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Pharma Policies and Procedures
July 1, 2013

Policies and Procedures

Bayer HealthCare

BHC2013

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INTRODUCTION

This booklet, **"Bayer HealthCare Pharmaceuticals Compliance Policies and Procedures,"** contains important rules and procedures that you are required to understand and follow. These policies and procedures are an essential part of the **HealthCare Compliance Program** at Bayer HealthCare Pharmaceuticals. The HealthCare Compliance Program includes, among other things, these Policies and Procedures, the Bayer HealthCare Code of Conduct and Division 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 HealthCare employees, contractors, consultants and agents and healthcare professionals.

Healthcare professionals is very broad 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 HealthCare Pharmaceuticals 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, technicians, 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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.

The Bayer HealthCare Pharmaceuticals Compliance Program Documents (*e.g.*, Policies and Procedures, Forms) are accessible via the intranet at URL: http://us-wcms01.us.bayer.cnb/apps/BSP/US/BSP-NJ/BSP-NJ.nsf/id/44550041C8BC1607852579B1006813E2?OpenDocument.

Importance of Complying with 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, 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 HealthCare Pharmaceutical's Compliance Policies and Procedures can have direct and severe consequences both to you and to Bayer.

Any Bayer HealthCare employee, contractor, consultant or agent who violates, or encourages others to violate, these Compliance Policies and Procedures is subject to a broad range of discipline, up to and including termination of employment. Each Bayer HealthCare 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. Performance on that compliance objective will be evaluated by each employee, contractor, consultant and agent's manager. Failure to adhere to these Compliance Policies and Procedures will be considered in connection with performance evaluations for all HealthCare Compliance Program Covered Persons (as defined below under the Corporate Integrity Agreement).

Employees, contractors, consultants and agents are required to report suspected violations of these Compliance Policies and Procedures to their supervisor, the Law and Patents Department, or the Bayer HealthCare Compliance Officer. Reports may also be made anonymously and confidentially via Bayer's Confidential Disclosure Program, which includes a toll free number (Bayer IntegrityLine), **1-888-765-3846**. 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 action based upon such reports.

Corporate Integrity Agreement

Bayer HealthCare LLC ("Bayer HealthCare") entered into a **Corporate Integrity Agreement (CIA)** with the U.S. Department of Health and Human Services, Office of Inspector General (OIG) on November 25, 2008. The CIA will be in effect for five (5) years from the date it was signed. These Compliance Policies and Procedures are designed to assist Bayer HealthCare in complying with applicable laws and in meeting its CIA obligations.

Violations of the CIA may result in monetary fines, including fines for each day that Bayer HealthCare does not fully comply with certain obligations under the CIA. For example, Bayer HealthCare will be assessed daily fines if Arrangements Procedures are not being followed for each Focus Arrangement. Violations may also lead to exclusion from federal and state healthcare programs such as Medicare, Medicaid and the Department of Defense. Any Bayer HealthCare employee, contractor, consultant or agent who violates,

or encourages others to violate, the conditions of the CIA is subject to a broad range of discipline, up to and including termination of employment. If you have any questions regarding your obligations under the CIA, please consult with the Law and Patents or Bayer HealthCare Compliance Department.

Anti-Kickback Statute

The CIA puts policies and procedures in place to help ensure that Bayer HealthCare does not violate the Anti-Kickback Statute. The Anti-Kickback Statute is a federal law that prohibits entities that, such as manufacturers of drugs or medical devices from offering or giving "remuneration" (*e.g.*, anything of value) 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 HealthCare Compliance Program Covered Person?

The CIA uses the term "Covered Persons" to describe who must be covered under Bayer Healthcare's Compliance Program. HealthCare Compliance Program Covered Persons include both Covered Persons and Arrangements Covered Persons.

Covered Persons include:

- All owners of Bayer HealthCare and any Bayer HealthCare Affiliate who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading);
- All officers, directors and employees of Bayer HealthCare or any Bayer HealthCare Affiliate except (1) any person not reasonably expected to work more than one hundred sixty (160) hours during the calendar year; or (2) any employee engaged solely in manufacturing functions; and
- All contractors, subcontractors, agents, and other persons who perform any of the following functions on behalf of Bayer HealthCare or any Bayer HealthCare Affiliate and who are expected to work more than 160 hours per year: (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.

Arrangements Covered Persons include:

- Each Covered Person 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 HealthCare or any Bayer HealthCare Affiliate and any actual or potential source of referrals or sales of Government Reimbursed Products.

Compliance with these Policies and Procedures is mandatory for all Covered Persons and Arrangements Covered Persons.

Bayer AG Global Corporate Compliance Policy

In addition to the **HealthCare Compliance Program** described above, the **Corporate Compliance Policy** published by Bayer AG in Germany 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 HealthCare 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 HealthCare employees, contractors, consultants and agents are required to comply with all applicable Bayer HealthCare Compliance Policies and Procedures. The Corporate Compliance Policy may be found at: http://www.bayer.co.th/webphp/eng/compliance.php.

Bayer HealthCare AG Compliance Manual

The principles set forth in the Bayer HealthCare AG Compliance Manual also represent a broad outline of the minimum standards of business conduct that Bayer HealthCare 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 US. However, where stricter local standards exist, such as your business' Compliance Policies and Procedures, such stricter Policies and Procedures always takes precedence. The Bayer HealthCare AG Compliance Manual may be found at: https://by-margo.bayer-ag.com/view.aspx?id=0912107e8000ca1d.

The Foreign Corrupt Practices Act

Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 or candidate, 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceutical's business.

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, the Law and Patents Department or the Bayer HealthCare Compliance Department concerning any matter on which there is a question.

1. OPERATING THE CONFIDENTIAL DISCLOSURE PROGRAM

The Bayer HealthCare Confidential Disclosure Program allows employees, contractors, consultants and agents to disclose, confidentially and without retaliation, any issues or questions associated with Bayer HealthCare's policies, practices, or procedures with respect to 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 IntegrityLine, a toll-free telephone line (**1-888-765-3846**) administered by a third party vendor, Global Compliance Services, Inc.

Global Compliance Services provides service twenty-four hours per day, seven days per week and prepares reports of all disclosure calls. Each report is assigned a Report Control Number and a PIN code, which is provided to the caller. Callers may be provided a date on which to make a follow-up call for the purpose of receiving a response from Bayer HealthCare or for the caller to provide additional information. The reports are transmitted to the Bayer HealthCare Compliance Officer (or designee) within 24 hours of receipt.

To ensure complete confidentiality, Global Compliance Services will mark any reports that name a designated report recipient or investor (the Bayer HealthCare 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 General Counsel & Sr. Vice President for Bayer HealthCare.

PUBLICATION OF CONFIDENTIAL DISCLOSURE PROGRAM

Information about the Bayer IntegrityLine is advertised to all Bayer HealthCare 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 IntegrityLine should be used to report issues or questions associated with Bayer HealthCare's policies, practices, or procedures with respect to 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 IntegrityLine.

