policy, the supervisor must take appropriate action, to include discussing the situation with the employee, documenting corrective action, notifying the next supervisory level and the Law, Patents and Compliance Department. Please refer to Policy and Procedure, "Disciplinary Action."

Record Retention

T&E reports are retained by the Accounting Department for a period of 10 years.

Audits

Business meal spending is subject to auditing by Bayer Internal Audit and the Law, Patents and Compliance Departments to ensure compliance with this Policy. This includes submitting proper documentation, adhering to spending limits, and observing company spending policy. The government (e.g., IRS) may also request to audit or review expense reports.

13. Educational Items for Healthcare Professionals

The Patient Protection and Affordable Care Act, Sunshine Law provision, 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 each employee's, contractor's, consultant's, and agent's responsibility to report 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 a 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 as well as the OIG guidance. The policy covers interactions with all healthcare professionals who may purchase, recommend, order, refer, use, or prescribe Bayer's pharmaceutical products.

Note that the definition of "Healthcare Professionals (HCP)" is a very broad term and includes individuals who directly interact with patients and/or have a role in the diagnosis or treatment of patients and includes entities which are involved in the provision of healthcare services and/or items to patients and which may purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Bayer's pharmaceutical products in the U.S. Generally, this definition includes physicians, nurses, nurse practitioners, physician assistants, medical assistants who treat patients, and other allied healthcare professionals, such as pharmacists, radiology technologists, and therapists. However, the definition is not limited to these individuals alone; the term includes any person in a position to recommend or influence the purchase or prescribing of Bayer's pharmaceutical products. In some instances, this may include individuals who do not work directly with patients but who have influence over the recommendation, purchase, or prescribing of Bayer's pharmaceutical products—such as purchasing agents at hospitals, physician practice managers, management personnel within group purchasing organizations (GPOs), managed care organizations (MCOs), pharmacy benefit managers (PBMs), health plan administrators, wholesalers, distributors, pharmacies, Pharmacy & Therapeutics Committee members, Formulary Committee members, or other customers who do not see patients. Some positions and titles within the industry are not considered healthcare professionals such as, Original Equipment Manufacturers (OEMs) or retail managers.

Special Requirements for Federal Government Employees

There are federal laws that 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. 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." It is Bayer's policy 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 that is 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 the provision of educational items that are more restrictive than Bayer's policies. Please refer to the Policy and Procedure section on "State Laws, prior to 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 and textbooks must include with each shipment a list 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 not available. The price of clinical reprints is calculated by the respective marketing departments and represents the production cost to Bayer for the reproduction of the material. These costs are loaded into Veeva.

Educational Purpose Required

You may provide educational items to healthcare professionals that are designed primarily for the education of 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 any such items are permitted by relevant laws. *It is Bayer's policy to not provide subscriptions to scientific journals to a healthcare professional. Bayer may provide transcripts or journal articles or reprints so long as the value does not exceed $100 per item.*

Medical textbooks may be offered only through the Marketing Department's "textbook program." Under no circumstances may you procure textbooks on your own through your T&E expense account.

Printed medical booklets and text materials, such as review guides, pocket books, and handbooks, may be obtained from the Marketing Department. The Marketing department is responsible for obtaining approval from the Legal, Medical, and Regulatory (LMR) review committee. The purchase of 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 Bayer's Code of Conduct and Bayer U.S.

Pharmaceuticals Compliance Policies and Procedures. Please refer to Policy and Procedure, "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. The purchase of any medical books, text materials or other educational item not procured through Bayer (e.g., purchased at a local bookstore or on-line) is prohibited. Do not procure educational items on your own through your T&E expense account.

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 management of disease
- Clinical Reprints – Delivered in person by a Sales Representative (not sent via email or through an electronic link)

Under federal and state law regulations, Bayer is required to report to certain government agencies applicable transfers of value (e.g., clinical reprints). Bayer will, as required, disclose name, address, the 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, 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 items and therefore are not permissible. In addition, stethoscopes, pedometers, stopwatches, and general fitness items which are designed primarily for patient treatment and not for education of the patient or healthcare professional 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. None of the prohibited items described above may be provided at conferences or third party professional or scientific meetings.

Items that can also be used by the healthcare professional for personal use unrelated to patient education (such as tablet computers, electronic or digital devices 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 specifically prohibit these items.

Items provided to a healthcare professional may 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:

1. Is this the only educational item (including textbooks) that I'm giving this healthcare professional for his/her professional use in this calendar year?
2. Is it designed primarily to educate the healthcare professional or to benefit patients?
3. Am I certain that the recipient is not a federal government employee or does not practice in a state with special restrictions or reporting requirements?
4. 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 provided by Bayer's pharmaceutical sales representatives must be recorded in Veeva. An accurate description of the business purpose of the educational item must be documented. Medical Science Liaisons (MSLs) distributing reprints should use the clinical reprint receipt form to obtain the HCP signature which serves as proof a transfer of value has been provided.

Record Retention

Invoices are retained by the Accounting Department for a period of 10 years. The Sales Operations Department will retain the distribution of educational items to HCPs in Veeva for a period of 10 years.

Audits

Spending for educational items is subject to auditing by Bayer Internal Audit and the Law, Patents and Compliance Department to ensure compliance with this Policy, including proper documentation, spending limits, and company spending policies. The government (e.g., IRS) may also request to audit or review related spending.

14. Patient Education

Bayer supports the provision of patient education programs so patients may gain a greater understanding of their disease and how to cope with the challenges of managing their disease with drug therapy. 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 his/her own patients to educate them on disease states and treatment options. All patient education/support group programs must be unsolicited and in conjunction with 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 conducive to patient education to patients. (Hematology business only: caregivers are defined as people who may be parents, grandparents, guardians, or other family members and can be offered this meal.) The meal cap for patient event meals is $50 per attendee. (For Hematology only, caregivers also have a $50 per attendee meal cap per person). It is not appropriate for Bayer to pay for, or reimburse patients for, personal meals. Providing a patient with a meal solely for "relationship building" is not acceptable. Offering patients a meal outside the context of an educational program is also unacceptable. Lastly, offering meals in any location without a Bayer representative present, or providing "take-out" meals, is not allowed.

Meals provided to patients must be "occasional" and "modest" in cost as judged by local standards. A modest business meal must cost no more than $50 per person (including food, beverage, tax, and gratuity). Such meals should consist of sandwiches, pizza, snacks, or soft beverages. Meals cannot consist of alcohol only. If alcohol is provided, it must accompany a meal, must not be excessive, and the cost must be included in the total cost of the meal.

Educational, Disease or Treatment Related Items

In accordance with the requirements of this policy, Bayer representatives may provide patients with items that are intended to educate patients and are important 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 Multiple Sclerosis Society and 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 necessarily be provided. Charitable contributions 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 patient may be no more than $10 and the retail value of any combination of items given at any one time, not to exceed three items, must not be more than $25. Educational/treatment items should be provided only occasionally to patients and the total value of all educational/ treatment items provided 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 at a walk where the water bottles must be intended for single-use only can be provided at walks. Such educational and treatment related items may be Bayer branded and must be approved through LMR and the Law, Patents and

Compliance Department. Specific questions regarding educational/disease state items should be directed to the U.S. Office of Compliance.

Items that are not related to patient education, disease or treatment may not be provided, regardless of whether they contain a Bayer or brand logo. Supplies, such as pens, folders and paper may 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. None of the prohibited items described above may be provided to patients in connection with a product display or exhibit. 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 Law, Patents and Compliance Department. You may not procure items on your own to provide to patients.

Documentation of Patient Meals

Patient meals – in conjunction with an educational event with paid speaker or Bayer employee must be arranged through the Bayer Speaker Bureau. Sign-in sheets are required for appropriate documentation of cost-per-attendee as well as for adherence with IRS rules. All other meals accompanying an education presentation must be recorded in Concur.

Due to the Patient Privacy Rule (HIPAA), disclosure of the patient names cannot be included on the sign-in sheet. Patients should be listed as “Patient 1,” “Patient 2,” etc., in order to document the total number of patients in attendance and to calculate the appropriate cost per attendee.

Supervisor Review of T&Es

Complying with the expense reporting and approval policies is a critical responsibility for managerial employees within the company, to ensure proper control of business expenses.

Immediate supervisors are responsible for regularly reviewing T&Es for all employees, or any contracted third party sales professional, they oversee to ensure that consistency with this Policy and Procedure and other applicable Bayer requirements. This includes a detailed review that the guideline limit per person per meal is not exceeded, the correct number of attendees is reported, the attendees are appropriate, the venue is appropriate, and the total number and amount of business meals provided to any single patient are consistent with this Policy and Procedure.

If the review reveals potential divergence from Bayer policy, the supervisor must take appropriate action, to include discussing the situation with the employee, documenting corrective action and notifying and consulting with the next supervisory level. If a supervisor determines an employee has not followed this policy, the supervisor must notify the Law, Patents and Compliance Department. Please refer to Policy and Procedure, “Disciplinary Action.”

Record Retention

T&E reports are retained by the Accounting Department for a period of 10 years.

Audits

Spending for patient educational meals is subject to auditing by Bayer Internal Audit and the Law, Patents and Compliance Department to ensure compliance with this Policy, including proper documentation, spending limits, and company spending policy. The government (e.g., IRS) may also request to audit or review expense reports.

15. Fee-For-Service Arrangements

The Patient Protection and Affordable Care Act, Sunshine Law provision, 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 each employee's, contractor's, consultant's, and agent's responsibility 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 certain criteria are met. Bayer's policy on fee-for-service arrangements is consistent with the Personal Services Safe Harbor, the PhRMA Code on Interactions with Healthcare Professionals, the AdvaMed Code of Ethics 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 individuals (or the companies that employ them) are compensated by Bayer for services rendered. Contracted partners may opt-out of any compensation if they wish to; however intended compensation cannot be transferred by Bayer 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 they are 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 and 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, and clearly understand that they are being retained to provide a service and not merely to passively receive promotional presentations. An advisory board meeting cannot be designed to (1) influence the invited consultants or to change their prescribing preferences; (2) provide participants with an opportunity to meet and mingle with their peers; or (3) have participants merely listen to information about Bayer's pharmaceutical products.

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.

Data purchases include any compiled information offered by a customer that may have commercial value, such as product utilization information, clinical or sales data that is necessary for a commercially reasonable Bayer business purpose. Permissible data purchases and other arrangements are those designed to (1) foster increased understanding of scientific or clinical issues in order 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 the data for legitimate business purposes.

Market research is aimed at obtaining information on customer requirements, preferences, product performance, and purchasing options for use by 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. 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 not appropriate for sales personnel to design marketing research questionnaires for physicians or to 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 U.S. Pharmaceuticals knows the identity of the participant, 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 provides healthcare professionals the opportunity to be trained by other qualified healthcare professionals proficient in the use of Bayer U.S. Pharmaceutical's products. The content of the training 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 LMR review process and be on-label.

Promotional speaker events include speakers who are acting or speaking on Bayer U.S. Pharmaceutical's behalf. Such events are considered promotional events. Speaker fees must be consistent with fair market value and provided pursuant to a written agreement approved by the Law, Patents and Compliance 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 (Dermatology, Hematology, Neurology, Oncology, Pulmonology, Radiology, Women's Health) and speaking arrangements may not exceed $75,000 annually. Prior to the speaker's first speaker event, he/she must complete Speaker Training, which includes training on the respective Bayer product or the product related disease state, products, Bayer Compliance and FDA regulatory requirements as well as compliance-related procedures and expectations.

Speaker training can be done either 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 to develop speakers to effectively deliver presentations. 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 of more speakers than would be reasonably required 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; all meeting content must be approved through the Legal, Medical and Regulatory review process and must relate to approved/cleared uses of Bayer U.S. Pharmaceutical products; and must be planned using Bayer's approved Speaker Bureau.

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

Bayer prohibits a promotional speaker from presenting only to his/her staff and/or patients in their own practice. The promotional program must be open to the community and not limited to a specific physician practice or healthcare organization.

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 LMR review of presentation content. For information on entering into such agreements, please contact the Law, Patents and Compliance Department. The Bayer employee who is hosting or attends the speaker training, advisory or consultant meeting or promotional speaker program event, is responsible for ensuring a sign-in sheet is completed and submitted appropriately. While a third-party vendor assists with the logistics at these events, the Bayer employee remains responsible for ensuring the completion and timely submission of a sign-in sheet.

Scanner Testing provides Bayer the opportunity to test Radiology products with the site or hospital equipment. The testing is performed by a Bayer engineer 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, the purchase or recommendation of 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 a fair market value fee to the customer 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 of running its business, nor may fees paid pursuant to an agreement be determined by taking into account 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 of the following are true:

- A legitimate need for the services has been clearly identified in advance of requesting the services.
- Compensation paid represents fair market value for the services rendered.
- Individuals are chosen based upon relevant qualifications, experience and expertise as well as the value their services would provide to Bayer, and cannot be based on the volume or value of business they 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 speaker training event, advisory board, or consultant meeting.
- Consultant meetings, speaker training meetings and advisory board meetings must be approved by the Law, Patents and Compliance Department 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 written contract must specify the nature of the services and the basis of payment for those services. The contract must be approved by the Law, Patents and Compliance Department before it is signed by the speaker or consultant and Bayer. No Bayer employee may execute any contract or other legally binding document without review and approval from the Law, Patents and Compliance Department. If a healthcare professional refuses to sign the agreement provided by the Law, Patents and Compliance Department prior to the initiation of the program, he or she cannot be retained to provide the service.

Procedures for all Types of Fee-For-Service Arrangements

Initial Written Request

The initial request for a fee-for-service arrangement must be made using the Agreement Request Form and approved by the requestor's supervisor. The approved request is submitted to the Law, Patents and Compliance Department for legal review and contract generation. The Agreement Request Form 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 need 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 using fair market value calculations; and
- Description of the expense to be reimbursed, if any.

The Agreement Request Form is retained by the Contract Compliance Administrator in the Law, Patents and Compliance Department. The necessary information from the request form is included in the contract for all types of fee-for- service arrangements. The Law, Patents and Compliance Department's approved, executed contract must be included in all fee-for-service payment request packages.

Before generating the contract, the Law, Patents and Compliance Departments will determine whether a Master Services Agreement ("MSA") exists for the potential speaker or consultant. If a MSA exists, the Law, Patents and Compliance Department determines whether the new arrangement conforms to the terms of the MSA, including any limit on the number of engagements or maximum amount paid annually. No speaker may be paid more than $75,000

for speaking engagements annually. If Bayer plans to use the speaker, consultant, or advisory board member for more than one event over the course of the next year, and the consultant does not already have a MSA, a new MSA that identifies a maximum value and type of services to be provided must be created.

Contents of the Contract

Each healthcare professional retained as a speaker, consultant or for another fee-for-service arrangement must sign a contract or Letter of Agreement that has been approved by the Law, Patents and Compliance Department and must include the following:

- A description of the services to be provided;
- When known in advance, the schedule on which the services will be provided;
- The 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; and
- 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.

Third Party Contracts

Bayer may work with third parties who contract with speakers, moderators, or consultants on behalf of Bayer. Third parties are prohibited from entering into contracts with HCPs on Bayer's behalf. The Law, Patents and Compliance Department will generate all agreements with HCPs in accordance with the procedures described above. If the third party engages the consultant or speaker, the third party must send to Bayer the proposed list of speakers, moderators, or consultants that it plans to use for the event. The Law, Patents and Compliance Department must verify that each consultant has not exceeded the terms of any applicable MSA or the $75,000 annual limit on speaker fees. Certain payments that are 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).

The Law, Patents and Compliance Department will provide or approve the third party contract(s) to use for the consultants that includes the terms described above. In addition, the reviewing attorney must assess whether the proposed arrangement complies with the Anti-Kickback Statute and assesses compliance with relevant Safe Harbor(s). This review/assessment, his/her name, and the date it was conducted, must be documented.

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. Prior to 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 Law, Patents and Compliance Department (if you are interested in contracting with a federal government employee).

In addition, and to comply with requirements of the Department of Veterans Affairs, certain language (excerpted below) must be included in all fee-for-service agreements entered into

with VA employees. It is, therefore, mandatory that any fee-for-service request involving a VA employee clearly state that the party involved is an employee of the Department of Veterans Affairs. To fulfill this requirement, VA employee status must be included on the Speaker or Consultant Approval Form under "A Statement of the Speaker's Qualifications" and in the cover memo that accompanies the form.

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 a period of administrative or personal leave so as not to affect performance of official duties. Invitations for services are extended solely on the basis of expertise, not as a result of employment with the VA.

VA Employee 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 he or she has conducted, participated in, or supervised. Employee may not refer patients to Bayer-sponsored clinical trials.

A VA employee may not receive compensation from Bayer if he/she serves in a position of decision- making authority (e.g., formulary committee) in which purchasing or prescribing decisions 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

The Law, Patents and Compliance 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, his/her name and the date it was conducted.

The Law, Patents and Compliance Department also confirms that the proposed payment (e.g., speaker compensation or fees for a commercial exhibit) represents fair market value. Fair Market Value is based on an independent, third-party provider who benchmarks industry standards. The methodology used to determine individual fair market value calculations is contained in a database. Any exception from the fair market value methodology and the rationale for such exception must be approved by the Vice President and Head, U.S. Office of Compliance (or designee) and documented and maintained in the Law, Patents and Compliance Department.

The Law, Patents and Compliance Department sends each party associated with the interaction a copy of the approved contract and attaches a copy of Bayer's Code of Conduct and the Anti-Kickback Statute Policies and documents that these were sent. The attached documents may be sent electronically or by hard copy, and can be included as an exhibit to the contract or sent as separate documents.