THE CONFIDENTIAL DISCLOSURE LOG

Global Compliance Services, Inc. provides two reports to Bayer HealthCare Compliance Department each month; one summarizes reporting activity from the prior month and the other lists all open reports. Global Compliance Services, Inc. assigns the Report Control 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 the Human Resource and/or Law and Patents Department. This allows the status of any subsequent investigation to be tracked. The reports from Global Compliance Services, Inc. include all disclosures made to the Bayer IntegrityLine. Reports involving federal healthcare programs and/or Bayer HealthCare Bayer HealthCare Pharmaceuticals Compliance Policies and Procedures will be processed as described below and included in the Annual Report to the OIG. Reports that do not involve federal healthcare programs or Bayer HealthCare Pharmaceutical's Compliance Policies and Procedures, such as those involving employment or human resources issues, will be directed to the Law and Patents Department or the Human Resources Department within the related Bayer HealthCare business.

PROCEDURE UPON RECEIPT OF DISCLOSURE REPORT INVOLVING FEDERAL HEALTHCARE PROGRAMS

Upon receipt of a disclosure report, involving federal healthcare programs and/or Bayer HealthCare Pharmaceutical's Compliance Policies and Procedures, the Bayer HealthCare Compliance Officer (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 Bayer HealthCare Compliance Officer (or designee) initiates the investigation by providing a summary of the allegation, including the Report Control Number, to the Law and Patents Department and/or the applicable Human Resource Department, as appropriate.

By the follow-up date, the Bayer HealthCare Compliance Officer (or designee) will provide a statement of closure or a request for additional information to Global Compliance Services 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 Global Compliance Services, Inc.

A final written report is maintained in the Bayer HealthCare 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.

2. BUSINESS ACTIVITIES REQUIRING WRITTEN NOTIFICATION TO THE OFFICE OF INSPECTOR GENERAL (OIG)

WHAT MUST BE REPORTED

Under the CIA, Bayer HealthCare is required to report certain activities to the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services for all of Bayer HealthCare. For all such reports, Bayer HealthCare Pharmaceuticals Law and Patents will work with Bayer HealthCare's Compliance Officer to ensure proper and timely submission.

CIRCUMSTANCES THAT REQUIRE REPORTING

1. **Changes to the Bayer HealthCare Compliance Committee and Bayer HealthCare Compliance Officer**

Any changes in the identity or position description of the Bayer HealthCare Compliance Officer, or the composition of the Bayer HealthCare Compliance Committee, or any actions or changes that would affect the Bayer HealthCare Compliance Officer or Bayer HealthCare Compliance Committee's ability to perform their duties, must be reported to the OIG, in writing, within 15 days of such change.

2. **Government Investigations or Legal Proceedings**

Any ongoing investigation or legal proceeding known to Bayer HealthCare conducted or brought by a governmental entity or its agents which involves an allegation that Bayer HealthCare or any Bayer HealthCare Affiliate has committed a crime or has engaged in fraudulent activities must be reported to the OIG, in writing, within 30 days of discovery by Bayer HealthCare. The notification must include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of the investigation or proceeding.

Resolutions of legal proceedings or investigations must be reported to the OIG, in writing, within 30 days of the resolution with a description of the findings and/or results of the investigations or proceedings, if any.

3. **Reportable Events**

The CIA defines "Reportable Event" as any matter that a reasonable person would consider a probable violation of criminal, civil or administrative laws applicable to any federal healthcare program and/or applicable to any FDA requirements relating to the promotion of products for which penalties or exclusion may be authorized or a filing of bankruptcy petition by Bayer HealthCare or any Bayer Affiliate. Bayer HealthCare must notify the OIG in writing within 30 days after making a determination that a Reportable Event exists. The report to the OIG must include the following information:

- Description of the Reportable Event, including the relevant facts, persons involved, and legal and federal healthcare program and/or FDA authorities implicated;

- Description of Bayer HealthCare's or a Bayer HealthCare Affiliate's actions taken to correct the Reportable Event; and
- Any further steps Bayer HealthCare or a Bayer HealthCare Affiliate plans to take to address the Reportable Event and prevent it from recurring.

4. **Changes to Business Locations**

Any change or closure of a Bayer HealthCare or Bayer HealthCare Affiliate business unit or location that performs Promotional and Product Services Related Functions or performs Government Pricing and Contracting Functions must be reported to OIG, in writing, within 30 days of the date of change or closure. Any purchase, establishment of a new unit, or sale of a Bayer HealthCare business unit or location that performs Promotional and Product Services Related Functions or performs Government Pricing and Contracting Functions must be reported to OIG, in writing, no later than the date the sale is publicly disclosed. For new units or locations, the notification must include the address of a new operation(s), phone number, fax number, federal healthcare program provider number(s) (if any), and the corresponding contractor's name and address that issued the provider number. For sales, the notification must include a description of the business unit or location to be sold, a brief description of the terms of the sale, and the name and contact information of the prospective purchaser.

5. **Notification of Communications with FDA**

In the event Bayer HealthCare or any Bayer HealthCare Affiliate receives any written report, correspondence, or communication between Bayer HealthCare or any Bayer HealthCare Affiliate and the FDA that materially discusses Bayer HealthCare, a Bayer Affiliate's or a Bayer HealthCare Covered Person's actual or potential unlawful or improper promotion of Bayer HealthCare's products (including any improper dissemination of information about off-label indications), Bayer HealthCare must provide written notice to OIG within 30 days after the date of the report, correspondence or communication and provide to the OIG a copy of the report, correspondence or communication.

In addition, Bayer HealthCare must provide written notice to the OIG within 30 days after the resolution of any such disclosed matter as well as provide a description of the findings and/or results of the matter, if any.

PROCEDURES

Bayer HealthCare Compliance Committee Members, individuals within the Law and Patents Department, and others who learn of specified changes that need to be reported to the OIG must immediately contact the Bayer HealthCare Compliance Officer. The Bayer HealthCare Compliance Department also publishes monthly reminders requesting relevant information.

3. DETERMINING INELIGIBLE PERSONS

Bayer HealthCare 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 HealthCare Pharmaceuticals may not bill federal healthcare programs for items or services furnished, ordered, or prescribed by an Ineligible Person.

SCOPE

This Policy applies to all Bayer HealthCare employees, contractors, consultants and agents.

PROCEDURES

New Hire Self-Disclosure and check against Government websites.

1. The appropriate Human Resource Department Recruiter or the Hiring Manager, prior to hiring a Bayer HealthCare employee, contractor, consultant or agent or permitting internal transfers and job changes, 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 Bayer HealthCare Pharmaceuticals 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 HealthCare Code of Conduct. Bayer Human Resources Department must provide the Bayer HealthCare Code of Conduct to the applicant as part of the onboarding process (electronically or manually) before the applicant completes the paper certification.

2. Prior to hiring internal transfers or to approving job changes involving a Bayer HealthCare Pharmaceuticals employee, contractor, consultant or agent, Human Resources or the Hiring Manager will provide the Self-Disclosure form and the Bayer HealthCare Code

of Conduct to the prospective Bayer HealthCare Pharmaceuticals employee, contractor, consultant or agent. In addition, Human Resources or the Hiring Manager will arrange with the contracted consumer reporting agency to complete the government exclusion checks for each prospective Bayer HealthCare employee, contractor, consultant or agent. The government exclusion checks required by the CIA 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 http://www.hhs.gov/oig and the General Services Administration's List of Parties Excluded from Federal Programs at http://www.sam.gov (formerly www.epls.gov). Bayer HealthCare's consumer reporting agency conducts the required government screenings and maintains the reports permanently.

3. The exclusion check and the Self-Disclosure form must be completed, scanned and emailed to Bayer HealthCare Compliance Department at: compliance_lms_admin@bayer.com before the hiring process is complete and before the applicant's first day in the position. If a Bayer HealthCare Pharmaceuticals employee, contractor, consultant, or agent is listed on either of the government websites, the Human Resource Representative follows procedures detailed in the following section entitled "Change in Eligibility Status of a Covered Person."

If any potential Bayer HealthCare Pharmaceuticals employee, contractor, consultant or agent fails to satisfy these requirements or is determined to be an Ineligible Person, Bayer HealthCare Pharmaceuticals 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. The Bayer HealthCare Compliance Department retains the fax or electronic copy of the Self-Disclosure form in a binder in the Bayer HealthCare Compliance Department. The certifications will be retained for a period of 10 years from the date they are completed. Records are subject to review and audit by Bayer HealthCare and the OIG.

ANNUAL CHECK AGAINST GOVERNMENT WEBSITE FOR ALL BAYER HEALTHCARE EMPLOYEES

The Bayer HealthCare Compliance Department will make a request to the Bayer Human Resources Department (HR//Direct) to arrange for the annual government exclusion checks to be conducted for all Bayer HealthCare Pharmaceuticals employees. HR//Direct prepares a report of all active and inactive Bayer HealthCare Pharmaceuticals employees and submits the report to the Bayer HealthCare Compliance Department to utilize in conducting the government screenings. The Bayer HealthCare Compliance Department will complete the annual exclusion process by February 23rd of each year for all Bayer HealthCare Pharmaceuticals employees, contractors, consultants and agents.

If it is determined that the Bayer HealthCare employee is listed as ineligible, written notice records will be forwarded to the Human Resource Department by the Bayer HealthCare Compliance Officer (or designee). For any confirmed match, see section "Change in Eligibility Status of a Bayer HealthCare Employee" of this procedure.

Documents used in completing the annual check against government websites will be retained by the Bayer HealthCare Compliance Department for a period of 10 years.

CHANGE IN ELIGIBILITY STATUS OF A BAYER HEALTHCARE PHARMACEUTICALS EMPLOYEE, CONTRACTOR, CONSULTANT OR AGENT

The Bayer HealthCare Compliance Officer (or designee) and the appropriate Human Resource Representative must be notified immediately if a Bayer HealthCare Pharmaceuticals employee, contractor, consultant or agent:

- Becomes an Ineligible Person;
- Is proposed to be included on the exclusion list of either the General Service 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 or Contingent Labor will suspend the Bayer HealthCare Pharmaceuticals 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 by the Government to be eligible within the one-week suspension, the Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals employee, contractor, consultant or agent will be terminated or transferred to a position that does not involve responsibility for or involvement with Bayer HealthCare Pharmaceutical's business operations related to federal healthcare programs or a position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are not paid in whole or part, directly or indirectly, by federal healthcare programs or otherwise with federal funds.

COVERED PERSONS WHO ARE NOT BAYER HEALTHCARE EMPLOYEES

Bayer Contingent Labor Program representatives, vendors, consultants and agents contracted by Bayer HealthCare must follow similar processes to meet the requirements of determining eligibility. The appropriate Human Resource representative and/or Contingent Labor Program representative are responsible for completing and communicating the eligibility requirements to the temporary staffing vendors and completing the government exclusion checks.

Annual government exclusion checks for Bayer HealthCare contractors, consultants and agents are conducted by the Bayer HealthCare Compliance Department.

The Bayer HealthCare Compliance Department will create a list of all contractors, consultants and agents, based on data from Bayer HealthCare's internal HealthCare Compliance database and Human Resource and Contingent Labor Program databases, along with manual records. The list will be compared to the government exclusion lists identified above. Additional information will be used in a more refined comparison and research performed for any possible match. Written records will be generated and retained to show why/how the individual was determined not to be ineligible.

Records are subject to review and audit by Bayer HealthCare and the OIG. All agreements and contracts with an effective date of November 25, 2008 or later must reflect Corporate Integrity Agreement requirements. Active contracts with an effective date prior to November 25, 2008 have been adjusted and agreements made with vendors to reflect obligations imposed by the Corporate Integrity Agreement.

REPORTING TO THE OIG

A summary of any personnel action taken as a result of self-disclosures and checks against the government websites will be forwarded to the Bayer HealthCare Compliance Officer (or designee) and included in the Annual Report to the Office of Inspector General.

HEALTHCARE COMPLIANCE PROGRAM SELF DISCLOSURE

Bayer HealthCare employees, contractors, consultants and agents

Self-Disclosure Certification

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)(1)-(3), 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 HealthCare Code of Conduct booklet and certify that I have read, understand, and agree to abide by this code.

_____ _____
Signature Date

_____
Printed name

For Internal Use Only: Bayer HealthCare Pharmaceuticals

Please Print

Title: _____ Supervisor: _____

Department: _____ Location: _____

Cost Center: _____ Hire Date: _____

Exclusions Check Date: _____ Match ____ No Match ____

HR Rep/Hiring Manager: _____

Employee: _____ **Contractor**_____ **Consultant:** _____

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

4. 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 and agents) resulting in a new role or position that qualifies the employee, contractor, consultant and agent as a Covered Person or Arrangements Covered Person in the HealthCare Compliance Program. Supervisors must follow this procedure to ensure that Bayer HealthCare Pharmaceuticals meets all the HealthCare Compliance Program requirements for Covered and Arrangements Covered Persons and the requirements of the Corporate Integrity Agreement. Immediate supervisors are primarily responsible for ensuring that training and certification occurs on schedule, as well as for appropriate and timely communication with the Bayer Human Resources Department and the Bayer HealthCare Compliance Department.

New Covered Persons and new Arrangements Covered Persons include individuals who have been newly hired, transferred, or promoted into a position that the Bayer HealthCare Compliance Department has determined is a Covered Person or Arrangements Covered Person in the HealthCare Compliance Program. New Covered Persons and Arrangements Covered Persons also include contractors, consultants and agents (expected to work more than 160 hours per year), in positions covered under the HealthCare Compliance Program and the Corporate Integrity Agreement. The supervisor who has hired a contractor, consultant or agent is referred to as a Bayer HealthCare Pharmaceuticals Sponsor.