The written 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 expenses associated with the spouse or guest of a consultant, such as travel or meals. A spouse or guest may share a hotel room with the consultant, provided Bayer incurs no additional costs.

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 services provided by the consultant. 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 for 10 years. The contract must permit Bayer to observe the services rendered or otherwise obtain proof of service.

Payment Generation

Payment for fee-for-service arrangements is contingent upon:

- Approved written contract;
- Documentation as to need for service;
- Completed fair market value analysis; and
- Proof of services 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" in order 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 Corporate U.S. Signature Authorizations Policy Group Regulation 1990.

Procedures Specific to Service Types with a Meeting

Contracting with Consultants, Advisory Board Members, Speaker Training Participants and Others

The Requestor must follow the Bayer Meetings & Conventions Management Department procedures if external and Bayer attendees are invited to an offsite group meeting. The procedures can be found at:
http://us.bayernet.cnb/en/organization/us-corporate-departments/meetings-and-conventions.aspx
The online system to initiate a meeting request can be found at:
https://www.cvent.com/EVENTS/Websites/Login.aspx?rwstub=b51e9b00-cd4e-4cd8-9c15-25919cf96aba.

Record Retention

The Accounting Department will retain the full payment request information according to Procedures for a period of 10 years. The Agreement Request/Transmittal Form is retained in the Law, Patents and Compliance Department, or by the Requestor, for a period of 10 years. For tangible services (e.g., consultant reports), the Bayer employee requesting the service must retain the proof of service in the department files (organized by contract number) for a period of 10 years.

Audit

All fee-for-service arrangements are subject to auditing by the Bayer Internal Audit and Law, Patents and Compliance Departments to ensure compliance with this Policy. The government (e.g., IRS) may also request to audit or review fee-for-service agreements. The Requestor requesting the service or information must be prepared to demonstrate a legitimate business need for the program and, as applicable, demonstrate how information obtained from the program was used. The Requestor must keep proof-of-performance for 10 years.

16. 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 the prescribing of medicines generally have significant experience in their fields. That experience can be of great benefit to pharmaceutical companies and ultimately to 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 beyond contract termination. If these healthcare professionals serve as speakers or consultants for Bayer, they are also required to follow the procedures set forth by the committee(s) of which they are a member, which 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

> "The parties acknowledge that Bayer U.S., LLC conducts its relationships with healthcare professionals in compliance with applicable laws (including, without limitation, 42 C.F.R. §1001.952(d), the "safe harbor" to the U.S. Anti-Kickback Statute, 42 U.S.C.§1320a-7(b), with respect to personal services) and the PhRMA Code on Interactions with Healthcare Professionals (the "PhRMA Code") promulgated by the Pharmaceutical Research and Manufacturers of America (PhRMA). Consultant, in the performance of Consultation Services on behalf of Bayer, shall conduct its relationships with healthcare professionals (and, to the extent applicable, shall cause its employees and subcontractors to conduct their relationships with healthcare professionals) in accordance with all applicable laws and the PhRMA Code. Further, to the extent Consultant is a member of a committee that sets formularies or develops clinical practice guidelines, Consultant shall disclose to such committee the existence and nature of his or her relationship to Bayer and follow any procedures set forth by the committee in connection therewith; this requirement shall survive expiration or termination of this Agreement for two (2) years."

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.

17. Medical Practice Training

The Patient Protection and Affordable Care Act, Sunshine Law provision, 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 each employee's, contractor's, consultant's, and agent's responsibility to report 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. Bayer does not engage in preceptorship arrangements as traditionally defined within the pharmaceutical industry.

Procedures

A healthcare professional must be contracted as a consultant prior to 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 in the arrangement 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 him or her 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 or 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 the use of Bayer's pharmaceutical products to provide hands-on training to other healthcare professionals. The content of the training must be on-label, approved through LMR 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.

18. Corporate Sponsorships

Bayer may provide funds for 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 the improvement of patient care or continuing education of professionals.

Bayer may provide general funding for a professional association's patient support group or other organization's activities or meetings under appropriate circumstances. The recipient organization must have sole control over the sponsorship funding paid by Bayer. Sponsorship may be recognized by the organization, including the level of sponsorship 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 Law, Patents and Compliance 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. It is Bayer's policy 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 the travel, lodging, or other personal expenses of attendees, to compensate attendees for their time, or to provide any type of gift to the attendees or presenters. Sponsorship funding also may not be provided on behalf of any customer, patient, or other individual.

It is important 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 focus of the event or activity (e.g., education or fundraising). For example:

- A charitable contribution is funding provided to a non-profit organization to support the organization's activities where Bayer does not expect to receive anything of value in return.
- A sponsorship is funding provided to support the activities of an 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 where the primary purpose of the event/activity is fundraising/charity. The sponsorship opportunity is offered to other similarly situated industry members and not just Bayer.
- A medical education grant is funding provided to support an event where the primary focus is educating the participants/attendees.

Key Characteristics: Charitable Contributions vs. Corporate Sponsorships vs. Education Grant

Characteristics	Charitable Contributions	Corporate Sponsorships	Education Grants
Promotional in nature	No	Yes	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	Yes	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 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 who provide a similar level of sponsorship.

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 the improvement of 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.

Attendance

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. Extra tickets need to be given back to the requesting organization. Tickets cannot be provided to customers, patients, family of the patient, or Bayer employee's families.

Procedures

Requestor

A medical or professional society or other organization may solicit sponsorship through a website, e-mail, or paper mailing. No Bayer employee may commit the Company to funding a sponsorship request without review and approval in accordance with this policy. All requests for sponsorship must be made in writing from the requesting organization on its letterhead and must 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)

For all requests that involve interactions with HCPs and HCOs, the Law, Patents and Compliance attorney must verify that the agreement contains a certification by the parties that the parties shall not violate the Anti-Kickback Statute with respect to the performance or activities related to the sponsorship.

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, his/her name, and the date it was conducted.

The Law, Patents and Compliance Department also confirms whether the sponsorship 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 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 documented and maintained in the Law, Patents and Compliance Department.

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

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

Record Retention

The recipient of the request for sponsorship will retain the request documentation and all proof of service documents for a period of 10 years.

Audit

All requests for sponsorship are subject to auditing by the Bayer Internal Audit and Law, Patents and Compliance Departments to ensure compliance with this policy. The government (e.g., IRS) may also request to audit/review sponsorship payments.

19. Providing Free Product for Charitable Purposes

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

Scope

This policy covers all free products provided under Bayer's charitable programs for U.S. destinations only. For hematology product donations to non-US destinations, please refer to the policy "Hematology Product Donation Policy" retained by the Law, Patents and Compliance Department.

Product shipped under a zero dollar invoice to correct billing or shipping errors or to replace damaged or short-dated product does not constitute free product as defined by this policy and can be provided, as those circumstances require.

Free products and/or samples, which are provided free of charge to healthcare professionals for free distribution to patients, pursuant to the Prescription Drug Marketing Act, are not free product as defined by this policy and must comply with the provisions of Policy and Procedure, "Providing Samples at No Charge and Device Evaluations."

Specific Programs

Bayer operates the following charitable programs that provide free product to qualifying entities:

Bayer Patient Assistance Programs (PAP)

The Patient Assistance Program provides free product to eligible, financially disadvantaged patients. Patients must: (1) reside in the U.S., (2) be financially disadvantaged, (3) not have coverage for the requested Bayer product, and (4) have a valid prescription from a healthcare provider for the product. Bayer has contracted with third-party vendors to administer the Patient Assistance Programs. The vendors approve all medications requested via the Patient Assistance Program and are responsible for implementing Bayer's written procedures for the programs. The Reimbursement and Patient Assistance Program reviews all program requests to ensure compliance with Bayer's procedures.

- Patients may register for Betaseron product by calling 1-877-875-7882
- Patients may register for Women's HealthCare products by calling 1-877-442-7714
- Patients may register for any other available Bayer products by calling 1-877-442-7709

The Reimbursement and Patient Assistance Program reviews all applications and determines if the request for the product is in compliance with Bayer's policies. The Medical Communications Department reviews the prescription submitted for the product to ensure it meets prescription guidelines and confirms that the proposed recipient country is acceptable to Bayer. The program is periodically monitored by reviewing internal transaction reports.

Approvals

Free product provided under the above programs must be processed in compliance with the procedures applicable to each individual program.

The Law, Patents and Compliance Department must approve all requests to provide free product under any program not listed in this Policy.

Record Retention

The Reimbursement and Patient Assistance Program will retain all documents relating to free goods transactions for a period of 10 years.

Audits

Free goods transactions are subject to auditing by Bayer Internal Audit and the Law, Patents and Compliance Department to ensure compliance with this Policy. The government (e.g., IRS) may also request to audit/review free goods transactions.

20. Displays and Exhibits for Hospitals and other Customers

The Patient Protection and Affordable Care Act, Sunshine Law provision, 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 each employee's, contractor's, consultant's, and agent's responsibility to report 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, as well as 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 where payment is made to a customer or potential customer, such as a hospital, healthcare facility, advocacy organization that runs a pharmacy or wholesaler. 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 or other individuals attending the event.

Exhibits or Displays where payment is made to an entity that is not a customer or source of sales or referrals, such as medical societies, patient groups, disease state groups, etc. are not covered by this policy. Please refer to Policy and Procedure, "Displays and Exhibits for Non-Customers".

Questions regarding whether a product exhibit or display request constitutes an Interaction with HCPS and HCOs (Focus Arrangement) must be directed to the Law, Patents and Compliance Department.

Displays are typically table top units used for educational discussions at such locations as hospitals or other healthcare facility, or at a retailer or wholesaler, sponsored educational event.

- 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 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.

Fees for displays and exhibits to actual or potential customers may not be paid directly by the requesting Bayer employee. Display fees may never be paid to individual physicians or private physician practice groups.

Appropriate Promotional Activities

Product displays are promotional forums. All discussions with healthcare professionals must be consistent with product labeling (e.g., they must be on-label) within the United Sates. A discussion with non U.S. healthcare professionals in a U.S. promotional forum is limited to the U.S. product labeling. Sales and Marketing personnel may not discuss an unapproved Bayer product or unapproved use for an approved Bayer product.

Only promotional materials that have been approved for distribution through the LMR process may be located in and distributed from a product display. Likewise, any items (beverage or snack) provided in the booth must also be approved by LMR. 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 provide directions to the medical/scientific booth but may not walk the healthcare professional over to the medical/scientific booth. If there is no medical/scientific booth, the healthcare professional must be referred to the Bayer Medical Affairs Department for off-label inquiries.

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, 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 Pharmaceutical's Grant Review Committee will make the appropriate determination regarding 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 needs to walk out of one booth to enter the other booth.
- The medical/scientific booth must have a different look than the commercial exhibit booth, must be marked, and must not have any product-specific banners or panels.
- Sales and Marketing personnel may not distribute promotional literature or detail products in or near the medical/scientific booth. Only promotional materials approved for distribution may be located in and distributed from a commercial exhibit or booth. If a healthcare professional asks an off-label question about a Bayer product, Bayer Pharmaceuticals Sales or Marketing personnel must refer the healthcare professional to the Bayer Pharmaceuticals medical/ scientific booth. The Bayer Pharmaceuticals representative may provide directions to the medical/scientific booth but may not walk the healthcare professional over to the medical/scientific booth. If there is no medical/ scientific booth, the healthcare professional must be referred to the Bayer Pharmaceuticals Medical Affairs Department for off-label inquiries.

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

Procedures for Requesting Displays/Exhibits

Requestor of Arrangement

The Requestor of arrangement, at least six weeks before the product display date, submits a "Request to Exhibit" package via the Bayer GIFTS or other contract management tool, 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 W-9 from the entity hosting the display; and
  - A completed Display Agreement from the entity hosting the display.

The package will be reviewed and accepted or rejected by Field Operations. Once accepted, the package will flow to the applicable reviewers in contract management tool for approval/ denial. When all approvals are obtained, the submitter will be notified accordingly. Fees for displays that are paid to a source of sales or referrals of Bayer's pharmaceutical products (e.g., a hospital or wholesaler) are considered an Interaction with Focus Arrangements (Interaction with HCPs and HCOs). Fees paid to a trade or medical societies (e.g., American Society of Clinical Oncology) are not interactions with HCPs and HCPs because patient groups and medical societies are not sources of sales or referrals of Government Reimbursed Products.

Supervisor

The Supervisor reviews and approves the product display request only after receiving the complete request package. The Supervisor reviews all documentation and makes an independent judgment as to whether the product display is consistent with Bayer's policies. If appropriate, the Supervisor approves, then forwards the complete request package to the Law, Patents and Compliance Department.

If the Supervisor does not approve the request, he/she informs the Requestor that the proposed request has been denied.

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

For all product display requests involving payments to actual or potential Bayer customers, the Law, Patents and Compliance 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 and must include a certification by the parties that the parties shall not violate the Anti-Kickback Statute with respect to the performance or activities related to the product display and a certification by the parties that the parties shall not violate the Anti-Kickback Statute with respect to the performance or activities related to the product display. The Law, Patents and Compliance 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, his/her name, and the date it was conducted.

The Law, Patents and Compliance 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 Law, Patents and Compliance Department.

The Law, Patents and Compliance Department must send each party to the arrangement (e.g., the entity hosting the event), along with an approved contract, a copy of Bayer Code of Conduct with Anti-Kickback Statute Policies and Procedures attached and must document that these were sent. These documents may be sent electronically or by hard copy, and can be included as an exhibit to the contract or sent as separate documents. Law, Patents and Compliance must document that these documents were sent.

Proof of Service

The Requestor of the arrangement must confirm that he/she 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 the reason that the event did not occur.

Record Retention

Field Operations retains the payment request package in contract management tool for a period of 10 years.

Audits

All displays and exhibits are subject to auditing by Bayer Internal Audit and the Law, Patents and Compliance Department to ensure compliance with these policies. The government (e.g., IRS) may also request to audit/review product display documentation. If a Bayer representative attended the event, he or she must be able to provide confirmation of his or her attendance and proof that the display was in fact provided.

21. Displays and Exhibits for Non-Customers

Displays of Bayer's pharmaceutical products potentially implicate prohibitions against off-label promotion under the Federal Food, Drug, and Cosmetic Act. 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 (Displays) as well as commercial exhibits (Exhibits) where payment is made to an entity that is not a customer, potential customer, or source of sales or referrals. Appropriate entities under this policy include medical societies, patient advocacy groups, disease state groups and similar organizations. In all cases, an equal opportunity for display participation must be afforded to other pharmaceutical and/or biotech companies.

Exhibits or Displays where payment is made to an entity that is a customer or source of sales or referrals, such as hospitals and wholesalers, are not covered by this policy. Please refer to Policy and Procedure, "Displays and Exhibits for Hospitals and Other Customers".

Displays are conducted by sales personnel at educational events sponsored by medical, disease state, or patient organizations.

Exhibits are booths at conventions or trade shows and typically include exhibit property from the exhibit house vendor.

Fees for displays and exhibits may not be paid directly by the requesting Bayer Pharmaceuticals employee.

Questions regarding whether a product exhibit or display request constitutes a Focus Arrangement must be directed to the Law, Patents and Compliance Department.

Appropriate Promotional Activities

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

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

If a healthcare professional asks an off-label question about a Bayer pharmaceutical product, including questions about uses that have not received FDA approval, Bayer Sales or Marketing personnel may not answer the question and must provide directions to the medical/scientific booth but may not walk the healthcare professional over to the medical/scientific booth. If there is no medical/scientific booth, the healthcare professional must be referred to the Bayer Pharmaceuticals Medical Affairs Department for off-label inquiries.

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 Pharmaceuticals 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 representatives from non-promotional activities by scientific representatives.

- The medical/scientific booth must be separated from Bayer's commercial exhibit booth by walls so that one needs to walk out of one booth to enter the other booth.
- The medical/scientific booth must have a different look than the commercial exhibit booth, must be marked, and must not have any product-specific banners or panels.
- Sales and Marketing personnel may not distribute promotional literature or detail products in or near the medical/scientific booth. Only promotional materials approved for distribution may be located in and distributed from a commercial exhibit or booth. If a healthcare professional asks an off-label question about a Bayer pharmaceutical product, Bayer Sales or Marketing personnel must refer the healthcare professional to the Bayer medical/scientific booth. The Bayer representative may provide directions to the medical/scientific booth but may not walk the healthcare professional over to the medical/scientific booth. If there is no medical/scientific booth, the healthcare professional must be referred to the Bayer Medical Affairs Department for off-label inquiries.
- 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 the commercial or medical exhibit booth must have completed the annual Interactions with U.S. Customers at Industry Meetings and Conventions training. All commercial employees with an exhibitor badge must have prior approval from their manager prior to attending any of the scientific sessions to ensure the topics of sessions are appropriate for the employee's position.

Procedures for Requesting Displays/Exhibits

Requestor of Arrangement

The Requestor of arrangement, at least six weeks before the product display date, submits a "Request to Exhibit" package via the Bayer GIFTS or other contract management tool, 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 W-9 from the entity hosting the display; and
- A completed Agreement from the entity hosting the display or exhibit.

The package will be reviewed and accepted or rejected by Field Operations. Once accepted, the package will flow to the applicable reviewers in the contract management tool for approval/denial. When all approvals are obtained, the submitter will be notified accordingly.

Supervisor

The Supervisor reviews and approves the request only after receiving the complete request package. The Supervisor reviews all documentation and makes an independent judgment as to whether the requested fees are reasonable and whether the display or exhibit is consistent with Bayer's policies. If appropriate, the Supervisor approves, then forwards the complete request package to the Law, Patents and Compliance Department.