If an employee, contractor, consultant and agent who is not a current HealthCare Compliance Program Covered Person is transferred or promoted into a Covered position, the employee, contractor, consultant and agent must meet the same Compliance training and certification requirements as that of a New Hire covered employee, contractor, consultant and agent. A transfer or promoted employee who is moving from an active Covered Person position to an Arrangements Covered Person position must comply with the Arrangements training and certification requirements within 21 days of the transfer or promotion. Communication from the Supervisor is relied upon to ensure the HealthCare Compliance Program requirements are met for transferred and promoted employees, contractors, consultants or agents. Covered and Arrangements Covered Persons who do not complete the HealthCare Compliance training and certification requirements within 30 days of becoming a Covered or Arrangements Covered Person are deemed HealthCare Compliance Program exceptions. Bayer HealthCare is required to report all HealthCare Compliance Program exceptions to the OIG. As a result of this reporting obligation, Bayer HealthCare Compliance requires that all assigned training be completed prior to the 30 day OIG requirement and sets the due date for training at their discretion which is 21 days.

PROCEDURES

PRIOR to the Effective Date of Becoming a Covered Person or Arrangements Covered Person

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 Bayer HealthCare 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 Bayer HealthCare Compliance Department electronically and/or manually sends to the new Covered or Arrangements Covered Person a training package that includes training materials, training instructions, the HealthCare Compliance Helpline telephone number, the Bayer HealthCare Pharmaceuticals Compliance Policy and Procedures booklet, and the Bayer IntegrityLine materials.

The immediate supervisor must ensure that the new Covered or Arrangements Covered Person has access to a computer capable of connecting to the Bayer intranet or is internet enabled. This may require the immediate supervisor to use his or her credentials to log the new Covered Person on to the Bayer intranet. The new trainee (employee, contractor or consultant) must use his or her own Concern-Wide User Identification (CWID) or assigned unique log in to enter and complete the training session and certification process. Only the employee, contractor, consultant or agent can train and certify completion of training for himself or herself.

The immediate supervisor is responsible for ensuring that the new Covered Person completes the training and certification process within 21 calendar days of the hire/transfer date. For Arrangements Covered Persons, the immediate supervisor is also responsible for ensuring that he or she reviews the trainee's work involving Arrangements (as that term is defined in the CIA) until the trainee has completed Arrangements Training and certified completion.

The Bayer HealthCare Compliance Department will monitor training progress and send weekly reminders to the new Covered Person and their supervisor if training and certifications are not completed.

Notification is also sent to the Bayer 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 Covered Persons who do not complete training by the due date will be communicated to by their supervisor and the Bayer Human Resources Department. The Bayer Human Resources Department will take the appropriate corrective action including the suspension of the new Covered Person from work for a minimum of one-week (seven calendar days), without pay. If training and certifications are not completed within this suspension period, the new Covered Person will be subject to further disciplinary action, up to and including termination of employment.

Changes in Employment Status of Covered Persons

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

Contractors, Consultants and Agents

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

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

- Inform the agency or vendor that the position to be filled is a Covered Person position.
- Inform the Bayer HealthCare Compliance Department immediately (prior to the first work day) upon placing a contractor, consultant or agent a Covered Person position.
- Inform the Bayer HealthCare Compliance Department immediately (the same day) upon a contractor, consultant or agent leaving a Covered Person position.

5. COMPLIANCE TRAINING

GENERAL TRAINING

Within 21 days of becoming a HealthCare Compliance Program Covered Person, an employee must complete two hours of Compliance General Training. At a minimum, the training covers: (a) Bayer HealthCare's obligations under the Corporate Integrity Agreement and (b) Bayer HealthCare's Compliance Program (including the Code of Conduct and the Policies and Procedures, as they pertain to general compliance issues).

All Covered Persons must complete at least one additional hour of General "refresher" Training annually.

ARRANGEMENTS TRAINING

HealthCare Compliance Program Covered Persons who are involved with the initiation, negotiation, proposal, development, approval, implementation, management, oversight (including accounting functions), or review of Bayer HealthCare Pharmaceuticals' Arrangements must complete three hours of Arrangements Training, in addition to the General Training described above, within 21 days of becoming a Covered Person requiring Arrangements Training. For more information on what constitutes an "Arrangement" as defined by the CIA, please consult Policy and Procedure 8, "Focus Arrangements." At a minimum, Arrangements Training covers the following:

- Arrangements that potentially implicate the Anti-Kickback Statute, as well as the regulations and other guidance documents related to this statute;
- Bayer HealthCare Pharmaceutical's policies, procedures and other requirements relating to Arrangements, including but not limited to the Focus Arrangements Database, the internal Arrangements review and approval process, and the tracking of remuneration to and from sources of referrals or sales;
- The personal obligation of each individual involved in the initiation, negotiation, proposal, development, approval, implementation, management, oversight (including accounting functions), or review of Arrangements to know the applicable legal requirements and Bayer HealthCare Pharmaceuticals Compliance Policies and Procedures;
- Legal sanctions under the Anti-Kickback Statute; and
- Examples of violations of the Anti-Kickback Statute.

In addition to the annual General "refresher" Training described above, all individuals involved with Arrangements must complete at least three additional hours of "refresher" Arrangements Training annually.

SUPERVISION OF NEW ARRANGEMENTS COVERED PERSONS

Until a new Covered Person completes his/her Arrangements Training, a Covered Person who has completed this training will review all of the untrained person's work related to Arrangements.

CERTIFICATION

All General and Arrangements Covered Persons will be required to complete a certification, which may be in electronic form, confirming that they have completed the applicable training.

6. REVIEW OF COMPLIANCE TEXT MATERIALS

Bayer HealthCare is committed to appropriate and timely communications to all HealthCare Compliance Program Covered Persons regarding significant changes in the Bayer HealthCare Pharmaceutical's Compliance Policies and Procedures (Compliance Policies and Procedures) and the Bayer HealthCare Code of Conduct ("Code of Conduct") materials.

Annually, (or more often as necessary), Bayer HealthCare will review the Code of Conduct, Compliance Policies and Procedures and the Compliance training text to determine if revisions are appropriate and make any necessary revisions based on such review.

Revisions to the Code of Conduct will be distributed to all Bayer HealthCare employees, contractors, consultants and agents within thirty (30) days of finalizing such changes. All Bayer HealthCare employees, contractors, consultants and agents must certify that they have received, read, understood and will abide by the revised Code of Conduct within thirty (30) days after distribution of revisions.

Revisions to the Compliance Policies and Procedures will be distributed to all HealthCare Program Covered Persons whose job functions are related to the revised Compliance Policies and Procedures within thirty (30) days of the effective date of the revisions.

The Compliance training programs are updated as necessary and/or as a result of the text reviews.

7. DISCIPLINARY ACTION

GENERAL RULE

Bayer HealthCare Pharmaceuticals takes seriously all violations of (1) applicable federal, state or local laws or regulations, (2) applicable industry guidelines, and (3) the Bayer HealthCare Code of Conduct and the Bayer HealthCare 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 HealthCare Code of Conduct, or the Bayer HealthCare Pharmaceuticals Compliance Policies and Procedures.

NON-RETALIATION

Bayer HealthCare Pharmaceuticals will not retaliate, or tolerate retaliation, against any Bayer HealthCare Pharmaceuticals 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 HealthCare Code of Conduct or the Bayer HealthCare Pharmaceuticals Compliance Policies and Procedures.

DISCIPLINARY ACTION, TERMINATION AND REFERRAL TO LAW ENFORCEMENT

Bayer HealthCare Pharmaceuticals employees, contractors, consultants or agents who violate applicable federal, state or local laws or regulations, industry guidelines, the Bayer HealthCare Code of Conduct or the Bayer HealthCare Pharmaceuticals Compliance Policies and Procedures may be subject to disciplinary action up to and including termination of employment or other contractual arrangement. Any disciplinary action taken by Bayer HealthCare in response to a violation of the Bayer HealthCare Pharmaceuticals Compliance Policies and Procedures should be commensurate with the severity of the violation, as determined in Bayer HealthCare Pharmaceutical'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.

BAYER HEALTHCARE PHARMACEUTICALS EMPLOYEES, CONTRACTORS, CONSULTANTS AND AGENTS SUBJECT TO DISCIPLINARY ACTION

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

Any Bayer HealthCare Pharmaceuticals 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.

8. FOCUS ARRANGEMENTS

Under the terms of its Corporate Integrity Agreement ("CIA"), Bayer HealthCare is required to establish a review and approval process, as well as a tracking database for certain transactions and arrangements involving individuals or entities that may purchase or make referrals for Bayer HealthCare products. This Policy defines those arrangements and outlines the policies and procedures that Bayer HealthCare must follow when entering into these transactions. The specific procedures that must be followed for each type of arrangement (*e.g.,* medical education grant) are incorporated into the individual procedures particular to that arrangement.

CIA DEFINITIONS

Arrangements are defined as every arrangement or transaction that involves, directly or indirectly, the offer, payment, solicitation, or receipt of anything of value between Bayer HealthCare and any *actual or potential* source of referrals or sales of Government Reimbursed Products.

Focus Arrangements are defined as every Arrangement between Bayer HealthCare or any Bayer HealthCare Affiliate and any "actual" source of Government Reimbursed Product referrals or sales that involves, directly or indirectly, the offer, payment or provision of anything of value. Because Bayer HealthCare cannot accurately determine whether any person or entity is an "actual" source of sales or referrals, you must treat any potential source of referrals as an "actual" source for purposes of compliance with the CIA.

Referrals or sales are defined as referring, recommending, arranging for, ordering, prescribing, or purchasing Government Reimbursed Products.

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

Promotional and Product Services Related Functions are defined as anything that includes (a) the promotion, advertising, distribution, marketing, and sale of Government Reimbursed Products; and (b) the development or dissemination of materials or information about, or the provision of services relating to, Government Reimbursed Products.

Source is defined as anything that (of referrals or sales) includes, but is not limited to, a distributor, wholesaler, supplier, physician or other healthcare provider, contractor or agent. Because Bayer HealthCare cannot always accurately determine whether any person or entity is an "actual" source of sales or referrals, Bayer HealthCare must treat any potential source of referrals as an "actual" source for purposes of this policy.

Third Party Personnel are defined as personnel of the entities with whom Bayer HealthCare or any Bayer HealthCare 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

Below are examples of activities and Arrangements that could constitute Focus Arrangements 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
- Grants for Continuing Medical Education
- Consultant arrangements
- Advisory board arrangements
- Business Meals outside the recipient's normal working hours
- Disease management programs
- Service agreements with customers
- Data purchases
- Exhibit or display fees
- Educational items in excess of 1 per calendar year or in excess of $100 per item
- Contracts for discounted product purchase
- Advertising fees/promotional funding
- 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 be Focus Arrangements. If you have any questions about whether a potential activity or transaction may constitute a Focus Arrangement, you must consult the Law and Patents Department.

EXCEPTIONS TO FOCUS ARRANGEMENTS

The following activities and arrangements are **not** considered Focus Arrangements for purposes of the CIA or this policy:

- *Bona fide* employment arrangements with sales representatives;
- Provision of drug samples free of charge for free distribution to patients pursuant to the Prescription Drug Marketing Act ("PDMA");
- Provision of **one educational item per calendar year** valued at $100 or less to a healthcare practitioner and designed primarily for the education of patients or healthcare providers (*e.g.*, anatomical model) if the item does not have value to the healthcare provider outside his or her professional responsibilities;
- Business meals offered in connection with a presentation or discussion of Bayer HealthCare products led by a Bayer HealthCare representative where the presentation is made during the healthcare professional's working day, including mealtime, where the presentation provides scientific or educational value, and where the meal is (a) modest as judged by local standards; (b) not part of an entertainment or recreational event; and (c) provided in a manner conducive to informational communication;
- Bills of sale; and
- Contracts for the purchase of product where the only items of value exchanged are the purchase price and (1) a *bona fide* fee paid to a GPO (group purchasing organization); and/or (2) a prompt-pay discount or rebate for payment within a designated time period.

The above exceptions are defined by the CIA. Any deviation from the exception as stated above is not acceptable and the Arrangement must be considered a Focus Arrangement for purposes of this policy.

PROCEDURES FOR ARRANGEMENTS AND FOCUS ARRANGEMENTS

Bayer HealthCare has established a written review and approval process for Focus Arrangements of a contractual nature. All Focus Arrangements other than business meals and educational items are considered contractual in nature. If you are unsure whether a transaction, contract, program, or other activity constitutes a Focus Arrangement, you must consult with the Bayer HealthCare Compliance Department or the Law and Patents Department for assistance to ensure proper procedures are followed.

The general Focus Arrangements Procedures are described below. Specific procedures for each type of Focus Arrangement are found in the policy specific to that type of Focus Arrangement (*e.g.*, policy on fee-for-service agreements). The first step in the review and approval process for all Focus Arrangements is to comply with the Bayer HealthCare Pharmaceuticals policy specific to that individual Arrangement.

Bayer HealthCare must follow the following procedures outlined below for all Focus Arrangements. The purpose of these procedures is to help ensure that all new and existing Focus Arrangements do not violate the Anti-Kickback Statute.

1. Each Focus Arrangement must be set forth in writing prior to the services being performed.

2. Each Focus Arrangement must be signed by Bayer HealthCare Pharmaceuticals and the other party(ies) to the arrangement.

3. The written agreement must include a certification by the parties to the Focus Arrangement that the parties shall not violate the Anti-Kickback Statute with respect to the performance of the Focus Arrangement.

4. If the party to the Focus Arrangement is a person who is involved in, or an entity whose employees are involved in, Promotional and Product Services Related Functions, Bayer HealthCare Pharmaceuticals must send each entity that is a party to the Focus Arrangement: a Third Party Personnel Letter, as defined by the CIA along with (1) a copy of Bayer HealthCare's Code of Conduct and (2) applicable Anti-Kickback Statute Policies and Procedures attached. The Third Party Personnel Letter and attachments may be sent electronically or by hard copy, and can be included as an exhibit to the contract or sent as separate documents. The Third Party Personnel Letter requires the receiving party to inform Bayer HealthCare Pharmaceuticals whether it will either: (a) make a copy of Bayer HealthCare's Code of Conduct and a description of Bayer HealthCare's Compliance Program available to its Third Party Personnel (or, in the case of an individual, to himself or herself) or (b) represent to Bayer HealthCare Pharmaceuticals that it has and enforces a substantially comparable Code of Conduct and Compliance Program. The required

notification can be included as a provision in the contract or in a separate document, and requires the party to the agreement to check the appropriate option. A description of each party's response to the Third Party Personnel Letter must be noted in the Focus Arrangements Database.