If the Supervisor does not approve the request, he/she informs the Requestor that the proposed request has been denied.

Law, Patents and Compliance Review

The Law, Patents and Compliance Department reviews and approves display or exhibit requests only after receiving the complete request package. The Law, Patents and Compliance 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 Law, Patents and Compliance Department approves the request and generates a written agreement to be signed by all parties.

Record Retention

Field Operations retains the payment request package in GIFTS for a period of 10 years.

Audits

All displays and exhibit are subject to auditing by Bayer Internal Audit and the Law, Patents and Compliance Department to ensure compliance with these policies. The government (e.g., IRS) may also request to audit/review commercial exhibit booth documentation. If a Bayer representative attended the event, he or she must be able to provide confirmation of his or her attendance and proof that the exhibit was in fact provided.

22. 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, in order 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 the policy of Bayer 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's 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 as well 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 memberships 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. Upon approval of your supervisor, individual professional organization memberships must be submitted through Concur T&E.

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, "Charitable Contributions (Other than Free Bayer Product)," 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's main focus should be to increase 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.

Membership in organizations that primarily consist of healthcare professionals which are 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 same 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 subject 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 as to 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 Government Relations Department.

If the Supervisor does not approve the request, he/she informs the Requestor that the proposed request has been denied.

Public Policy and Government Affairs Department

The Government Relations Department reviews all documentation and makes an independent judgment as to 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 Government Relations Department approves by signing the "Bayer Certification for Corporate Membership" form and "Internal Payment Demand" and forwards both documents to the Law, Patents and Compliance Department.

If the 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 Law, Patents and Compliance Department reviews all documentation and makes an independent judgment as to whether the contribution is consistent with Bayer's policies. If appropriate, the Law, Patents and Compliance Department approves by signing the "Bayer Certification for Corporate Membership" form and "Internal Payment Demand" and forwards both documents to the Accounting Department.

Record Retention

The Accounting Department must maintain the payment request package for a period of 10 years.

Audits

All Corporate Membership payments are subject to auditing by Bayer Internal Audit and the Law, Patents and Compliance Department to ensure compliance with these policies. The government (e.g., IRS) may also request to audit or review corporate memberships.

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 the improvement of patient care or 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 the same membership or membership level to other corporations 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:_____

RECORD RETENTION INSTRUCTIONS

The Accounting Department must maintain the payment request package for a period of 10 years.

23. Charitable Contributions (other than Free Bayer Products)

The Patient Protection and Affordable Care Act, Sunshine Law provision, 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 each employee's, contractor's, consultant's, and agent's responsibility to report 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 medical research, indigent care programs, patient education, public education, community organizations within a Bayer business community, and charitable events that directly benefit patients. 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 and its employees to provide legitimate charitable 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 include, but are not limited to, cash or cash equivalents (e.g., checks, gift cards/certificates, reward points, your credit card, etc.) and items contributed for raffles or other fundraising/sponsorship efforts (e.g., Bayer branded ice packs, squeeze balls, etc.)

It is important 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 focus of the event or activity (e.g., education or fundraising).

- A **charitable donation** is funding provided to a non-profit organization to support the organization's activities where Bayer does not expect to receive anything of value in return.

- A **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. The sponsorship opportunity is offered to other similarly situated industry members and not just Bayer.

- A **medical education grant** is funding provided to support an event where the primary focus is educating the 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 Grant

Characteristics	Charitable Contributions	Corporate Sponsorships	Education Grants
Promotional in nature	No	Yes	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	Yes	No

Charitable contributions may not be provided to Bayer customers unless the customer is a non-profit entity and the request is for patient support related programs such as camps for children with hemophilia. The Bayer customer requesting funding for such programs must submit the request for a charitable contribution via the website: http://grants-contributions.bayerweb.com/en/home/. This type of transaction would be considered an Interaction with HCPs and HCOs and must comply with all requirements of Policy and Procedure, Focus Arrangements (Interactions with HCPs and HCOs)
.
Bayer will not make charitable donations to individuals, political parties or causes, or religious groups for religious purposes. In addition, it is Bayer policy not to provide charitable donations to Bayer customers or potential customers of any Bayer pharmaceutical product or physician practice groups, or to non-profit entities controlled by or affiliated with Bayer customers or potential customers of any Bayer pharmaceutical product or physician practice groups, except in the limited circumstances referenced above. Requests for non US charitable organizations must be directed to 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.

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 medical research, indigent care, patient education, public education, community organizations within a Bayer business community affiliated with, or potentially affiliated with, any Bayer pharmaceutical products and other charitable events that directly benefit patients which

are all considered charitable contributions under Bayer's U.S. Pharmaceuticals Compliance Policies and Procedures. The Contribution Review Committee is responsible for the review and approval of all Charitable Contributions. In addition, Sales and Marketing may not be included in any communication regarding 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 website: http://grants-contributions.bayerweb.com/en/home/ ***and/or customer service telephone number (1-888-84-Bayer or 1-888-842-2937).***

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 acknowledgement of Bayer's sponsorship 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. A tax exempt letter is required for submission of a charitable contribution.

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 his/her individual capacity (e.g., a request by a physician to support his/her favorite charity).
- Intended as payment for services or goods.
- Provides a benefit to Bayer.

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

Invitations for Exhibit Space at the Charity Event

It is not appropriate to receive exhibit space or advertising space in return for a charitable contribution. It is Bayer's practice to request a separate invoice for exhibit fees. However, in certain limited circumstances, it may not be possible to separate the exhibit fee in the documentation submitted by the requesting organization. In these situations, the Bayer Charitable Contribution Review Committee will determine whether the contribution will be approved and/or whether Bayer may display at the event.

Limited Attendance at Events

Bayer, as a supporter of charitable organizations, may be offered tickets to event(s) that were not expected at the time of providing the charitable contribution. If tickets are offered involving charitable events sponsored by certain patient support groups (e.g., Hemophilia Federation of America, National Multiple Sclerosis Society, National Hemophilia Foundation), designated Bayer employees, as approved by the Donations Manager (with input from the Vice President and Head,

U.S. Office of Compliance, as requested), may be permitted to attend such events in order 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 who are not part of the commercial organization (such as Law, Patents and Compliance, Government Relations & Policy, Regulatory, or Medical Affairs). The representative(s) of Bayer who do attend approved events must not engage in any promotional activity at the event or use the event as a promotional opportunity. Only the designated Bayer employees may use the event tickets provided by the event sponsor for admission. Inviting customers, healthcare professionals, or any other non-Bayer personnel to these charity events is not permitted.

Contributions for Health Fairs/Medical Screenings

Under certain circumstances, Bayer may provide charitable contributions to support health fairs and medical screenings. These events must be offered by charitable organizations other than customers free of charge to the general community and promote disease awareness or be intended to detect medical issues. Examples include free prostate exams, blood pressure screening, 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 to any charity that is controlled by, related to, or operated by a customer or physician practice group.
- More than one medical group or more than one healthcare professional, each from different medical groups, must be taking part 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., 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 approval of the organization. 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

All Charitable Contribution requests must be submitted electronically by the requestor through the Bayer website: **http://grants-contributions.bayerweb.com/en/home/**. The requestor (or institution-designated staff member) shall electronically input all required charitable contribution information and attach a copy of the requestor’s organization 501(c)(3) letter, indicating its status as a tax-exempt charitable organization. Additional backup documentation (e.g., agenda, budget) may also be required. The requestor is responsible for providing all Charitable Contribution related documentation.

Under **NO** circumstances will the Law, Patents and Compliance Department accept a charitable contribution request after the event has occurred.

Donations Manager

The Charitable Contribution request will first be reviewed by the Donations Manager. If the request is deemed to be complete and within budget and strategic plan, it will be placed on a schedule to be reviewed and approved by the Charitable Contribution Review Committee.

If the Donations Manager, after attempts to obtain appropriate documentation, finds the request incomplete he/she will inform the requestor of the denial of request.

Charitable Contribution Review Committee

Sales and Marketing personnel do not participate in the Contribution Review Committee; however, they may provide a strategic plan relating to the subject matter of contributions to be considered.

The Review Committee reviews Charitable Contribution Requests from a regulatory and legal perspective consistent with the following objectives:

- Each Committee member certifies that there are no legal or compliance issues that would prohibit Bayer's approval of the contribution request (e.g., no conflict with government or industry guidelines or Compliance Policies and Procedures).
- Approval of request is based on the support of indigent care, public education, or other charitable activities that benefit patients.
- The request for support is within the budget.
- The request for support 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.

Upon review of the Charitable Contribution requests, the Review Committee may request that additional questions be answered prior to consideration of the Charitable Contribution request. For each such Charitable Contribution request, the Review Committee will approve or decline in conformance with these Policies and Procedures. If the Law, Patents and Compliance representative is not present, Law, Patents and Compliance must review the charitable contribution before it is approved.

Law, Patents and Compliance Review

For all charitable contribution 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 with respect to 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, his/her 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, 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 Law, Patents and Compliance Department.

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

Donations Manager Post Approval Documentation

A letter documenting the Review Committee's decision will be provided to the requestor (or institution-designated staff member).

The Donations Manager is responsible for updating the electronic system with the decision.

Record Retention

The Donations Manager will retain the payment request package for a period of 10 years.

Audits

All charitable contributions are subject to auditing by Bayer Internal Audit and the Law, Patents and Compliance Department to ensure compliance with these policies. The government (e.g., IRS) may also request to audit or review charitable contributions.

24. Medical Education Grants (including Continuing Medical Education)

The Patient Protection and Affordable Care Act, Sunshine Law provision, 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 each employee's, contractor's, consultant's, and agent's responsibility 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 medical education activities that foster increased understanding of scientific, clinical, or healthcare issues that contribute to the improvement of patient care. Bayer's policy conforms to the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, the AdvaMed Code of Ethics, the PhRMA Code on Interactions with healthcare Professionals, ACCME standards for commercial support and other accreditation agencies and relevant industry guidance. Bayer prohibits offering a medical education grant to encourage the recipient to prescribe, purchase, order, use or recommends Bayer pharmaceutical product(s). In addition, if medical education grants were to be provided as price terms or in lieu 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 they are sponsored by an a organization other than Bayer and they will contribute to the improvement of patient care. All CE/CME programs must be sponsored by an accredited medical organization. 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 expenses 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 or ordering Bayer's pharmaceutical products, to encourage off-label use, or 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 important 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 focus of the event or activity (e.g., education, fundraising). For example:

- A **charitable contribution** is funding provided to a non-profit organization to support the organization's activities where Bayer does not expect to receive anything of value in return.

- A **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 association's publication or the primary purpose of the event/activity is fundraising/charity. The sponsorship opportunity is offered to other similarly situated industry members and not just Bayer.

- A **medical education grant** is funding provided to support an event where the primary focus is educating the participants/attendees.

Key Characteristics: Charitable Contributions vs. Corporate Sponsorships vs. Education Grant

Characteristics	Charitable Contributions	Corporate Sponsorships	Education Grants
Promotional in nature	No	Yes	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	Yes	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 content of the program. 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 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 website: http://grants-contributions.bayerweb.com/en/home/ ***and/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:

- Grand Rounds
- 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 an additional level of evidence that the program is independent of commercial influence. Bayer supported educational events must conform to the ACCME and/or other applicable accreditation entity's 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 funding of the program and any significant relationships between the vendor and Bayer;
- Financial or other relationships between individual presenters or moderators and Bayer
- Any limitations on information that is presented at the programs, such as data that represents 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 on their own to a Bayer supported CME event to healthcare professionals. 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 in conjunction 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. The CME provider at its own discretion may apply the financial support provided by Bayer to provide 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, member of a Bayer speaker's bureau, 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 specifically 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 rest room.

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, in 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 attend 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 identified need for the medical education.

- Bayer representative's attendance is for educational purposes only, no discussion of any Bayer products during the educational event or immediately before or after can be discussed. 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 that are likely to 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 or Bayer's pharmaceutical products

- Bayer employees who are given permission 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 which relate 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 at Hospitals and Other Customers" and Policy and Procedure, "Displays and Exhibits for Non-Customers."

Acceptable Medical Education Grants

In summary, a grant is permitted only if:

- The grant is provided to foster increased understanding of scientific clinical, or healthcare issues that contribute to the improvement of patient care; and
- It will be used solely for legitimate expenses related to education or training of healthcare professionals or patients in connection with the improvement of patient care; and
- It is awarded to an organization and not an individual or private practice group; and
- The organization, not Bayer, controls the disbursement of the funds; and
- The responsibility for and control over the selection of content, faculty, educational methods, materials, and venues belongs to the organizers of the conference in accordance with their guidelines; and
- The grant is provided in response to a request that:
  - Describes the purpose/intended use of the grant or references 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 for expenses of attendees.
  - Acknowledges that Bayer may audit or review the use of the grant.
  - Provides a detailed budget describing planned usage of requested grant.
  - 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 lieu of a price concession; or
- Intended to encourage off-label use; or
- Contingent on the purchase of or recommendation to purchase Bayer products; or
- Intended to encourage the recipient to order, prescribe, or recommend Bayer products or reward or compensate the recipient for so doing; or
- Made at the request of a healthcare professional in his/her individual capacity (e.g., a request to fund his/her "pet project"). A healthcare professional may request a grant in his/her official capacity, such as the head of a hospital department; or
- Made in return for anything of value provided to Bayer by the recipient, with the exception of disclosure in program materials that the program is funded by Bayer; or
- Provided for the purchase of equipment, educational books, or other items of value; or
- Provided to fund salaries of hospital nurses, residents, or other healthcare professionals, or any other routine administrative costs of a healthcare professional (with the exception of certain fellowship programs); 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
- 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 payment to customers, the display and medical education grant must be processed as separate transactions in order 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 website: **http://grants-contributions.bayerweb.com/en/home/**. 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; and
- 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 for expenses of attendees.

Requestor

All medical education grant requests will be received electronically from the requestor through the Bayer website: **http://grants-contributions.bayerweb.com/en/home/**. The requestor (or institution-designated staff member) must electronically input all required medical education grant information. 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 from the Grant Review Committee of the grant request a signed letter of agreement is required for distribution of 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 makes an initial determination 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 Law, Patents and Compliance Department, which makes the final determination whether the grant is an Interaction with HCPs and HCOs (Focus Arrangement).

If the grant request is deemed to be 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, after attempting to obtain appropriate documentation, finds the request incomplete, he/she 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 Law, Patents and Compliance. Sales and Marketing personnel do not participate in the Grant Review Committee; however, they may provide a brand plan relating to 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 that would prohibit 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 increased understanding of scientific, clinical or healthcare issues that contribute to the improvement of 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 education or training of healthcare professionals or patients to improve patient care.

If the Grant Review Committee needs additional information in order 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 Law, Patents and Compliance 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 with respect to 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, his/her name, and the date it was conducted.

The Law, Patents and Compliance 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 Law, Patents and Compliance Department.

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

If the reviewing attorney is not present at the Grant Review Committee meeting, the attorney may conduct the required review at a later date. However, this review must be completed before the grant is approved and before 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 for further discussion.

A letter documenting the Grant Review Committee's decision will be provided to the grant requestor (or institution- designated staff member) by the Grant Manager following the meeting. 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 Anti-Kickback Statute Policies and Procedures attached. 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 with respect to the performance or 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 otherwise obtain proof of service.

Grant Approval of Arrangements

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

Record Retention

The Medical Affairs Department will retain the payment request package for a period of 10 years. Proof of service documents are retained in the medical education grant system database for a period of 10 years.

Audit

All medical education grants are subject to auditing by Bayer Internal Audit and the Law, Patents and Compliance Department to ensure compliance with these policies. The government (e.g., IRS) may also request to audit/review medical education grant payments. The Patient Protection and Affordable Care Act, Sunshine Law provision, 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 each employee's, contractor's, consultant's, and agent's responsibility to report accurate, complete and timely data to applicable Bayer systems, as this is the data Bayer will report to CMS.

25. Providing Samples at No Charge and Device Evaluations

Bayer may provide a limited number of product samples of Bayer pharmaceutical products to customers at no charge. Samples are limited to initial customer product evaluation, education, training and/or for distribution directly to patients. The quantities of product samples provided must not exceed an amount that is 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 Sample Accountability system. 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 received. Bayer conducts annual physical inventories of drug samples in control of each representative and maintains records of such inventories. Therefore, it is important that the provision of samples be recorded accurately. Guidelines (SOP PWA 00720) for dispensing product samples may be obtained from the Sample Accountability Department.

Under no circumstances is a sample to be given to a healthcare professional for personal use or for use by their immediate families or office staff – so-called "professional courtesy units." Offering free samples to healthcare professionals for their personal use potentially implicates the Anti-Kickback Statute if one purpose of the offer is 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 other public or private insurer for that sample. This statement is included on every sample request form signed by the practitioner.

Product samples are not the same as charitable product donations. Samples are provided for patient or provider evaluation purposes only. Products that are 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) require 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; and
- 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 making the request for 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 30-day period to a healthcare professional or facility to permit an evaluation of its use and functionality in order to determine whether to use or buy the product. Evaluations may not exceed 60 days without approval by Law, Patents and Compliance, or unless a specific evaluation program has been approved by Law, Patents and Compliance.

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 of the specific product being evaluated. 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 the responsibility of the Bayer representative to track the location and status of evaluation equipment at all times and removes or deactivates 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 is 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 at the time the evaluation equipment is provided. The Bayer representative assigned to the account must make arrangements for the prompt removal of the equipment at the conclusion of the limited evaluation period unless the healthcare professional has agreed to purchase/lease the 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 adequate evaluation of the disposables and related equipment by the healthcare professional. The procedures described above for a written notification must be followed.