5. If the party to the Focus Arrangement is a person who is not involved in, or an entity whose employees are not involved in, Promotional or Product Services Related Functions, the contract must include a requirement that all individuals who meet the definition of Covered Persons as defined in the CIA shall comply with all applicable elements of Bayer HealthCare's Compliance Program, including applicable training related to the Anti-Kickback Statute. In addition, Bayer HealthCare Pharmaceuticals must provide each individual that is a party to the Focus Arrangement a copy of (1) Bayer HealthCare's Code of Conduct and (2) applicable Anti-Kickback Policies and Procedures. The Bayer HealthCare Code of Conduct and applicable Anti-Kickback Statute Policies and Procedures may be sent electronically or by hard copy, and can be included as an exhibit to the contract or sent as separate documents.

Law and Patents Review of Focus Arrangements

The Law and Patents Department evaluates whether each proposed Focus 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 and Patents Department also confirms that the proposed payment (*e.g.*, speaker compensation or fees for a commercial exhibit) 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 HealthCare Compliance Officer (or designee) and documented and maintained in the Law and Patents Department.

Proof of Service

The Focus Arrangement Owner must be able to confirm that the services and/or items required to be provided pursuant to the Focus Arrangement were in fact provided. The form of the proof of service will differ depending on the type of Focus Arrangement (*e.g.*, speaker sign in sheets, slide decks, time sheets or exhibit booth attendance forms), so the Bayer HealthCare Pharmaceuticals Compliance Policies and Procedures for the individual Focus Arrangement (*e.g.*, medical education grant) must be consulted.

Payment for Focus Arrangements

All fees and expenses associated with a Focus Arrangement must be correctly linked with the contract for reporting purposes. The contract number assigned to each Focus 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.

Focus Arrangements Database

The CIA requires that Bayer HealthCare maintain a database of all existing, new and renewed Focus Arrangements. This Focus Arrangements Database contains certain information to assist Bayer HealthCare in ensuring each Focus Arrangement does not violate the Anti-Kickback Statute. In particular, the database:

- Allows Bayer HealthCare to track remuneration to and from all parties to Focus Arrangements;
- Tracks service and activity logs – or other documented proof of performance – to ensure that parties to Focus Arrangements are performing the services required; and
- Includes appropriate documentation of all internal controls.

The following information must be included in the database for each Focus Arrangement.

1. Name of each party involved;
2. Type of Focus Arrangement (*e.g.*, medical education grant, clinical research agreement);
3. Term of the Arrangement (if applicable) and any automatic renewal provisions;
4. Compensation to be paid;
5. Means by which compensation is paid (*e.g.*, check, product, periodic payments);
6. Verification of payments made by Bayer HealthCare;
7. Methodology or basis for determining that the compensation represents fair market value;

8. Whether the amount of compensation to be paid is determined based on the volume or value of referrals between the parties;

9. Whether each party has fulfilled the requirements of the CIA, including a description of each response to Third Party Personnel Letters (as described above);

10. Whether the services and/or items to be provided have been provided; and

11. Name and title of attorney who assessed whether the Focus Arrangement satisfies the requirements of an Anti-Kickback Safe Harbor and the date the assessment was made.

Compliance Officer Review

The Bayer HealthCare Compliance Officer will review the Focus Arrangements Database, the internal review and approval process, and Arrangements Procedures on at least a quarterly basis. The Bayer HealthCare Compliance Officer will prepare a report on the results of this review and provide it to the Bayer HealthCare Compliance Committee.

Should Bayer HealthCare discover a suspected violation of the Anti-Kickback Statute, Bayer HealthCare will implement appropriate and effective responses, including disclosing the information to the OIG to the extent required by the CIA.

AUDITS

Bayer HealthCare will retain and make available to OIG upon request the Focus Arrangements Database and all supporting documentation of the Focus Arrangements described in this procedure, and (to the extent available) all non-privileged communications related to the Focus Arrangements and the actual performance of the duties under the Focus Arrangements.

9. INTERACTIONS WITH GOVERNMENT INVESTIGATORS

GENERAL RULE

Bayer HealthCare Pharmaceuticals 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 agency. It is Bayer HealthCare Pharmaceuticals policy to cooperate fully with federal and/or state government officials or agents who conduct an inquiry, audit or otherwise investigate Bayer HealthCare Pharmaceuticals. Bayer HealthCare Pharmaceuticals expects all employees, contractors, consultants, distributors, and agents to extend the same cooperation within the guidelines of this Policy.

REPORTING GOVERNMENT INQUIRIES OR AUDITS

All Bayer HealthCare Pharmaceuticals employees, contractors, consultants and agents must immediately report to the Law and Patents Department any notice of a government inquiry or audit with respect to Bayer HealthCare 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 HealthCare Pharmaceuticals employees, (2) presentation of search warrants, (3) on-site visits to or inspections of Bayer HealthCare Pharmaceutical's premises by government officials or agents, or (4) visits by government officials to the homes of Bayer HealthCare Pharmaceuticals employees, contractors, consultants and agents.

CONTACT BY GOVERNMENT INVESTIGATOR

In the event a Bayer HealthCare Pharmaceuticals employee, contractor, consultant or agent is contacted by a federal or state investigator with respect to Bayer HealthCare related activities, the employee, contractor, consultant or agent must obtain proper identification from the government investigator prior to answering questions. Bayer HealthCare Pharmaceuticals employees, contractors, consultants and agents: (1) are not required to answer any questions asked by the government agent without the assistance of the Law and Patents 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 HealthCare Pharmaceuticals employee, contractor, consultant or agent at his or her respective home and/or any location which is off Bayer HealthCare Pharmaceuticals premises with respect to Bayer HealthCare 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 HealthCare Pharmaceutical's premises during regular business hours or at an alternate time and place that is otherwise convenient or to have independent counsel present during questioning by the government agency. If so requested by the employee, contractor, consultant or agent Bayer HealthCare Pharmaceuticals will have an attorney or other representative attend such interview.

GOVERNMENT INTERVIEWS

If a Bayer HealthCare Pharmaceuticals employee, contractor, consultant or agent decides to be interviewed or to respond to questions from a government investigator, with respect to Bayer HealthCare related activities, the employee, contractor, consultant or agent must answer all questions completely, accurately and truthfully. Bayer HealthCare Pharmaceuticals 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 and Patents 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 and Patents Department or Bayer HealthCare Pharmaceutical'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 and Patents 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 HealthCare Pharmaceuticals counsel. Alternatively, Bayer HealthCare Pharmaceuticals may recommend qualified counsel and, under the appropriate circumstances, will pay for such counsel to represent the Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals employees, contractors, consultants and agents must contact the Law and Patents Department if asked by a government investigator or anyone outside the company for Bayer HealthCare Pharmaceuticals documents. Bayer HealthCare 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 HealthCare's businesses. For example, Bayer HealthCare Pharmaceuticals 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 itself is Bayer HealthCare property and is subject to this policy.

In addition, Bayer HealthCare Pharmaceuticals employees, contractors, consultants and agents must not provide privileged Bayer HealthCare Pharmaceuticals documents to the government or anyone outside the company without specific authorization from the Law and Patents Department. Privileged documents include any documents involving the Law and Patents Department or Bayer HealthCare Pharmaceutical'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 and Patents 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals does not authorize you to sign or initial any such documents or statements as a Bayer HealthCare Pharmaceuticals employee, contractor, consultant or agent unless expressly authorized by the Law and Patents 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 HealthCare Pharmaceutical's policy.

10. 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 $5,500 to $11,000 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 HealthCare Pharmaceutical's customers may submit information to Bayer HealthCare Pharmaceuticals on their policies and procedures related to the FCA. Please direct all such submissions to the Bayer HealthCare Compliance Officer.

Bayer HealthCare Pharmaceuticals has established comprehensive policies and procedures to prevent, detect, and correct violations of law and company policy. Bayer HealthCare Pharmaceuticals 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 and Patents Department or Bayer HealthCare Compliance Department. Third, you may file an anonymous report via the confidential disclosure process, the Bayer IntegrityLine, at 1-888-765-3846.

11. VENDOR CREDENTIALING (FORMERLY HOSPITAL REGISTRATION)

Transactions under this Policy may constitute Focus Arrangements as defined by the CIA. Prior to initiating a transaction covered under this policy you must familiarize yourself with Policy and Procedure 8, "Focus Arrangements."

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 HealthCare Pharmaceuticals representatives must follow all institutional access policies pertaining to restricted areas as well as restrictions involving meals and educational items.

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

SCOPE

This policy is designed to allow compliance with credentialing requirements imposed by hospitals and other healthcare facilities. Bayer HealthCare Pharmaceuticals is committed to protecting employees' privacy and personal information. As such, all vendor credentialing and registration requirement documents must be sent to Law and Patents Department prior to signing any documents provided by a third party or a customer.

For additional guidance and specific instructions please go to:

http://us.pharmatoday.bhc.cnb/APPS/BSP/US/BSP-SalesView/BSP-SalesView.nsf/id/EN_Credentialing.

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 HealthCare Pharmaceuticals 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 and Patents 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 HealthCare Pharmaceuticals 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 a Focus Arrangement because the hospital or healthcare entity is a source of referrals or sales of Bayer HealthCare Pharmaceuticals 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 a Focus Arrangement must be directed to the Law and Patents Department.

Law and Patents Review of Focus Arrangements

The Law and Patents Department generates a written agreement that meets the requirements for Focus 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 both parties to the arrangement (*e.g.*, Bayer HealthCare Pharmaceuticals 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 or activities related to the Focus Arrangement; and

- The requirement that all individuals who meet the definition of Covered Persons shall comply with all applicable elements of Bayer HealthCare's Compliance Program, including applicable training related to the Anti-Kickback Statute.

The Law and Patents 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 and Patents 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

HealthCare Pharmaceuticals. Any deviation from the fair market value methodology and the rationale for such deviation must be approved by the Bayer HealthCare Compliance Officer (or designee) and documented and maintained in the Law and Patents Department.

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

Focus Arrangements Database Procedures

When the executed contract is returned from the hospital, the Bayer HealthCare Pharmaceuticals representative forwards it to the Law and Patents Department to be entered into Efilia with information required for the Focus Arrangements Database.

Proof of Service

The Focus Arrangement Owner must confirm that the services purchased were performed and/or satisfactorily received before payment is generated. The Focus Arrangement Owner formally confirms proof of service by maintaining the confirmation of registration or a copy of the badge. The same Focus Arrangement Owner must retain the proof of service records for 10 years.

Payment

Representatives are permitted to pay registration fees using their corporate credit cards (and seek reimbursement) for payments made directly to a third party (*e.g.*, Vendormate, Reptrax, VendorClear). Payments made directly to a customer constitute a Focus Arrangement and must go through a purchase requisition and follow the procedures for Policy and Procedure 8, "Focus Arrangements." Payments must not be made in cash or with a personal check. Once paid, access to the institution must be recorded in the IMPACT database on the account or hospital profile. Instructions on where and how to do this are listed in Sales View in the Impact Reference Guide.

Permissible Activities or Information to Release

Biographical Information

- Company Information
  - Company name – Bayer HealthCare Pharmaceuticals Inc.
  - Address – 6 West Belt, Wayne NJ
  - Supervisor information
  - Tax ID Number
    - Bayer HealthCare Pharmaceuticals Inc.: 22-2273583
    - Bayer HealthCare LLC: 06-1653795
- Representative Information
  - Name
  - Address
  - Phone number

Immunizations and Immunization Records

Some registrations require that representatives be immunized against certain infectious agents. Below are options for obtaining the necessary immunizations and records:

Bayer Occupational Health Department Arranging for Immunization and Records

1. The Sales consultant will notify Occupational Health by calling 973-305-5477 and by faxing the HealthCare Facility's written notice of such requirement (fax 973-305-5360) indicating the testing or immunizations required.

2. Occupational Health will review the employee's medical record and document for the employee all immunizations previously given and/or provide previous test results.

3. Occupational Health will select a local provider for blood work, PPD or immunization and will send the request form to the employee.

    - When antibody titers indicate no immunity, and the requesting HealthCare Facility requires immunity, the employee will be sent to a local Occupational Health provider for immunization.

    - Titers will be drawn three months after the last Hepatitis B immunization to check for immunity.

    - For employees needing an annual PPD, Occupational Health ("OH") will send an annual reminder, provided OH is aware of the need.

    - For employees needing other immunization, Occupational Health will schedule the appointment and notify the employee of time and location.

4. All testing results must be returned to Occupational Health. All immunization documentation must be reported to OH, to be logged into the employee's medical record.

5. Each employee will be provided with his or her immunization records and is responsible for providing the records to the requesting vendor.

Medical testing and immunization will be paid for by Occupational Health.

Personal Physician Immunizations

Should an employee desire, he or she may arrange for and obtain the required immunizations from his or her personal healthcare provider. If this process is followed, medical testing and immunization fees will be reimbursed on the employee's expense report.

Team Immunizations

Team immunizations at POAs or other meetings are available upon request to Sales Training.

Other Requests

Requests for medical information beyond that described above *(e.g.,* request for medical records generally) must be addressed to your supervisor, the Compliance Department and/or the Law and Patents Department before any such information is provided.