Vermont Disclosure of Samples of Prescribed Products

Pharmaceutical manufacturers are required to report annually certain information relating to samples of prescribed products, including prescription drugs, nonprescription medical devices, nonprescription durable medical equipment, and OTC products provided to Vermont healthcare providers for the preceding calendar year, provided that any public reporting of such information shall not include information that allows for the identification of individual recipients of samples or connects individual recipients with the monetary value of the samples provided.

Samples of prescription drugs that are reported to HHS under Prescription Drug Sample Transparency Provision of the PPACA do not need to be reported to the Vermont Attorney General if the Attorney General determines that HHS will collect and provide Vermont with recipient-specific distribution of samples. In the event that the Vermont Attorney General does not determine that HHS will provide recipient- specific information to Vermont, manufacturers must report the distribution of samples covered by the PPACA.

Regardless of the Attorney General's determination, samples of prescribed products that fall outside the reporting requirements of the PPACA, such as samples to health care providers who are not physicians, samples of medical devices and OTC products, and coupons and vouchers that allow a patient to receive product free or at a discounted price, must be reported for distributions.

Manufacturers are required to identify the relevant product, recipient, number of units, and dosage of each sample distributed. Unlike other expenditures, the Vermont law does not require manufacturers to report the value of samples.

26. Patient Protection And Affordable Care Act (PPACA) Transparency Requirement

Legislative, regulatory, and enforcement authorities are aggressively pursuing 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 referred to as the "Physician Payment Sunshine Act" or simply 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 referred to as the "Prescription Drug Sample Transparency" provision in this policy. Under the Prescription Drug Sample Transparency provision, a disclosure report is due to the federal government no later than April 1 and 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.

It is the responsibility of each Bayer employee to accurately and completely capture any transfers of value from HCP and HCO interactions to the Company in a timely manner. These steps are extremely important 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 publically traded security and mutual fund. The Aggregate disclosure to the federal Government is made annually on March 31. The information disclosed is made publicly available on a searchable website on June 30 of each year.

Covered recipients are defined under the Sunshine Act to mean certain U.S. teaching hospitals and U.S. licensed physicians, unless the physician is a Bayer employee. The following information must be disclosed in connection with a reportable payment to a covered recipient:

- Name of the physician or teaching hospital;
- Primary business address of the physician or teaching hospital;
- Specialty and National Provider Identifier (NPI), in the case of a physician;
- State professional license number(s) (for at least one state where the physician maintains a license), and the State in which 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
- 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).

There are a limited number of transactions that are excluded from the definition of a covered "payment or other transfer of value".

These are individual transfers of value generally under approximately $10.00 that cumulatively does not exceed approximately $100.00 during a calendar year. Bayer tracks all payments (transfers of value) and these cumulative amounts will determine if the spend on this individual or institution is reportable. CMS changes the allowable limit for individual transfers of value annually based on inflation. To find the latest de minimus charges, visit the CMS website: **https://www.cms.gov/OpenPayments/Program-Participants/Applicable-Manufacturers-and-GPOs/Data-Collection.html**.

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 making the request for 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 at No Charge and Device Evaluations" for more information on sample distribution. Also, guidelines for dispensing product samples may be obtained from the Sales Operations Department.

27. STATE LAWS – OVERVIEW

		State Law Overviews	Bayer Actions
Limits/Prohibitions	California	Annually declare adherence to compliance program including the annual spend limit of $1,500 per HCP for meals, gifts, educational items and other items of value	Track and manage all relevant activities involving spend and adhere to spend limits
	Minnesota	Limits gifts and business meals to a total of $50 per calendar year per HCP	Track all relevant activities involving spend and adhere to spend limits
	Vermont	Prohibits gifts, including but not limited to meals and charitable donations to HCPs	No meals, gifts or charitable donations to Vermont HCPs
Compliance Program	Connecticut	Adopt compliance program; adopt training program; conduct training and regular audits to monitor compliance	Adopt compliance program
	Nevada, Massachusetts	Adopt Marketing Code of Conduct; adopt training program; conduct annual audits to monitor compliance; adopt investigation policies & procedures; includes prescriber data management;	Report annually documentation and certification of annual audits.
Annual / Quarterly Disclosure	Connecticut	Report annually payments or other transfers of value provided to advanced practice registered nurses "not practicing in collaboration with a physician"	Track and report all relevant spend through internal Bayer Spend Source Systems (*e.g.*, Concur, SAP) and disclose periodically, as required by the applicable statute
	D.C.	Report payments, fee-for-service, expenses, meals and gifts (greater than >$25), provided to DC licensed healthcare professionals and healthcare entities Report marketing costs over $25 directed toward D.C. residents including the general public, prescribers, healthcare professionals and patient Report the aggregate cost of employees who engage in these advertising and promotional activities within D.C	
	Massachusetts	Annually report fees, payments, subsidies or other economic benefit (greater than >$50) to Massachusetts covered HCPs & HCOs, except those covered by federal reporting requirements. Report any non-compliance activity. Quarterly report non- CME meals outside of the office or hospital setting is pending as of 1/1/2017	
	Minnesota	Report cumulative payments >$100 made to MN licensed Nurse Practitioners, Physician's Assistants, Veterinarians and Dental Therapists, for practitioners who serve on the faculty at a professional or educational conference or meeting, and for professional or consulting services in connection with a genuine research project.	
	Vermont	Report "allowable expenditures," including fee-for-service payments, expenses, certain samples, fellowship salary support, discounts and rebates to the extent not preempted by PPACA	
Ethics Reform	Louisiana Exec Branch Lobbying	Prohibits most gifts and other items of value, including fee-for-service payments to state employees including Medicaid P&T Committee members; individuals who make expenditures greater than $500 (*e.g.*, gifts, meals or entertainment) or present before Louisiana executive branch officials to register as lobbyists and to report certain lobbying expenditures	Prohibit meals, gifts or payments of any kind to state employees; no Bayer sales rep may register as a lobbyist in Louisiana
	D.C. SafeRx	Prohibits meals and gifts to Medication Advisory Committee (MAC); licensure of pharmaceutical detailers including medical science liaisons	Prohibit meals to MAC members; ensure all applicable employees are licensed
	Tennessee Ethics Act	Prohibits meals and gifts to all state employees, including political action committee (PAC) members.	Prohibits meals, gifts, and anything of value to an official in the legislative or executive branch, to any candidate for state office, or any immediate family members of such officials or candidates
Price Disclosures	Vermont AWP	Requires disclosure of AWP of drug product as well as AWP of similar drug in same therapeutic class to HCPs during promotion/ marketing activities	Provide Short Form to Vermont HCPs when discussing Bayer products (applicable to products in pill form only) Provide Long Form via website with an update each quarter.
	California	Manufacturers of blood factors must submit the average sales price (ASP) for each blood factor product on a quarterly basis.	Comply with reporting requirements.
	New Mexico, Texas	Manufacturers must report AMP and Best Price (BP). TX=AMP & price paid by wholesalers	

State Laws — Data Collection

How Data is Collected

In order to capture the relevant data for federal, state and global reporting purposes, Bayer employees in Pharmaceuticals and Animal Health must internally report all payments made to HCPs and HCOs.

Data is collected in the Focus Arrangements Database (FADb) based on transactions recorded in SAP, Concur, Veeva, FA Upload, GIFTs and other Bayer systems. Data is also uploaded into the FADb from CROs, Third Party Vendors and Bayer Meeting Planners.

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

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

Compliance Operations monitors and reviews all FADb data in order 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: 1) 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 2) the vendor will exclude healthcare professionals licensed in D.C. or any State with similar reporting requirements or payment limits.

PPACA Preemption

In light of the federal Physician Payments Sunshine Act's preemption of state law, payments reported pursuant to 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.

State Laws:

California – Compliance Program and Spending Limits; Price Disclosure for Blood Factors

Compliance Program and Spending Limits

The State of California requires pharmaceutical companies to adopt a comprehensive compliance
The State of California requires pharmaceutical companies to adopt a comprehensive compliance
program (CCP) in accordance with the "Compliance Program Guidance for Pharmaceutical Manufacturers," which was developed by the United States Department of Health and Human Services Office of Inspector General (OIG). Pharmaceutical companies must include in their SOPs written policies for compliance with the Pharmaceutical Research and Manufacturers of America (PhRMA) "Code on Interactions with Healthcare Professionals" and the Advanced Medical Technology Association ("AdvaMed Code of Ethics"). They must post the CCP on their website and provide a toll-free telephone number by which copies of the CCP may be obtained.

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 the State of California in accordance with the PhRMA and AdvaMed Codes and OIG Compliance Guidance.

California law defines "medical or healthcare professional" as:

- A person licensed by state law to prescribe 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 $1,500.

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 provided by a healthcare or medical professional. 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 compliance with its CCP and the state law.

Publish Compliance Program and Declaration

Bayer must make its CCP and written acknowledgement of compliance available to the public on its Web site: **http://www.bayer.us/en/products/bayer-pharmaceuticals/** and provide a toll-free telephone number (1-877-256-3562) where a copy of the CCP and written declaration of compliance may be obtained.

B. California Price Disclosure

Blood Factors Only

Pharmaceutical manufacturers are required, under California law, to calculate and report to the California Department of Health Services (the "Department") on a quarterly basis, the ASP of their blood factor products.

The California definition of ASP is the same as the Medicare definition of ASP.

The ASP information for blood factors must be reported on a quarterly basis when the data is submitted to the Centers for Medicare and Medicaid Services (CMS), or soon thereafter as determined by Medi-Cal.

State Laws:

Connecticut

A. 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 of the requirements prescribed in the PhRMA and AdvaMed Codes as such codes were in effect on January 1, 2010. Additionally, pharmaceutical manufacturers must adopt a comprehensive compliance program in accordance with the "Compliance Program Guidance for Pharmaceutical Manufacturers," which was developed by OIG. Pharmaceutical manufacturers are required to adopt a compliance program.

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

As of January 1, 2017, no regulations have been implemented by the Connecticut Department of Consumer Protection, the agency tasked with enforcing the Connecticut compliance program law.

B. REPORTING REQUIREMENTS FOR PAYMENTS TO ADVANCED PRACTICE REGISTERED NURSES

Connecticut also requires manufacturers of a "covered drug, device, biological, or medical supply," as such term is defined by the federal Physician Payments Sunshine Act, 42 U.S.C. § 1320a-7h (the "Sunshine Act"), to report, on an annual basis, "payments or other transfers of value" provided to advanced practice registered nurses practicing "not in collaboration with a physician" in the state, for the preceding calendar year. A "payment or other transfer of value" is defined to include a "(A) transfer of anything of value, except a transfer of anything of value that is made indirectly to an advanced practice registered nurse through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the advanced practice registered nurse, or (B) a transfer of anything of value that meets the requirements for exclusion under [the Sunshine Act,] 42 USC 1320a–7h(e)(10), as amended from time to time."

Reports must be provided in a form and manner prescribed by the Connecticut Commissioner of Consumer Protection and, with respect to advanced practice registered nurses, contains information that is required under the Sunshine Act for payments or transfers of value to physicians and teaching hospitals.

In determining whether a report must be submitted, applicable manufacturers must refer to the list of advanced practice registered nurses who are authorized to practice not in collaboration with a physician published by the Commissioner of Public Health on the Department of Public Health's Internet web site: **http://www.ct.gov/dph/cwp/view.asp?a=3121&q=587910**.

The first reports are due July 1, 2017. The Connecticut Department of Consumer Protection has stated that the Drug Control Division within the Department will accept all reports in the format that is found on the Centers for Medicare and Medicaid website **(https://www.cms.gov/OpenPayments/About/Resources.html)** titled "PY 2013-2015 CSV Sample File: General Payments [CSV]." This file should be emailed to DCP.DrugManufacturers@ct.gov.

Manufacturers that fail to report in accordance with the transparency requirement will be assessed a civil penalty of $1,000 to $4,000 for each payment or other transfer of value not reported.

State Laws:

District of Columbia – Promotional Cost Reporting, Licensure of Company Representatives and Gift and Remuneration Prohibition

A. 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.

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 persons employed by them in D.C., carriers, health plans, benefits managers, pharmacies, nursing facilities and clinics):

- Educational or informational programs, including (i) support for medical education, (ii) 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; and
- Product samples, except those intended for free distribution to patients.

Gifts to "physicians" and "teaching hospitals" given after July 31, 2013 are not required to be reported to the D.C. A "physician" is defined as a doctor of medicine or osteopathy, a doctor of dental surgery or medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor. "Teaching hospitals" are those hospitals identified by the Centers for Medicare and Medicaid Services at **https://www.cms.gov/OpenPayments/About/Resources.html**.

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:

- Expenses of $25 or less;
- 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 that includes advertising in D.C. if the portion of the costs pertaining to or directed at D.C. or cannot be reasonably allocated, distinguished, determined or otherwise separated out; and
- Payments made to health care practitioners for participation in market research if: (i) the market research is conducted by an independent survey research organization; (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 are due on July 1 covering the previous calendar year.

Reports must be submitted in the electronic format specified by the Department of Health. The regulations state that each annual report must also 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" as specified by the regulations. The regulations further require manufacturers to submit a $5,000 fee payable to "D.C. Treasurer," along with the hard copy filing.

B. 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 the formularies of District-administered health programs. Similarly, such medication advisory committee members are prohibited from accepting such 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 term "medication advisory committee" is defined as "any committee or panel that is responsible for making recommendations or decisions regarding a formulary to be used by [the District]." 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 prior to engaging in interactions 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.

C. 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, as defined in the Act, to obtain a license prior to engaging in those interactions. 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. This definition does not apply to Bayer employees who only sell, market, or promote veterinary drugs. However, individuals engaged in the practice of 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 other persons that come once a year for a short duration of time 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 will return to D.C. again within the same calendar year.

Individuals who engage in activities covered by the Act without a license may be subject to a monetary penalty imposed by the District of up to $10,000, in addition to other penalties and sanctions. This includes individuals engaging in activities covered by the Act on a temporary or emergency basis. 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 at: **http://doh.dc.gov/service/saferx-pharmaceutical-detailers** and are summarized below.

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

- Completed and signed application form, including your social security number, and relevant supporting documents;
- A check or money order in the amount of $175.00 made payable to "D.C. Treasurer." Cash or credit card payment will not be accepted;
- Two (2) identical recent passport type photographs (2x2 inches in size). The photos must be original photos and cannot be computer-generated copies or paper copies;
- One (1) photocopy of a government issued photo ID, such as your valid driver's license;
- Official certificate of graduation from a recognized institution of higher education, in a sealed envelope from the educational institution to the Board, or a completed application for a waiver of educational requirements, if applicable;

- Completed, signed and notarized "Affidavit to Abide by Code of Ethics" Form which promises adherence to the code of ethics, developed by the Board that governs interactions with healthcare professionals; and

- A sealed envelope with the results of an FBI and State criminal background check. In addition, health professionals can also receive live scan Criminal Background Check services with L-1 Enrollment Services. Visit the L-1 website or call 1-877-783-4187.

If applicable, applicants also need to include:

1. Sworn affidavit stating that he or she does not have a social security number, if that is the case; and/or

2. Name change documents (e.g., marriage certificate, divorce decree or court order).

If applying for a waiver of educational requirements, an applicant must submit the information specified in the waiver, including the:

1. Notarized statement on "Waiver of Educational Requirement" Form;
2. List of past and current employers for the last three (3) years; and
3. Two (2) attestations from current supervisors or from one supervisor and one professional colleague.

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. Upon final approval, you will be issued a license to engage in interactions with healthcare professionals in the District of Columbia. If your license is denied, you will receive a "Notice of Intent to Deny Licensure" document in the mail which will state the basis for the proposed denial and advise you of your right to request a hearing and the procedures for doing so.

License Renewal Activities

All pharmaceutical detailer licenses will expire at 12:00 Midnight, 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 period preceding the date the license expires;

- Attest to completion of the required continuing education credits on the renewal application form; and

- Be available for audit inquiries, which will be conducted at random.

At the conclusion of each renewal period, the Board will conduct a random audit. Those licensees selected in the random audit will be required to submit proof of having completed the required fifteen hours of continuing education.

Proof of completion of required continuing education credits includes the following information with respect to 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.

You are responsible for obtaining certificates of completion immediately after completing qualifying training programs. You need to retain these certificates so that you are able to submit them to the District as proof of completing your required continuing education credits

Continuing Education Courses

Training courses must be approved by the Board of Pharmacy before they can be applied to the 15 credit hours of continuing education requirement. The applicant must verify whether a program is approved by the Board prior to 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 be an educational program covering 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
- An institution of higher learning.

Bayer will submit an application 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 with employees or representatives of licensed health professionals located in the District. The Board expects a reply within ten (10) business days of their request.

If you receive such a request, you must immediately contact the Vice President and Head, U.S. Office of Compliance or the Law, Patents and Compliance Department. They will work with you to coordinate your response.

The documentation that needs to be maintained must include: who the detailer visited, the date and time of the visit, the products discussed, whether samples were provided, and the type of materials provided to the healthcare professional. Sales consultants need to maintain this information in the Bayer Veeva system. Those not on the Veeva system will need to 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 your use.

You must retain, for a period of five (5) years, documents and information relating to your communications with healthcare professionals and those that work for them.

Upon Leaving Bayer

A licensed individual must notify the Board within ten (10) calendar days of leaving the employ of a pharmaceutical company. This notification must be written and must include the name, address, email, and telephone number of the person within the company (your immediate supervisor) who may be contacted for retrieving the records required to be maintained under this chapter. 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 who are leaving Bayer must be vigilant about obtaining the employee's records relating to communications with healthcare professionals in the District and reminding 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 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 in a timely manner.

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 the District. If you are not on the Bayer Veeva system, you must use this form to document these interactions and retain it for 5 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.

If you receive a request for information from the DC Board of Pharmacy, you must contact the Vice President and Head, U.S. Office of Compliance or the Law, Patents and Compliance Department immediately. They will work with you to coordinate your response. You have only ten (10) business days to reply to the Board.

Upon leaving Bayer, you must provide your documentation files to your immediate supervisor for ongoing record retention. Also, licensed individuals must also provide a written notification to the DC Board of Pharmacy within ten (10) calendar days of leaving Bayer with a copy to your supervisor. Notifications must be sent to 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

State Laws:

Illinois, City of Chicago

Licensure of Company Representatives

Effective July 1, 2017, Title 4, Chapter 4-6, Article XXXI of the Municipal Code of the City of Chicago (the "Code") requires all pharmaceutical representatives who market or promote pharmaceuticals to health care 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 health care professionals), as well as pharmaceutical representative managers or supervisors who do not interact directly with health care professionals while in the City of Chicago. In addition, the requirements do not apply to individuals who provide information about a pharmaceutical product solely for the purpose of clinical trials, investigational drugs, or a Risk Evaluation and Mitigation Strategy pursuant to the federal Food, Drug, and Cosmetic Act.

To become initially licensed, a pharmaceutical representative must complete an online application at **www.cityofchicago.org/bacp** and a professional education course that will be available as part of the licensing process. The course will cover the pharmaceutical representative license, ethical standards and disclosure requirements, and other topics that are determined to be appropriate to the license. Pharmaceutical representatives will receive a Certificate of Completion, which must be submitted online to complete the license application.

Licensed pharmaceutical representatives must complete five hours of continuing professional education each year. The continuing education must focus primarily on one of the subject areas designated by the Chicago Department of Public Health ("CDPH") and be provided by a CDPH-approved institution. CDPH will post of list of approved course providers on its website, **www.cityofchicago.org/health**. 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.

When applying for a license renewal, a pharmaceutical representative will affirm that he or she has completed the continuing education requirement during the previous year. Each year, CDPH will audit a subset of renewal applications 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)
- Signed certificate(s) of completion

Disclosure of Certain Interactions with Health Care 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 August 2017, 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 August 2017, Bayer does not sell, market, or promote such medications. Accordingly, Bayer representatives who were licensed before August 2017 are not required to track their interactions with health care professionals or make any such disclosures.

Representatives who are licensed or renew their licenses after August 2017 should check the list, which is available at **www.cityofchicago.org/health**, to confirm it has not changed. If a pharmaceutical representative markets or promotes pharmaceuticals, pharmacological classes, or categories of pharmaceuticals that are listed at **www.cityofchicago.org/health** during the month the representative obtains or renews a license, then he or she should begin tracking interactions with health care professionals using the spreadsheet that is available at **www.cityofchicago.org/health**. Please contact Law, Patents and Compliance if you have any questions, including whether you need to track your interactions with health care professionals.

For pharmaceutical representatives who do market or promote products that are included on CDPH's list at the time of licensure or renewal, upon request by the Commissioner of Public Health, the representative shall provide the following information, in the format described at **www.cityofchicago.org/health**, for the time interval no greater than the period between license renewals:

- A list of health care professionals within the City of Chicago contacted;
- The number of times the health care professionals were contacted;
- The location and duration of contact;
- The pharmaceuticals promoted;
- Whether product samples, materials, or gifts of any value were provided to the health care profession and the value of the products, materials, or gifts; and
- Whether and how the health care 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 health care professional or the representative are 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 take place concurrently with the conference, symposium, convention, or other event but are not officially part of the event.

Ethical Standards

The Code and its associated rules set out ethical standards to which pharmaceutical representative must adhere. Under the ethical standards, a pharmaceutical representative must (1) comply with the applicable policies and procedures of the health care facilities and health care professional offices he or she visits and (2) provide health care 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 health professional, or an employee or representative of a licensed health 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 licenses to practice that health occupation;

- Attend patient examinations without the express, written consent of the patient;
- Enter an area meant primarily for health care providers and patients, other than a designated waiting area, unless invited by a health care provider working on site.
- Harass, intimidate, or coerce a health care professional, or an employee or representative of a health care professional, through any form of communication;
- Continue making sales calls to a health care professional, or an employee or representative of a health care professional, if the health care professional requests it in writing or verbally to the pharmaceutical representative or the representative's employer; or
- Make any misleading statements to gain access to a health care professional.

Proof of Licensure, Complaints & Violations

Upon request by a health care professional, a pharmaceutical representative must show his or her license or an exact copy thereof (e.g., a photocopy or image saved on an electronic device). Health care 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 will have an opportunity to respond to such complaints and provide relevant information.

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 under of two years from the date of revocation.

STATE LAWS:

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

Louisiana law prohibits public employees from accepting most gifts and other items of value. It also requires individuals who make expenditures of $500 or more (e.g., for gifts or entertainment) on Louisiana executive branch officials to register as lobbyists and to report certain lobbying expenditures.

Identification of Louisiana Executive Branch Officials

A list of executive branch departments and agencies can be found on the State of Louisiana website at: http://louisiana.gov/Government/Agency_Index/. 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 he/she is an executive branch official before providing any meal, speaker fee, or other fee-for- service payment.

Prohibition on Gifts to Public Employees

Under Louisiana's gift law, the only items of value that state employees are permitted to accept are "promotional items" of a nominal value and "food and drink" valued at $60 or less that is consumed in the presence of the gift giver. Accordingly, state employees may not accept medically- related gifts, speaker fees, textbooks, etc. Bayer's "Educational Items for Healthcare Professionals" policy prohibits the provision of promotional items, regardless of value, to any healthcare professional. Thus, you may not provide any promotional items or other gifts to state employees in Louisiana, although food and drink valued at $60 or less is permitted, provided that such food or drink is consumed in your presence and otherwise provided in compliance with Bayer policy limits. You must assume that healthcare professionals working at state facilities, such as state hospitals, universities, clinics and prisons are state employees. Under Louisiana law, they remain state employees even when they are not physically located at a state facility (e.g., on their days off or when working at a civilian facility). It is your responsibility to determine whether a Louisiana healthcare professional is a state employee before offering or providing a meal or entering into a fee-for-service arrangement in compliance with Bayer policies.

Pharmaceutical Samples

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. Thus, 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.

Lobbying Registration and Disclosure

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

Because of the stringent reporting requirements as well as additional legal ramifications, no Bayer sales force employee should be registered as a lobbyist in Louisiana. (Note that Government Relations employees must register as lobbyists as a requirement of their job.)

Under no circumstances should a Bayer employee entertain or appear before an executive branch official without first contacting the Government Relations & Policy Department well in advance of the contemplated activity.

Fee for Service Events

Louisiana's Code of Governmental Ethics prohibits a public servant from receiving compensation for services rendered by the public servant if such services are compensated for by an entity from which the public servant may not receive a gift under Louisiana law. Accordingly, you must consult the Law, Patents and Compliance Department before Bayer enters into a financial arrangement with, reimburses travel expenses for, and/or engages any Louisiana healthcare professional as a consultant, advisor or speaker.

Louisiana law does, however, provide a limited exception for faculty or staff members of a public higher education institution to provide certain consulting services in their field of expertise, provided the consulting arrangement is properly approved according to the process specified by Louisiana law. These Louisiana laws significantly impact the consulting arrangements that pharmaceutical companies may enter into with healthcare professionals who are executive branch officials. The Louisiana Board of Ethics has discussed the application of the gift law to pharmaceutical fee-for-service arrangements in a number of Advisory Opinions. Some of the key Advisory Opinions regarding fee-for-service arrangements with Medicaid P&T Committee members and employees of Louisiana public universities are discussed below.

District Hospital Employees

Ethics Advisory Opinion No. 2013-1560 (January 23, 2014) analyzed a fee-for-service consulting arrangement between a parish district hospital employee (a director of therapy services) and a manufacturer of medical equipment from which the hospital purchased products for resale at a retail establishment owned and operated by the hospital. The Board concluded that Louisiana law prohibited the hospital employee from providing consulting services to the manufacturer to help in the design of new products while the individual remained in the hospital's employ. The Board explained that such conduct would be prohibited because the law "prohibits a public servant from receiving compensation for services rendered to any person who has a business, contractual or financial relationship with the public servant's agency."

Medicaid Pharmaceutical & Therapeutics Committee Members

Ethics Advisory Opinion No. 2008-424 (May 13, 2008) analyzed fee-for-service arrangements between pharmaceutical companies and members of the Louisiana Medicaid P&T Committee. The Board concluded that Louisiana law prohibited the P&T member from providing the following services to pharmaceutical companies:

- Service on scientific advisory boards and speakers' bureaus to provide an opinion about needs in the P&T member's medical field and the best direction and use of available resources for planning future research and marketing;
- Service on the faculty of a national council which is supported by a grant from a pharmaceutical company, and for which the P&T member receives an honorarium and expenses;
- Service as a consultant and co-principal investigator on a clinical trial for which the P&T member receives an hourly honorarium/consultation fee; and
- Recipient of a grant from a pharmaceutical company to support research endeavors.

Louisiana Public University Employees

Ethics Advisory Opinion Nos. 2006-247 (April 18, 2006) and 2006-654 (Sept. 14, 2006) analyzed fee-for-service arrangements between pharmaceutical companies and employees of Louisiana public universities. The Board concluded as follows:

- Although Louisiana law does provide a limited exception for faculty or staff members of a public higher education institution to provide certain consulting services in their field of expertise (provided the consulting arrangement is properly approved according to the process specified by Louisiana law), speaking engagements are not considered consulting services. Therefore, executive branch officials who are employees of public universities in Louisiana may not accept compensation or related travel reimbursement for serving as a speaker at a seminar or other speaking engagement;

- Furthermore, the exception that permits executive branch officials to provide consulting services under certain conditions (discussed immediately below) does not apply to speaking engagements;

- Under certain conditions, executive branch officials employed by Louisiana public universities may serve as a paid consultant to a company to serve on an advisory board to assist in product development or advice on other issues particular to the practice of medicine, including developing continuing medical education materials. However, the following conditions must be met first;

- The services must be related to the executive branch official's academic discipline or area of expertise;

- Proper approval must be granted in writing by the chief administrative officer of the State agency in compliance with Section 1123(9) (b) of the Code of Governmental Ethics; and

- In circumstances where Bayer Pharmaceuticals has entered a written contract with a State agency to conduct a study or clinical research trial, executive branch officials may be reimbursed for travel expenses related to a study or clinical research trial only if the contract between Bayer Pharmaceuticals and the State agency obligates Bayer Pharmaceuticals to pay for all reasonable travel expenses incurred by participating physicians in connection with trial related meetings.

In summary, the Louisiana gift law places significant restrictions on the fee-for-service arrangements a pharmaceutical manufacturer may enter into with Louisiana executive branch officials. The Louisiana statutory provisions are very complex and are often amended by the legislature or subject to new interpretations by the Louisiana Board of Ethics. Again, you must consult the Law, Patents and Compliance 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.

STATE LAWS:

Massachusetts – Marketing Code of Conduct and Cost Reporting

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, as amended in 2012, require manufacturers to file quarterly reports detailing all non-CME educational presentations at which modest meals and refreshments are provided to health care practitioners outside of the office or hospital setting. However, as of Jan 1, 2017, guidance related to the required format for such quarterly reporting has not been issued by the Department.

Key Definitions

A "covered recipient," is defined as a person authorized to prescribe, dispense, or purchase prescription drugs or medical devices in Massachusetts, including a hospital, nursing home, pharmacist, health benefit plan administrator, or a health care 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 the purposes of payments by that company. Additionally, consumers who purchase prescription drugs or medical devices are not covered recipients.

The law defines "healthcare practitioner" as a person licensed to provide healthcare, who prescribes prescription drugs or medical devices for any person, 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 his employment, agency or contract related to or in support of the provision of healthcare to individuals. Independent contractors who do not have prescribing authority or who are not employed by or agents of physicians or other prescribers do not fall within the Massachusetts' definition of "healthcare practitioner."

By definition of the law, a "physician" is a person licensed to practice medicine by the board of registration in medicine who prescribes prescription drugs or medical devices or an employee or agent of such a licensed practitioner.

On November 21, 2012, the Department passed a final rule that defines "modest meals and refreshments" as food and/or drinks provided by or paid for by a pharmaceutical or medical device manufacturing company or agent to a health care practitioner that, as judged by local standards, are similar to what a health care practitioner might purchase when dining at his or her own expense.

STATE LAWS: Massachusetts

Marketing Code of Conduct

Under the law, pharmaceutical and medical device manufacturers that participate in a Massachusetts healthcare program and employ a person to sell or market prescription drugs or medical devices in Massachusetts are required to adopt and comply with a marketing code of conduct as promulgated by the Department. The Department's marketing code of conduct is required to be no less restrictive than the most recent versions of the PhRMA and AdvaMed Codes on interactions with healthcare professionals. The Department will update the marketing code of conduct no less than every two years.

A pharmaceutical or medical device manufacturing company that employs a person to sell or market in the state is required to:

- Adopt and comply with the Department's most recent marketing code of conduct;
- Provide regular training to appropriate employees including, without limitation, all sales and marketing staff, on the marketing code of conduct;
- Conduct annual audits and certify completion of the audit and compliance with the marketing code of conduct;
- Develop policies and procedures for investigating instances of non- compliance with the marketing code of conduct and take corrective action in response to non-compliance and the reporting of instances of non- compliance to the appropriate state authorities;
- Report all incidents of non-compliance to the Department and to the Massachusetts Office of the Attorney General in a format specified by the Department; Identify a compliance officer responsible for operating and monitoring the marketing code of conduct;
- Register with the Department annually and pay the annual registration fee; and
- Submit an annual report to the Department describing the above requirements and containing the compliance officer's certification.

Under the law, the Department's marketing code expressly permits:

- The distribution of peer reviewed academic, scientific or clinical information;
- The purchase of advertising in peer reviewed, scientific or clinical journals;
- The provision of prescription drug or medical device samples to healthcare practitioners for the use of patients;
- Compensation for professional or consulting services in connection with a genuine research project or a clinical trial;
- Payment of reasonable expenses necessary for technical training on the use of medical device;
- The provision of or payment for modest meals and refreshments to health care practitioners in the health care practitioner's office or hospital setting in connection with informational or educational meetings or presentations; and the provision of or payment for modest meals and refreshments to healthcare practitioners outside of the health care practitioner's office or hospital setting for the purpose of educating and informing health care 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.

The Department's marketing code expressly prohibits the provision of or payment for meals for healthcare professionals that:

- Are part of an entertainment or recreational event;
- Are offered without an informational presentation made by the sales consultant or without the sales consultant being present;
- Are provided to a HCP's spouse or other guest.
- The provision of entertainment or recreational items of any value;
- Sponsorship or payment for CME that does not meet ACCME standards, or that provides payment directly to a 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 to 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;
- Payments in cash or cash equivalents to HCPs, except as compensation for bona fide services; or
- Anything 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 set forth in the Massachusetts code of conduct regulations.

Other Code of Conduct Requirements

The law also requires companies to adopt and submit to the Department a description of a training program to provide regular training to appropriate employees, including all sales and marketing staff, on the marketing code of conduct. The training program must ensure that all representatives who are employed by or acting on behalf of the company and who visit Massachusetts health care practitioners have sufficient knowledge of: (i) the marketing code of conduct; (ii) general science; and (iii) product- specific information to provide accurate, up-to-date information that is consistent with state law and FDA requirements. Additionally, companies must regularly assess persons who are employed by or acting on behalf of the companies to ensure that they are in compliance with the Massachusetts code of conduct and other company policies.

Companies must also adopt and submit to the Department Policies and Procedures for investigating non-compliance with the Massachusetts marketing code of conduct law, taking corrective action in response to non-compliance, and reporting instances of non- compliance to the appropriate state authorities. The Department regulations explicitly require companies to report all instances of noncompliance to the Department and to the Massachusetts Office of the Attorney General in a form specified by the Department. As of Jan 1, 2017, the Department has not yet issued a form for such reports.

Additionally, companies are required to submit to the Department the name, title, address, telephone number and electronic mail address of the compliance officer they have identified as responsible for certifying compliance with the Massachusetts code of conduct law and

implementing, monitoring, and enforcing the company's marketing code of conduct. Furthermore, in all speaker and commercial consultant contracts, companies must require any health care practitioner who is a member of a committee that sets formularies or develops clinical guidelines and also serves as a speaker or commercial consultant for the company to disclose to the committee the nature and existence of his or her relationship with the company. This disclosure requirement must extend for at least two years beyond the termination of any speaker or consultant arrangement.

Companies must also annually conduct an audit by July 1 of each year to monitor compliance with the Massachusetts code of conduct law.

Finally, companies must submit annually complete and submit a Code of Conduct Compliance Form. The form is available on the Massachusetts Office of Health and Human Services website: **http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/healthcare-quality/pharm-code-of-conduct/information-for-manufacturers.html**

Annual Reporting of Payments of $50 or more

The law also requires companies, by July 1 of each year, to disclose to the Department the value, nature, purpose and particular recipient of any fee, payment, subsidy, or other economic benefit with a value of $50 or more which is provided to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, healthcare practitioner or other person authorized to prescribe, dispense, or purchase prescription drugs or medical devices in the state.

In light of the federal Physician Payments Sunshine Act's preemption of state law, however, the Department passed emergency regulations in September 2012 stating that reporting of such payments would not be required after reporting for the calendar year 2012 closed. In its final regulations published December 7, 2012, the Department reinstated a limited annual reporting requirement, but only with respect to information that is not reported pursuant to federal requirements. This means that payments reported pursuant to the federal Physician Payments Sunshine Act (such as those to physicians and teaching hospitals) are excluded from the Massachusetts reporting requirement. However, payments to nurse practitioners and physician assistants, as well as any other payments not covered by the federal Physician Payments Sunshine Act, must be reported.

For the purposes of computing the $50 threshold, fees, payments, subsidies and other economic benefits relating to separate events or transactions must be calculated on an individual transactional basis and cannot be aggregated. Companies are prohibited from structuring fees, payments, subsidies or other economic benefits to health care practitioners to circumvent the reporting requirements.

The Department will make all disclosed data publicly available and easily searchable on its website.

The Department will report to the Attorney General any payment, entertainment, meals, travel, honorarium, subscription, advance, services or anything of value provided in violation of the marketing code of conduct as adopted by the Department.

Quarterly Reporting of Non-CME Out-Of-Office Meals

Massachusetts law also requires pharmaceutical and medical device manufacturing companies to file quarterly reports detailing all non-CME educational presentations at which modest meals or refreshments are provided to health care practitioners outside of the practitioner's office or hospital setting. Such reports must include:

- The location of the non-CME presentation;

- A description of any pharmaceutical products, medical devices, or other products discussed at such presentation;
- The total amount expended on such presentation;
- An estimate of the amount expended per participant, factoring any meals, refreshments or other items of economic value provided at such presentation; and
- Such other information as determined necessary by the Commissioner of the Department of Public Health.

While emergency regulations passed in September 2012 stated that the Department would deem these quarterly reporting requirements satisfied for any manufacturer that complied with applicable federal reporting requirements, the Department reversed its decision in November 2012 and will require quarterly reporting. Manufacturers are not required to begin submitting quarterly reports until guidance is posted on the following website: **http://www.mass.gov/eohhs/gov/departments/dph/programs/hcq/healthcare-quality/pharm-code-of-conduct/medical-device-manufacturer-code-of-conduct.html**.

As of Jan 1, 2017, such guidance had not been issued by the Department.

Fee

Each annual registration must be accompanied by a $2000 fee.

STATE LAWS:

Minnesota – Promotional Spending Limits and Cost Reporting

The State of Minnesota limits gifts and business meals provided to any practitioner to a total of $50 per year. Thus, there is 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 the State of Minnesota.

Definition of "Practitioner"

For purposes of the Minnesota law, "practitioner" means any licensed:

- Doctor of medicine (M.D.);
- Doctor of osteopathic medicine (D.O.);
- Dentist (D.D.S.);
- Doctor of optometry (O.D.);
- Podiatrist (D.P.M.);
- Veterinarian;
- Physician assistant authorized to prescribe, dispense, and administer drugs; or
- Advance practice nurse authorized to prescribe, dispense, and administer prescription drugs.

The term "practitioner" also includes licensed practitioners who are not actively practicing (e.g., a non-practicing physician who serves as CEO of a managed care entity). It does not include pharmacists, non-licensed business managers within managed care organizations, patients, wholesalers and distributors.

A. 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. Minnesota practitioners may be included in bona fide market research conducted by independent market research organizations, where those organizations select and make payment to Minnesota practitioners, because such legitimate research activities qualify as an exception to the gift ban. The $50 annual limit applies to practitioners licensed in the State of Minnesota, regardless of where the meal occurs or 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 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 the business groups of Bayer combined, not to individual Bayer employees.

Applying the Limits

Note: Meals and other approved expenses provided in connection with speaker training meetings and advisory boards/consultants meetings do not count toward the annual $50 limit. However, payments to certain practitioners for these services must be reported to the State as described below.

Textbooks, subscriptions to online services that provide general medical and drug information, and other general references are considered "gifts" and are included in the $50 limit. Thus, textbooks and other similar items valued at over $50 may be provided only to a hospital department or other educational entity and not to individual practitioners (see Policy and Procedure, "Educational Items for Healthcare Professionals").

The $50 spending limit does not apply to Bayer funds provided to a non-Bayer sponsor of an industry meeting or conference. Bayer may also provide funds in excess of $50 to the sponsor of an educational program, provided that the sponsor is not a professional corporation owned by practitioners. Bayer hospitality suites at industry meetings must be funded through the meeting sponsor and be open to all meeting attendees.

Bayer product samples, product publications and other product educational materials are also excluded from the $50 spending limit.

B. Cost Reporting

Prior to 2012, Minnesota law required Manufacturers to annually report the following payments to Minnesota practitioners if such payments totaled $100 or more in a given year:

- a payment to the sponsor of a medical conference, professional meeting, or other educational program, provided the payment is not made directly to a practitioner and is used solely for bona fide educational purposes;
- reasonable honoraria and payment of the reasonable expenses of a practitioner who serves on the faculty at a professional or educational conference or meeting;
- compensation for the substantial professional or consulting services of a practitioner in connection with a genuine research project.

In light of the Physician Payment Sunshine Act's preemption of state law, the Minnesota legislature subsequently amended the law in 2013 to limit the reporting requirement, but only with respect to payments made to Minnesota-licensed practitioners that fall outside of the scope of the federal Physician Payments Sunshine Act (e.g., nurse practitioners, physician assistants, veterinarians, and dental therapists). The revised law also eliminated the requirement to report payments made to sponsors of a medical conference, professional meeting, or other educational program. Given these changes, the Board of Pharmacy has indicated that reporting for 2012 and 2013 was not required, but that, beginning in 2014, "[m]anufacturers should be tracking data . . . concerning payments made to nurse practitioners, physician assistants, dental therapists, and veterinarians." Reports have historically been due in May.

In order to comply with Minnesota's revised reporting requirements, Bayer must report cumulative payments of $100 or more to any Minnesota practitioner if such payments fall outside of the scope of

reporting under the federal Physician Payments Sunshine Act. In order 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).

The internal reporting requirement applies to all payments made to practitioners licensed in Minnesota, regardless of where the services were rendered. Payments to be reported include, but are not limited to:

- Speaker fees;
- Consultant fees;
- Advisory board fees;
- Data purchases;
- Market research data; and
- Expense reimbursements.

Under the Bayer Code of Conduct, payments for grants, research projects (clinical trials), and to sponsors of medical education programs must be made to an organization rather than to an individual practitioner or a practice group. Payments to entities unrelated to practitioners generally do not need to be reported under the Minnesota statute.

STATE LAWS:

Nevada – Marketing Code of Conduct

Nevada law requires each manufacturer which employs a person to sell or market a drug (prescription or non-prescription) or prescription device in Nevada to "adopt a written code of conduct which establishes the practices and standards that govern the marketing and sale of its products." The code of conduct must be based on applicable legal standards and must "incorporate principles of healthcare." The statute specifies that principles of healthcare include requirements that the company's sales and marketing activities are "intended to benefit patients, enhance the practice of medicine, and not interfere with the independent judgment of healthcare professionals." A marketing code of conduct that incorporates the most recent version of the Code on Interactions with Healthcare Professionals issued by the Pharmaceutical Research and Manufacturers of America (the "PhRMA Code") and the Advanced Medical Technology Association ("AdvaMed Code of Ethics") will be deemed to satisfy this element of the Nevada statute. In addition, the statute requires that manufacturers identify a compliance officer who will be responsible for "developing, operating, and monitoring" the code of conduct.

The statute also requires manufacturers to adopt a training program to "regularly" educate all "appropriate" employees, including all sales and marketing personnel on the marketing code of conduct. In addition, the statute mandates annual audits to monitor the Company's compliance with its marketing code of conduct.

Manufacturers are required to adopt policies and procedures for investigating non-compliance with the code of conduct. The policies and procedures must establish a reporting structure within the company that will promote effective lines of communication. In addition, the policies and procedures must describe how the company will investigate reports of non-compliance and what corrective actions the company will take in response to non-compliance. Finally, the policies and procedures must require the company to report instances of non-compliance to law enforcement authorities "in appropriate circumstances."

Manufacturers must annually file with the Nevada Board of Pharmacy the following information:

- A copy of the company's marketing code of conduct;
- A description of the company's training program;
- A description of the investigation policies;
- The Compliance Officer's name, title, address, telephone number, and e-mail address; and
- A certification that the company has conducted its annual audit and is in compliance with the marketing code of conduct. Every other year, the Board must submit to the Governor and the legislature a report which compiles the information from the annual submissions. The Board must also publish on the Internet information concerning company compliance with the statute. The statute prohibits the Nevada Board from disclosing any proprietary or confidential information.

The regulations contain a compliance form that is periodically updated and is available on the Board of Pharmacy web page, **http://bop.nv.gov/resources/ALL/WholesalersEPP/**.

The certification form must be completed annually and submitted to the Nevada Board of Pharmacy by June 1 of each year.

STATE LAWS:

New Mexico – Price Disclosure

The New Mexico Prescription Drug Pricing Law requires manufacturers of prescription drugs sold in New Mexico to report drug pricing information to the New Mexico Human Services Department (the "Department").

Manufacturers must report the following pricing information for each of their drugs:

- Average Manufacturer Price ("AMP"): The average price paid to the manufacturer for the drug in New Mexico, including rebates, discounts and market incentives, after deducting customary prompt-pay discounts;
- The price that each wholesaler or pharmacy benefit manager doing business in New Mexico pays the manufacturer to purchase the drug; and
- The price paid to the manufacturer by any entity in an arrangement or contract that purchases prescription drugs in New Mexico without the services of a wholesaler.

Manufacturers must file the pricing information annually by January 15 of each year covering the period from July 1 through September 30 of the prior calendar year (e.g., the third quarter if the prior calendar year) and may submit the information in the same format as it is submitted to CMS. All pricing information submitted is confidential and is not subject to public inspection.

The statute does not describe the reporting procedures, deadlines, or penalties for non-compliance and there are no regulations. However, the Department has mailed detailed information about reporting and the reporting format to all manufacturers

STATE LAWS:

Tennessee – Ethics Commission Act

The Tennessee Commissions Act regulates the activities of persons doing business within the state. This legislation does not require vendors and their representatives in Tennessee to register as lobbyists; they must, however, comply with provisions similar to those of a lobbyist.

The law states that vendors shall not offer or attempt to offer anything of value to an official in the legislative or executive branch, to any candidate for state office, or any immediate family members of such officials or candidates. This prohibition includes meals, travel expenses, or lodging. Product samples and product informational materials are not a part of the gift ban and can be given to anyone if otherwise permissible under applicable laws and Bayer policies and procedures. Promotional items (e.g., pens, clocks, pads of paper, etc.) that might otherwise be permitted under Tennessee law are prohibited consistent with Bayer's Compliance Policy and Procedure, "Educational Items for Healthcare Professionals."

Application of the Law

A Sales Consultant cannot purchase a meal for any members of the Tennessee legislative or executive branch. This includes state representatives and senators, TennCare officials, Department of Health officials, or anyone directly employed by the state of Tennessee. Also, they may not purchase any meals for physicians appointed to state boards like DUR or PAC committees. Sales Consultant can provide meals to county health department officials, First Health employees, and any hospital employed physician unless they are on a board stated above to the extent the provision of the meal is consistent with Bayer's Compliance Policy and Procedure, "Business Meals to Healthcare Professionals."

The Tennessee law applies to state employees only. However, local ordinances could prohibit gifts otherwise permitted by Bayer in a Tennessee county or city. Sales consultants need to check with local governments for those regulations.

STATE LAWS:

Texas – Price Disclosure

Manufacturers of prescription drugs sold in Texas must report to the Texas Health Care Policy Council (the "Council"):

- The Average Manufacturer Price ("AMP") of each drug sold in Texas; and
- The price that each wholesaler in Texas pays the manufacturer to purchase each drug.

The prices must be reported at least annually, or more frequently as determined by the Council. By the 25th of each month, the Council's designee will submit to the Bureau of Food and Drug Safety (BFDS) within the Texas Department of State Health Services ("Department") a list of prescription drugs about which it desires pricing information. By the 5th day of the following month, the BFDS will submit the request electronically to all manufacturers selected. Each manufacturer selected must report to BFDS, using a standardized electronic format, the above pricing information no later than 30 days after receiving the request from BFDS.

The disclosed pricing information may be provided by the Department to the Medicaid vendor drug program, but only for purposes of administering its drug programs, including Medicaid drug programs. Otherwise, the pricing information is confidential and, except as necessary to permit the attorney general to enforce state and federal laws, may not be disclosed by the Health and Human Services Commission or any other state agency in a form that discloses the identity of, or prices charged by, a particular manufacturer.

In addition, to apply for the addition of a drug to the Texas Drug Code Index ("TDCI"), a pharmaceutical manufacturer must submit a "Certification of Information for the Addition of a Drug Product to the TDCI" provided by the Texas Health and Human Services Commission ("Commission"). Manufacturers must also submit changes to the prices requested in the Price Certification section of the Certification of Information if requested by the Commission, within 10 calendar days of receiving the request.

STATE LAWS:

Vermont – Price Disclosure, Marketing Disclosure Law and Other Compliance Requirements

A. Per Pill Price Disclosure

The Vermont Pharmaceutical Marketer Price Disclosure Law requires pharmaceutical marketers who promote prescription drugs directly to Vermont doctors or other Vermont prescribers to disclose to those prescribers, on a form and in a manner prescribed by the Vermont attorney general, the Average Wholesale Price (AWP) per pill of the marketed drugs as well as the AWP of other drugs in the same therapeutic class.

Scope

This Vermont law applies only to prescription drugs in tablet or pill form that may be used outside of a hospital setting, such as oral contraceptives (e.g., YAZ). The law covers detailing, promotional activities, or other marketing of such drugs directly to any physician, hospital, nursing home, pharmacist, health benefit plan administrator or any other person authorized to prescribe, dispense or purchase prescription drugs in Vermont, as well as to their staffs.

The disclosure requirements are triggered by any of the following promotional activities, if directed into Vermont at a Vermont doctor or others licensed to prescribe drugs in Vermont, or at members of their staffs:

- Mailings;
- Face-to-face meetings, including promotional talks and continuing medical education programs not supported by an educational grant from Bayer;
- Telephone calls;
- E-mails and other electronic communications;
- Hand delivery or shipment of promotional materials, including samples; and
- Communications by the manufacturer in any of the above forms that are:
  1) made directly to a physician or other Vermont prescriber;
  2) about the product; and
  3) provided to the prescriber in response to an unsolicited request.

The following activities do not trigger the disclosure requirement:

- Advertisements placed in magazines, on television, or in other media;
- Reminder communications that call attention to the name of a drug but do not include information about indications or dosage, which the FDA has exempted from the requirement to disclose drug safety information;
- Independent continuing medical education programs supported by an educational grant from the pharmaceutical marketer or manufacturer;
- Drugs marketed to state or private payers of pharmaceutical benefits; and
- Drugs marketed for use in hospitals or by patients within a healthcare facility, such as in diagnostic facility, a dialysis facility, or an outpatient (or “day procedure”) setting.

Average Wholesale Price (AWP)

Manufacturers must disclose AWP on a per pill basis as published in a nationally recognized drug pricing file. The Vermont Attorney General currently includes the following as approved sources of AWP information: 1) First Databank; 2) Medispan; 3) Gold Standard or 4) Redbook. The same source must be used throughout the disclosure form. There is no disclosure requirement for a marketed drug if First Databank, Medispan, Gold Standard and Redbook all do not publish an AWP for the marketed product. The pricing information reported must be based on the smallest package size available for each drug strength.

Before September 2011, the Office of the Attorney General listed First Databank as an approved source of AWP information, but in September 2011, First Databank ceased publishing AWP information. At that time, the Vermont Attorney General stated that it would allow those pharmaceutical marketers who wished to continue to use First Databank data to provide the following prices in lieu of First Databank's AWP:

- Wholesale Acquisition Cost (WAC) plus 20%.
- If WAC is unavailable, Direct Price (DP) plus 20%.
- If both WAC and DP are unavailable, Suggested Wholesale Price (SWP).

Form of Disclosure

There is an electronic Long Form and a paper Short Form Disclosure. These forms are populated and maintained quarterly by the BPA Government Reporting Department. The completed forms for distribution can be found on the Bayer Internet website at the following URL: **http://www.compliance.bayerweb.com/VermontAWP.htm.**

Information on the Long and Short Forms regarding the AWP of Bayer product(s) and the AWP of drugs in the same therapeutic class ("related drugs") must be updated at the same time, and at least every three months.

Short Form Disclosure

Short Form Disclosures must contain the following information:

- The AWP per pill of the lowest dosage of the marketed drug;
- The average AWP per pill of the lowest dosage of all multi-source (e.g., generic) products in the same therapeutic class; and
- The AWP per pill of the lowest dosage of other products in the same therapeutic class. If First Databank, Medispan, Gold Standard or Redbook does not publish an AWP for a related drug, the Short Form Disclosure should not include that related drug, and that drug should not be used in calculating the average generic price of related drugs.

Bayer employees and contractors who engage in direct promotion must disclose the required pricing information on a separate sheet of paper that is no less than 8 ½ inches by 11 inches in size. They must use a separate Short Form for each product marketed. The Short Form also lists the Bayer website where the required Long Form Disclosure is available. Current Short Forms for all applicable products are available to employees and contractors for distribution from the internet at **http://www.compliance.bayerweb.com/VermontAWP.html**.

Additional Disclosure Requirements based upon Marketing Technique

When undertaking promotional activities covered under the Vermont law, the following additional requirements apply with respect to certain marketing techniques:

- More Than One Drug: If more than one drug is marketed during the same meeting or through the same mail communication, then separate Short Forms must be provided for each marketed drug.

- Face-to-Face and Mail Communications: If the communication is face-to-face, the relevant Short Form(s) must be provided to the Vermont prescriber at the time of the meeting. If the communication is provided in the mail, the relevant Short Form(s) must be provided in the same mailing packet that contains the promotional material.

- Electronic Communications: If the communication to the Vermont prescriber is electronic, then the electronic communication must contain as attachments the relevant Short Form(s) or the text of the Short Form disclosure(s) must be in a conspicuous and separate section of the email.

- Telephonic Communications: If the communication to the Vermont prescriber is telephonic, then the pharmaceutical marketer must inform the prescriber during the telephonic communications that the marketer will be sending the prescriber the relevant Short Form(s). The relevant Short Form(s) must be sent to the Vermont prescriber within 24 hours of the telephonic communication.

Long Form Disclosure

The Long Form Disclosure must be made available on Bayer's Internet website at the URLs listed above and on the Short Form Disclosures provided to Vermont prescribers. The Long Form Disclosure must contain the AWP per pill of the marketed drug and of all related drugs, including generic and chewable forms. If the publication Bayer has selected for the price information (First Databank, Medispan, Gold Standard or Redbook) does not publish an AWP for a related drug, Bayer must indicate on its Long Form Disclosure that its data source does not publish an AWP for that related drug. Bayer must still list the AWPs of all other related drugs.

Please see the sample Long Form Disclosure at the end of this procedure.

AHFS Pharmacologic-Therapeutic Classification

The law defines a therapeutic class based on the most recent version of the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification, which is published by American Society of Health System Pharmacists and is available at http://www.ahfsdruginformation.com/ahfs-pharmacologic-therapeutic-classification/

B. Marketing Disclosure Law

Scope

The Vermont Pharmaceutical Marketing Disclosure Law prohibits certain gifts to healthcare providers and to members of the Green Mountain Care board by manufacturers of pharmaceutical, biological and medical devices (referred to as "prescribed products") and requires such manufacturers of prescribed products to report annually to the Vermont Attorney General the value, nature, purpose and recipient information of any allowable expenditure or permitted gift to a Vermont healthcare provider or board member in connection with promotional activities. Additionally, each manufacturer must identify the prescribed product marketed and report certain recipient information, including the healthcare professional's Vermont license number or other designated identification number.

Manufacturers are also required to report certain information related to free samples provided to Vermont healthcare providers for the preceding calendar year.

Importantly, under Vermont law, if a company has multiple divisions, some of which market prescribed products to Vermont health care providers and institutions, and some of which do not, the entire company is bound by the Vermont gift ban and 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.

Definitions:

A "prescribed product" means:

- Drugs or devices defined in section 201 of the FDCA (21 U.S.C. § 321), a compound drug or drugs, a medical device (as defined below), biological products as defined by 42 U.S.C. §262 for human use, or a combination product as defined in 21 C.F.R. §3.2(e). The term includes prescription drugs, devices, and over-the-counter (OTC) products, but does not include prescription eyewear.

"Medical device" means:

- An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is: (i) recognized in the official National Formulary or the United States Pharmacopeia, or any supplement to them; (ii) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals; or (iii) intended to affect the structure or any function of the body of humans or other animals, and which does not achieve its primary intended purposes through chemical action within or on such body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

A "gift" means:

- Anything of value provided for free to a healthcare provider for free or to a member of the Green Mountain Care board;
- Any payment, food, entertainment, travel, subscription, advance, or service provided to a health care provider or board member; or
- Anything else of value provided to a health care provider or board member unless it is reimbursed by the healthcare provider or board member at fair market value or is an allowable expenditure as noted below.

A "healthcare professional" means:

- (i) a person who is authorized by law to prescribe or to recommend prescribed products, who regularly practices in Vermont, and who either is licensed by Vermont to provide or is otherwise lawfully providing healthcare in Vermont; (ii) a partnership or corporation made up of persons described in romanette (i); or (iii) an officer, employee, agent, or contractor of a person described in romanette (i) who is acting in the course and scope of employment providing healthcare to individuals, including nursing and office staff.

A "healthcare provider" means:

- A healthcare professional, a hospital or nursing home, a pharmacist, health benefit plan administrator or any other Vermont authorized dispenser or purchaser of prescribed products. The term "healthcare provider" does not include a hospital foundation that is organized as a nonprofit entity separate from a hospital.

A "sample" means:

- 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 pursuant to a manufacturer-sponsored or manufacturer-funded patient assistance program.

Gift Prohibitions

Vermont law prohibits a manufacturer of a prescribed product, or a wholesale distributor of medical devices, from offering or giving a gift to a healthcare provider. The Vermont Attorney General has published guidance for compliance with the gift ban and disclosure laws. Some banned gifts include:

- Monetary donations to a doctor or clinic;
- Charitable donations to a hospital;
- Sponsoring of a fellowship, even if the company does not select the recipient;
- Meals, drinks, or snacks in the doctor's office with Vermont HCPs including their 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 of a conference or seminar;
- Dinner provided in another state to a Vermont-licensed physician whose primary office is in Vermont; or
- Driving a Vermont physician to an event in another state.

Note, 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 provided in this policy, or contact the Law, Patents and Compliance Department.

Allowable Expenditures

Certain expenditures are allowed, including the following items: *(items with asterisks must be reported to the extent they are not preempted by the federal Physician Payments Sunshine Act, 42 U.S.C.*

1. ** Payment to a sponsor of a "significant" educational, medical, scientific or policy- making conference or seminar as long as the events is certified CME and content of the program does not promote specific products and is objective and free from industry control. Payment may not be made directly to a healthcare provider. The payment must be used for a bona fide educational purpose. Such payment may be used by the sponsor at its discretion to provide meals and other food for all conference participants.
2. **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: (i) no payment is made directly to a health care professional or pharmacist; and (ii) the funding is used solely for bona fide educational purposes, except that the manufacturer may provide meals and other food for program participants.

3. **The loan of a medical device for a short-term trial period, not to exceed 120 days, to permit evaluation of a medical device by a health care provider or patient. Such loans will not be reportable provided that the loan results in the purchase, lease, or other comparable arrangement of the medical device after issuance of a certificate of need pursuant to Vermont law.
4. **Payment or reimbursement for the reasonable expenses, including travel and lodging-related expenses, necessary for technical training of individual health care 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 health care provider and the manufacturer.
5. ** Certain honoraria and expenses for a healthcare professional who serves on the faculty of a bona fide significant educational, medical, scientific, or policy-making conference or seminar provided that is a specific contract in place that does not include marketing and the content of the presentation is determined by the healthcare professional.
6. ** Certain expenses associated with a bona fide clinical trial, as further detailed in the Vermont law and applicable guidance.
7. ** Certain expenses associated with research projects. Note that payments for clinical trials (including gross compensation for the Vermont location(s) involved; direct salary support per principal investigator and other healthcare professionals per year; and expenses paid on behalf of investigators or other healthcare professionals paid to review the clinical trial) need not be disclosed until the earlier of: (1) the date of FDA approval or clearance of the prescribed product for the use for which the clinical trial is conducted; or (2) four calendar years after the date the payment was made. For a clinical trial for which disclosure is delayed, the manufacturer shall identify the clinical trial, the start date, and the web link to the clinical trial registration on the national clinical trials registry.
8. ** Grants for fellowship salary support to an academic institution or hospital, provided that each of the following requirements are met: (i) such grants are applied for by an academic institution or hospital; (ii) the institution or hospital selects the recipient fellows; (iii) the manufacturer imposes no further demands or limits on the institution's, hospital's, or fellow's use of the funds; and (iv) fellowships are not named for a manufacturer and no individual recipient's fellowship is attributed to a particular manufacturer of prescribed products.
9. Royalties or licensing fees paid to healthcare providers in return for contractual rights to use or purchase patented or otherwise legally recognized discovery for which the healthcare provider holds an ownership right.
10. ** Certain other reasonable fees, payments, subsidies or other economic benefits provided at fair market value. Note that fair market value payments for promotional speaking must be reported even if, at the healthcare professional's request, the payment is made to a charity or other third party.
11. ** Samples of a prescribed product or reasonable quantities of an OTC drug, non-prescription medical device, an item of nonprescription durable medical equipment, an item of medical food, or infant formula provided to a health care provider for free distribution to patients. However, effective January 2, 2013, the provision of lotions, eye drops and like products to health care providers for free distribution to patients is impermissible.
12. ** The provision to a free clinic of financial donations or of free prescription drugs, OTC drugs, medical devices, biological products, combination products, medical food, infant formula, or medical equipment or supplies.

10 .Prescribed products distributed free of charge or at a discounted price pursuant to a manufacturer-sponsored or manufacturer-funded patient assistance program.

11.** Coupons, vouchers, and discount cards distributed to patients through pharmacies or other health care providers. The law does not apply to coupons, vouchers, or discount cards distributed directly to patients or to patients through a non-health care provider covered recipient.

12.Rebates and discounts for prescribed products provided in the normal course of business.

13.Payment of a healthcare professional's reasonable interview expenses in connection with a bona fide employment opportunity with the manufacturer or for health care services on behalf of an employee of the manufacturer.

14.Coffee, snacks and refreshments at a conference or seminar booth.

15 .** The provision or receipt of peer-reviewed academic, scientific, or clinical articles that serve a genuine educational function provided to a health care provider for the benefit of patients.

16 .** Scholarship or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policy-making conference or seminar of a professional association if the recipient is selected by the association.

17.** Prescription pads, if the purpose and function is predominantly educational, does not favor one manufacturer over another (by, e.g., omitting or deemphasizing the products of competitors), and the prescriber's access to the prescription pad benefits patients.

18 .** Food to health care providers as part of fair market value compensation package for service (e.g., advisory board, consulting or speaking).

Disclosure of Permitted and Allowable Expenditures (Excluding Samples of Prescribed Products)

Each manufacturer of prescribed products must annually disclose for the preceding calendar year the value, nature, purpose and recipient information regarding any allowable expenditures or permitted gifts made to healthcare providers, or to a member of the Green Mountain Care board, or to an academic institution, or to a professional, educational or patient organization representing or serving healthcare providers or consumers. The pharmaceutical, biological or medical device being marketed by the expenditure must also be disclosed. Disclosures of samples of prescribed products are discussed separately below.

The disclosure requires the names and types of the recipient to be disclosed including all prescribers, institutions, hospitals, nursing homes, pharmacists, and health benefit plan administrators. For prescribers, the report must include the Vermont license number of the authorized prescriber. When expenditure is remitted to one entity or person ("direct recipient"), but routed to another entity or person ("ultimate recipient") and only one of the recipients constitutes a covered recipient, disclosure should include only the name of the covered recipient. If both recipients are covered (e.g., research funding remitted to a hospital that ultimately benefits a physician), disclose the direct recipient only.

Bayer must report all expenditures for actively-licensed Vermont prescribers, even if the expense was not incurred in Vermont and even if the prescriber's primary practice is outside of Vermont. It is the responsibility of all Bayer employees to track expenditures on healthcare professionals in the appropriate tracking systems (Concur, Veeva, etc.) Continuing Medical Education programs must also be disclosed. However, disclosure is limited to the value, nature, and purpose of

the grant and the name of the grantee; the name of the individual participants in a Continuing Medical Education program funded by Bayer need not be disclosed.

As of January 1, 2012, some of Vermont's disclosure requirements are preempted by federal law. The gift ban and samples reporting will not be affected, but the state is prohibited from requiring manufacturers to disclose those expenditures and permitted gifts which would are reportable to the federal government under the Physician Payments Sunshine Act, 42 U.S.C. § 1320a-7h. The federal law is narrower than Vermont's law in several ways, however. For example, only physicians and teaching hospitals are covered recipients under the federal law. Therefore, manufacturers must take care to make all non-preempted disclosures regarding allowable expenditures and permitted gifts. Further, because manufacturers are not prohibited from making preempted disclosures to the states, the Vermont AG has instructed manufacturers to indicate on the compliance officer form whether they intend to submit data that is also being submitted to the federal government pursuant to the Physician Payments Sunshine Act.

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

Manufacturers of prescribed products shall disclose all samples provided to health care providers during the preceding calendar year, identifying for each sample the product, recipient, number of units, and dosage. If a manufacturer of prescribed products reports other allowable expenditures or permitted gifts, the manufacturer must also report certain information relating to nonprescription medical devices, nonprescription 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. Information on samples and donations to free clinics of prescribed products and of nonprescription medical devices, nonprescription durable medical equipment, medical food, infant formula, and OTC products shall be presented in aggregate form. Donations of prescribed products to free clinics should be included in the samples disclosures form rather than with disclosures of allowable expenditures and permitted gifts. Any public reporting of such information shall not include information that allows for the identification of individual recipients of such items or connects individual recipients with the monetary value of the items provided.

Under Vermont Law, "sample" means: "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. The term includes starter packs and coupons or other vouchers that enable an individual to receive a prescribed product free of charge or at a discounted price. The term does not include prescribed products distributed free of charge or at a discounted price pursuant to a manufacturer-sponsored or manufacturer-funded patient assistance program." Samples of prescription drugs that are reported to the Department of Health and Human Services (HHS) under Section 6004 of the Patient Protection and Affordable Care Act of 2010 (PPACA) do not need to be reported to the Vermont Attorney General if the Attorney General determines that HHS will collect and provide Vermont with recipient-specific distribution of samples. The Vermont Attorney General has reported that because it has not been notified whether HHS will provide recipient-specific information, all manufacturers must report directly to the Vermont Attorney General their distribution of all types of samples to all Vermont health care providers.

Regardless of any future Attorney General determinations, samples of prescribed products that fall outside the reporting requirements of Section 6004 of PPACA, such as samples to health care providers who are not physicians, samples of medical devices and OTC products, and coupons and vouchers that allow a patient to receive product free or at a discounted price, must be reported for distributions occurring on or after January 1, 2011.

Effective April 1, 2012, manufacturers are required to identify the relevant product, recipient, number of units, and dosage of each sample distributed. Unlike other expenditures, the Vermont law does not require manufacturers to report the value of samples.

Bayer will continue to monitor the future development of the sample reporting requirement.

All reportable permitted or allowable expenditures, regardless of the dollar amount, must be reported.

All Bayer employees are responsible for tracking all allowed expenditures within the internal spend source system, (e.g., Concur, Veeva, etc).

Compliance Officer Form

Bayer must complete and submit a Compliance Officer Form by January 1 of each year. A form identifying the compliance officer is at the Attorney General's website at: **http://agoprescribedproducts.atg.state.vt.us/register/.**

The Vermont law permits manufacturers to designate a single person responsible for reporting the activities of the entire company, or designate a single person responsible for reporting each of pharmaceutical products, biological products, or medical devices.

In addition to identifying the person responsible for overall compliance, the Compliance Officer Form allows a company to designate an additional person responsible for collecting and reporting the data. Both will receive updates electronically from the Attorney General's Office.

Confidentiality of Trade Secret Information

Trade secret protection has been removed from the previous version in the law and the marketing reports made will become public information.

Penalties for Failure to Report

Civil Penalties may be imposed in an amount up to $10,000.00 per violation. Each unlawful gift or failure to disclose constitutes a separate violation.

Reporting Deadlines

Reporting occurs on a calendar year basis, with reports due to the Attorney General by April 1.

January 1 of each year: Bayer must submit the name and address of the person responsible for the company's compliance with the Vermont law using the Compliance Officer Form for all covered Bayer entities. The Attorney General refers to that person as the "compliance officer."

April of each year: Bayer must submit marketing disclosure reports for all covered Bayer entities. Bayer will report for the preceding calendar year. The state disclosure will be conducted by the Compliance Operations Team.

Beginning April 1, 2012 and every April 1 thereafter: Bayer must report samples of prescribed products for the preceding calendar year for all covered Bayer entities.

Registration Fee

Manufacturers of pharmaceuticals who report expenditures above $0 are required to pay an annual $500.00 registration fee by the first day of each reporting period (January 1).

For further information, please refer to the Laws and the Vermont Office of the Attorney General Guidance, which can be found at http://ago.vermont.gov/divisions/ for-lawyers-and-businesses/pharmaceutical-manufacturer-payment-disclosure.php.

Bayer Policies

Bayer policies must be followed. However, in situations where state law is more restrictive (e.g., gift ban, prohibitions) than Bayer policies, Bayer employees must follow the state law requirements.

C. Drug Price Disclosure Requirement

Vermont's prescription drug law requires pharmaceutical manufacturers to report drug pricing information to the state's medical assistance program, the Office of Vermont Health Access. Manufacturers must disclose on a quarterly basis (i) the price each wholesaler doing business in Vermont pays the manufacturer for the drug, and (ii) the prices required to be provided to the Medicaid program under federal law, including prices defined in the Medicaid Rebate Statute, 42 U.S.C. § 1396r-8.

Along with the quarterly pricing submission, manufacturers must include a summary of the methodology used in determining AMP and best price. Manufacturers are permitted to submit the methodology information in the same format as it is submitted to the Centers for Medicare and Medicaid Services (CMS) pursuant to the Medicaid Drug Rebate Program requirements.

The manufacturer's president, CEO, or the president or CEO's "designated employee" must certify that the prices reported to Vermont are the same as those reported on a quarterly basis to CMS. The law defines "designated employee" as an individual "who reports directly to the CEO or president and who has been delegated authority to make the certification."

Information submitted pursuant to this law is confidential. However, data compiled by the Office of Vermont Health Access in aggregate form will constitute a public record, provided the data does not reveal trade information protected by state or federal law.

The Office of Vermont Health Access issued guidance in 2008 that requires quarterly disclosure of the prices noted above on a form provided by the Office on January 30, May 1, August 1, and November 1.

D. Manufacturer Fee

Vermont imposes an annual fee on pharmaceutical manufacturers. Specifically, pharmaceutical manufacturers or labelers of prescription drugs that are paid for by the Department of Vermont Health Access for beneficiaries of federal and Vermont state healthcare programs must pay an annual fee of 0.5 percent of the Department's prescription drug spending from the previous year. The fee is payable to the Vermont Agency of Human Services.

28. Restrictions on Interactions with Certain State and Local Executive and Legislative Officials and State and Local Employees (Including Healthcare Professionals)

Most states and many municipalities regulate the activities of persons doing business with state officials or state employees through state lobbying and/or ethics reform statutes. Some states and municipalities require vendors and/ or their representatives to register as lobbyists. Some states prohibit the receipt of 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 prohibit the offering of anything of value to any official in return for an official act.

The categories of state or local officials or employees which 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 Group Regulation 1985 ("Code of Conduct for Responsible Lobbying"); this can be found at: **http://www.bayernet.com/corp/policies/policies_detail.cfm?fileid=221**. 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)."

29. 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 Corporate Government Accounts Department 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 that is 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 for 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 with a goal of providing materials that can assist the customer in understanding and complying with CMS and other insurer's billing, coding and reimbursement policies and requirements. Bayer does not in any way 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 amount of 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 upon 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. If a customer requests that information, you must suggest the customer consult the CMS website, the state Medicaid office, other publicly available source (such as First Databank) where the information may be obtained, and/or direct the customer to the Managed Markets Department. Bayer shall strictly limit any communications relating to billing, coding and reimbursement to communications that comply with this policy.

It is Bayer's policy 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 promotion of products that are reimbursed by Medicare or Medicaid, or what constitutes proper promotional activity, contact your supervisor or the Law, Patents and Compliance Department.

30. Appropriate Target Audience for Promotional Activities

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.

The term "Healthcare Professionals (HCP)" is a very broad term and includes individuals who directly interact with patients and/or have a role in the diagnosis or treatment of patients and includes entities which are involved in the provision of healthcare services and/or items to patients and which may purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Bayer's pharmaceutical products in the U.S. Generally, this definition includes physicians, nurses, nurse practitioners, physician assistants, medical assistants who treat patients, and other allied healthcare professionals, such as pharmacists, radiology technologists, and therapists. However, the definition is not limited to these individuals alone; the term includes any person in a position to recommend or influence the purchase or prescribing of Bayer's pharmaceutical products. In some instances, this may include individuals who do not work directly with patients but who have influence over the recommendation, purchase, or prescribing of Bayer's pharmaceutical products—such as purchasing agents at hospitals, physician practice managers, management personnel within group purchasing organizations (GPOs), managed care organizations (MCOs), pharmacy benefit managers (PBMs), health plan administrators, wholesalers, distributors, pharmacies, Pharmacy & Therapeutics Committee members, Formulary Committee members, or other customers who do not see patients. Some positions and titles within the industry are not considered healthcare professionals such as, Original Equipment Manufacturers (OEMs) or retail managers. Accordingly, such persons are not considered healthcare professionals under the program.

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 that are 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.

31. Promotional Practices Outside the United States

If Bayer pharmaceutical products are being promoted for use in the United States – even if that promotional activity takes place outside the United States – these Compliance Policies and Procedures, as well as 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 will be 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., 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 who is outside the U.S. Please refer to Policy and Procedure “Business Meals with Healthcare Professionals.”

- Bayer complies with the reporting obligations for the European Federation of Pharmaceutical and Industry Associations (EFPIA) Disclosure Code. This is a formal code of conduct that 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 Operations for assistance with EFPIA-related questions or activities.

32. Materials for External Use

Bayer employees, contractors, consultants and agents may only distribute promotional and non-promotional materials that have been approved through the Legal, Medical, Regulatory ("LMR") 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 LMR review is not required under this policy, at any time Legal can request a full LMR 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.

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")

Creating your own promotional materials – also known as "homemade bread" – IS STRICTLY PROHIBITED. Self-created materials not only include detailing pieces, but also include publically available materials (websites, journals, press releases) and documents containing cost comparisons, reimbursement information or other materials that have not been approved through the LMR 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 LMR review process.

Non-Promotional Customer Education Materials

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

Educational or business materials that are 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 LMR prior to 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.

33. Materials for Internal Use Only

Bayer permits the distribution among its employees, contractors, consultants and agents of certain educational materials that are intended for education or to provide general business information. 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 LMR review is not required under this policy, at any time Legal can request a full LMR review if the Legal reviewer believes such review is warranted.

Communications and Materials to Sales Force

Educational or business materials that are 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.

Non-Promotional Internal Training Materials mean any training materials for Bayer Radiology internal personnel issued by or on behalf of the company provided that it does 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 LMR 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). 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, on-line news services, Pink Sheet, industry publications, medical journals, medical text books);
- 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, he/she 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."

Information gathered from the public domain must be forwarded for Legal, Medical, Regulatory review before it is disseminated. Together, these departments will formulate appropriate educational materials for the field.

34. 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 direct that person to Medical Communications for a phone discussion or to a Medical Science Liaison for an in-person meeting. 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, include 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 in accordance with applicable Medical Affairs policies and procedures. No discussions can take place in a public forum pertaining to unapproved uses of Bayer's pharmaceutical products.

Additional Guidance

Soliciting Discussion: It is against Bayer policy fora sales consultant to ask leading questions intended to encourage discussion of unapproved uses (e.g., "What was new at ASCO?"). Bayer representatives may not encourage 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 set up and use of Bayer Radiology device equipment. Bayer personnel may provide instructions on how to set up and use Bayer device equipment consistent with the equipment's labeled instructions for use.

Questions relating to technique or other questions that are not covered in the labeled instructions for use cannot be answered by the representative and 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 then 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.

35. ADVERSE EVENTS/PRODUCT TECHNICAL COMPLAINTS/DEVICE COMPLAINTS INVOLVING BAYER PRODUCTS

All Bayer employees, agents and contractors, are responsible for ensuring that any information relating to 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, agent or contractor becomes aware of the information.

The following information should be reported:

- Adverse Event (AE) – any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment.
- Product Technical Complaint (PTC) is any report received from a third party (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 is suspected to be counterfeit. The complaint may or may not represent a potential risk to the customer.
- 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 important to obtain the following:

- Identifiable Patient (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)
- Reporter information (e.g., Patient, Nurse, Physician, etc.) There are several options available to report an AE/PTC/DC:

For AE:
Phone: 1-888-842-2937
E-Mail: DrugSafety.GPV.US@Bayer.com
Facsimile: 1-973-709-2185

For DC/PTC:
Phone: 1-888-842-2937
E-Mail: MPS.Bayer@Bayer.com
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 his/her own contact information including date and time they were first notified about the report, in the event that GPV-US needs to follow up to obtain additional information.

36. Clinical Research and Clinical Study Support

The Patient Protection and Affordable Care Act, Sunshine Law provision, 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 each employee's, contractor's, consultant's, and agent's responsibility 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 for the purpose of developing 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 pursuant to a written agreement approved by the Law, Patents and Compliance 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
- A requirement for data to 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 that is 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 his or her colleagues.

Agreements to fund clinical trial or research may constitute an Interaction with Focus Arrangements (Interaction with HCPs and HCOs). An agreement to fund clinical research or clinical studies must be considered an Interaction with Focus Arrangements (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 Law, Patents and Compliance department must verify that the agreement contains a certification by the parties that the parties shall not violate the Anti-Kickback Statute with respect to the performance of activities related to the arrangement.

The Law, Patents and Compliance Department evaluates whether the proposed arrangement satisfy 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, his/her name, and the date the assessment was conducted.

The Law, Patents and Compliance 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 Law, Patents and Compliance Department.

Bayer must send 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 Law, Patents and Compliance Department, the Department of Monitoring & Study Management will send the approved agreement to the funds 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. In order to ensure that third party contracts comply with the Anti-Kickback Statute and Bayer Pharmaceuticals Compliance Policies and Procedures, the Law, Patents and Compliance Department will provide a template contract to use for the contracting entities. 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 his/her 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 with respect to the performance of activities related to the grant.

The third party must send to each party to the arrangement, in addition to 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 t hat 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 a period of ten years.

Record Retention

The Department of Monitoring & Study Management or Medical Communications Department will retain the payment request package, including the approved SAP Disbursement Requisition/Check Request, for a period of 10 years.

Audit

All clinical research and clinical study agreements are subject to audit by Bayer Internal Audit and the Law, Patents and Compliance Department to ensure compliance with this Policy. The government (e.g., IRS) may also request to audit/review clinical research and clinical study payments.

37. Investigator/Institution Initiated Research (IIR)

The Patient Protection and Affordable Care Act, Sunshine Law provision, 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 each employee's, contractor's, consultant's, and agent's responsibility 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 the improvement of patient care. Bayer's policy conforms to the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, the PhRMA Code on Interactions with Healthcare Professionals, 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 the 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 to 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 the selection of potential sites for investigator/institution initiated research.

If Sales and Marketingpersonnelareapproachedbyacustomerorpotentialinvestigator/ institution regarding a grant, they must direct the customer to the website: **https://sirius.bayer.com/IIRv3-Bayer-Prod/** and/or the customer service telephone number (1-888-84-Bayer or 1-888-842-2937).

Disclosure of Bayer Support

All publications which 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, or offered in lieu 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 provide 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 that are initiated or controlled by Bayer are not considered "investigator/institution initiated research" for purposes of this policy and instead 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: **https://sirius.bayer.com/IIRv3-Bayer-Prod/**. The initial request must:

- Describe the purpose/intended use of the grant or reference other documents attached, such as a 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., "investigator sponsored study") as the purpose of the expense;
- Include a budget; and
- Confirm that the grant will be used to support an investigator/institution initiated research.

Grant Requestor

The investigator/institution (or designated staff member) must electronically input all required grant information. 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 to be 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, after attempting to obtain appropriate documentation, finds the request incomplete, he/she will inform the requestor that the request is being denied due to insufficient documentation.

Grant Review Committee

The Grant Review Committee is comprised of members from Medical Affairs, Medical Operations, Field Medical Affairs, and Law, Patents and Compliance. 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 that would prohibit 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 the improvement of patient care.
- The request is within the budget for each therapeutic area.
- The request is aligned with Bayer's strategy and therapeutic focus.

If the Grant Review Committee needs additional information in order 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 Law, Patents and Compliance 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 with respect to 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, the date it was conducted, and who conducted it, must be documented.

The Law, Patents and Compliance Department confirms that the proposed amount of grant funds 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 Vice President and Head, U.S. Office of Compliance (or designee) and documented and maintained in the Law, Patents and Compliance Department.

If the reviewing attorney is not present at the Grant Review Committee meeting, the attorney may conduct the required review at a later date. However, this review must be completed before the grant is approved and before 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 for further discussion.

If approved, a letter documenting the Grant Review Committee's decision will be provided to the requestor (or institution- designated staff member) by the Grant Manager following the meeting. The Grant Manager is responsible for updating the electronic system with the decision.

The Grant Manager or other Bayer employee must send the grant recipient, along with the approved agreement, a copy of Bayer's Code of Conduct with the Anti-Kickback Statute Policies and Procedures attached. 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.

Proof of Service

The Grant Manager, or other Bayer employee, must confirm that the services and/ or deliverables of the grant were performed and/or delivered. Acceptable proof of performance includes clinical data, a report of clinical trial results, or a publication containing such results. The agreement must permit Bayer to obtain proof of service.

Record Retention

The Medical Affairs Department will retain the payment request package for a period of 10 years. Proof of performance documents are retained electronically by the Grant Manager for a period of 10 years.

Audit

All grants, including investigator sponsored grants, are subject to audit by Bayer Internal Audit and the Law, Patents and Compliance Department to ensure compliance with these policies. The government (e.g., IRS) may also request to audit/review grant payments.

38. Price Reporting

It is Bayer's policy to report, completely and accurately, cost, price and sales information about Bayer's pharmaceutical products 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 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

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 Law, Patents and Compliance Department or 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), Department of Veterans Affairs, US Department of Health and Human Services Pharmacy Affairs Branch, TRICARE, Department of Defense, Public Health Service, and the U.S. Department of Labor programs.

Price Reporting Entity – A private publisher, such as Redbook or First Databank that 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 for use by a Government Healthcare Program or a Price Reporting Entity must be accurate, complete and in accordance with government laws and regulations.

Government price reports are calculated and submitted by the Government Contracting and Price Reporting department in accordance with the reporting policies and procedures for each government program. The Government Contracting and Price Reporting department maintains and updates the policies and procedures in accordance with each government program 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 Law, Patents and Compliance Department. Only the Director of Government Contracting and Price Reporting may submit responses for such survey or request.

Record Retention

Government Contracting and Price Reporting will maintain copies of all price submissions to any agency of the federal or state government or Price Reporting Entity as well as documents (e.g., contracts) supporting those submissions. All documentation related to the Policy shall be retained in accordance with the Bayer Corporation Records Management Policy and Records Retention and Disposal Schedule.

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 Law, Patents and Compliance Department.

39. Reviewing and Approving Customer Contracts

Bayer often sells its products pursuant to written contracts that list all discounts and that 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 in a manner consistent with the discount Safe Harbor to the Anti-Kickback Statute, as determined by the Law, Patents and Compliance department. "Side deals" or price concessions offered outside of written contracts, whether oral or written, are not allowed.

Scope

This policy sets forth the process for reviewing and approving contracts for the purchase of Bayer pharmaceutical products as well as 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 actually sold and purchased and may not be paid or earned prior to 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 is to be applied. A rebate on any Bayer pharmaceutical product(s) may not exceed the sum 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, product, or credit.

If the value of the discount, rebate, or other price concession is unknown at the time 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 required to attain each tier must be disclosed in the contract.

Administrative Fees It is Bayer's policy to pay administrative fees only to non-possession- takers such as Group Purchasing Organizations ("GPOs") and Pharmacy Benefits Managers ("PBMs"). In order 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 is unable to 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.

Free Product It is against Bayer policy to provide free product as a discount or price term (e.g., "buy 10, get 1 free").

Procedures

Approval Process

1. The Bayer employee handling the account sends the proposed Request for Contract ("RFC") to Customer Business Strategies (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 has been documented.
    - The proposal matches the potential of the customer.
    - 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.

2. For contracts within "guidelines" previously established by the (EPC) once the above items have been reviewed, Customer Business Strategies presents the proposed custom contract to the Director of Contracting which will confirm that the above criteria are met.

3. As determined by the Director of the Contracting function, 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 Law, Patents and Compliance Department;
    - Appears to conflict with product and/or approved market strategies; or
    - Significantly impacts or changes the intent of the approved strategy.

4. The Director of the Contracting or designee function presents any custom contract with applicable justification to the CPS which is composed of:
    - Director, Controlling Director or designee;
    - Director of Contract Generation or designee;
    - Director, Customer Business Strategies or designee; and
    - Law, Patents and Compliance Department.

RFCs involving agencies of the federal government or state supplemental rebates are provided to Government Pricing and Reporting. Such contracts follow the procedures outlined in this policy, with Government Pricing and Reporting performing the functions of the Customer Business Strategies Group described in this policy.

The CPS reviews the custom contract and recommends revision, rejection, or approval of the custom contract. As part of its consideration of a requested contract, the CPS representative from the Law, Patents and Compliance Department will consider the applicability of Robinson-Patman. Director of Contract Generation or designee should provide to reviewing attorney documentation reflecting the basis and rationale for FMV. The CPS may act upon a custom contract by e-mail. The Director of Contracting or the CPS representative from the Law, Patents and Compliance Department may request that a custom contract proposal be reviewed by the EPC.

5. 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:
    - Vice President, Law and Patents
    - Vice President, Regional Finance and Controlling
    - Senior Vice President, Market Access

Requests that are approved by the EPC are subsequently forwarded to the President and Chief Executive Officer who may either approve the EPC's actions or return the proposed contract for the EPC's reconsideration.

6. Once a contract has been approved as outlined above, a copy is returned to the Bayer employee handling the account to provide to Law, Patents and Compliance for review. The contract must contain:
    - A certification by the parties that the parties shall not violate the Anti- Kickback Statute with respect to 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 for the purchase of Bayer pharmaceutical products may not be earlier than the day on which all material business terms are agreed upon by both of the parties 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 Law, Patents and Compliance department, may determine that there is a need to have an effective date prior to 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 contained in the original agreement or to avoid confusion as to 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 prior to the final execution of the contract, without delaying the effective date. Unless expressly approved in writing by the Director of Contracting and the Law, Patents and Compliance Department, no contract may have an effective date more than ninety days prior to 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 Law, Patents and Compliance Department.

Under no circumstances may a contract be backdated in order to provide retroactive price concessions or other preferential terms not included in the original agreement.

Proof of Service

Information confirming proof of product shipment and payment of rebates is maintained by Contracting either in a database (e.g., Vistex) or in hard copy, as appropriate. Contracting 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 for a period of 10 years

Record Retention

The Contracting Department will maintain copies of all contracts and related documentation (e.g., price concessions, rebate payments, chargeback information) for 10 years from the date any of the information is used in a government pricing submission.