HIPAA Training and Documentation

Although pharmaceutical and biologics manufacturers are not generally subject to HIPAA, Bayer HealthCare Pharmaceuticals nonetheless requires that all representatives conduct business in compliance with the HIPAA Privacy Regulations. Representatives must maintain the confidentiality of any patient's protected health information in the unlikely event it is inadvertently disclosed. All sales consultants are required to take the HealthStream HIPAA training course. Upon completion, each representative will be provided with a certificate of completion and must maintain and provide this certificate when required as a function of appropriate registrations.

During the registration process, representatives must not sign Business Associate Agreements. If asked to do so, the Law and Patents Department must be consulted.

Product Training

Certificates evidencing that a representative has been trained on relevant product(s) can be obtained from Sales Training. It is the representative's responsibility to maintain a copy of product training certificates for submission to entities that may request such documentation.

Background Checks and Drug Testing

Copies of pre-employment background checks and drug testing results are available from your HR representative.

Insurance Certificate

Copies of the current Bayer HealthCare Pharmaceutical Inc. and Bayer HealthCare LLC insurance certificates are available for download on Salesview, under the "Forms" menu.

Hospital/Institutional Training

Representatives are permitted to take part in additional training that hospitals may require as a function of registration, but any required certifications or agreements must be sent to the Law and Patents Department for review and approval. No fees (beyond the registration fees described above) may be paid for this training without the prior written approval of the Law and Patents Department.

12. PRESCRIBER DATA

Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals contains any identifiable patient information.

Bayer HealthCare Pharmaceuticals 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 AMA PDRP (defined below) and the PhRMA and AdvaMed Codes.

USES OF PRESCRIBER DATA:

Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals does not use for sales purposes Drug Enforcement Administration (DEA) registration numbers (assigned to prescribers who have authority to prescribe controlled substances). 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 contact the AMA or the Bayer HealthCare Pharmaceuticals Hotline (which, as discussed below, would generally direct the caller to the AMA). 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 HealthCare 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 HealthCare Pharmaceuticals 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 HEALTHCARE PHARMACEUTICALS HOTLINE FOR PRESCRIBERS

Bayer HealthCare Pharmaceuticals U.S. Sales Operations makes available a hotline, **888-RxBayer** (888-792-2937), to prescribers for a variety of purposes. Consistent with the PhRMA Code, this hotline is available to handle no contact requests, inquiries regarding Bayer's use of prescriber data, and any concerns regarding contact from sales consultants. For example, a physician caller requesting to opt-out of contact from all pharmaceutical companies would be directed to the AMA PDRP.

A physician caller requesting to opt-out of contact from Bayer HealthCare Pharmaceuticals specifically would have his or her request honored by Bayer HealthCare Pharmaceuticals through the use of a PDRP opt-out flag that is added to the physician profile in the Bayer Enterprise Data Warehouse (EDW), maintained by the Commercial Analytics and Support department. Once the flag is attached to the physician's record in EDW, it is passed to Veeva, Bayer Healthcare Pharmaceuticals' sales force automation system. A PDRP opt-out flag blinds the physician's prescribing information from views and screens available in Veeva to Bayer HealthCare Pharmaceuticals Sales Consultants and Regional Sales Managers. Physicians can also opt back in using the same AMA PDRP method.

The hotline is managed by the Sales Administration Manager.

BAYER HEALTHCARE PHARMACEUTICALS SYSTEM PROCESS FOR PDRP OPT-OUT FLAGS:

On a monthly basis, Bayer HealthCare Pharmaceuticals 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 EDW.
- On a monthly basis, the HIO data, including any PDRP opt-out flags related to specific physician profiles, is also loaded into IMPACT.
- Additional PDRP opt-out flags based on state laws and Bayer specific opt-out requests received through the Bayer Hotline, if any, are added to the EDW and IMPACT systems as necessary.

TRAINING

Training on proper uses of prescriber data as well as respecting the physician's choice to opt-out is provided in Sales Training programs.

VIOLATIONS AND SANCTIONS

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

13. 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 advocate 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 the 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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.

PROHIBITION OF EDUCATIONAL ITEMS AND BUSINESS MEALS

Federal law prohibits contractors such as Bayer HealthCare Pharmaceuticals 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 HealthCare (all divisions and subsidiaries), not to an individual sales consultant.

In order to ensure that Bayer HealthCare Pharmaceuticals complies with the law, it is Bayer HealthCare's policy that Bayer HealthCare Pharmaceuticals 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.

Product samples are not considered "educational items" and may be provided to federal employees, if permitted by the government entity and in accordance with applicable 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

Government officials, other than President Obama appointees, are permitted by federal law to attend certain group events, referred to as "widely attended gatherings," sponsored by contractors such as Bayer HealthCare Pharmaceuticals, even if the cost of these events exceeds the 20/50 Rule. 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 HealthCare Pharmaceuticals -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 HealthCare Pharmaceuticals -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 HealthCare Pharmaceuticals sponsored limited target audience event (*e.g.*, dinner at a "Bayer HealthCare Pharmaceuticals table" at ASCO) or invite individual government physicians to dinner at an AMA conference or similar event.

Fee-for-Service Arrangements

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 and Patents 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals, 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 26, "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 Corporate Audit and Bayer HealthCare Compliance to ensure compliance with these policies. The government (*e.g.,* OIG, IRS) may also request to audit/review grant payments at any time.

14. BUSINESS MEALS WITH HEALTHCARE PROFESSIONALS

Transactions under this Policy may constitute Focus Arrangements as defined by the CIA. Prior to initiating a transaction covered under this policy you must familiarize yourself with Policy and Procedure 8, "Focus Arrangements."

Note: Transactions under this Policy are reportable to the federal government under the Patient Protection and Affordable Care Act when implemented. It is each employee, contractor, consultant and agent's responsibility to report accurate, complete and timely data.

SCOPE

The Bayer HealthCare Pharmaceuticals policy for business meals conforms 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 HealthCare Pharmaceuticals products.

Bayer Corporation 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/.

Note that the definition of healthcare professionals is very broad and includes individuals who directly interact with patients and/or have a role in the diagnosis and treatment of patients or 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 HealthCare Pharmaceuticals 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, technicians, 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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.

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 HealthCare Pharmaceuticals products, disease states relevant to Bayer HealthCare Pharmaceuticals products, medical education, or other legitimate business discussions related to Bayer HealthCare Pharmaceuticals products; (4) take place in a setting conducive to such discussion; and (5) involve only individuals who are necessary for the conduct of Bayer HealthCare Pharmaceuticals business.

Providing a healthcare professional with a meal solely for "relationship building" is not acceptable. Further, it is not appropriate for Bayer HealthCare Pharmaceuticals to pay for, or reimburse healthcare professionals for, personal meals. Offering meals in any location without a Bayer HealthCare Pharmaceuticals representative present, or providing "take-out" meals, is not allowed.

All Bayer HealthCare Pharmaceuticals employees, contractors, consultants and agents must exercise sound judgment and discretion when providing modest food or beverages to HCPs in conjunction with product promotion. The central focus must be the product 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. Generally, alcoholic beverages must not be offered because they are not conducive to a scientific or educational exchange. **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 or Bayer HealthCare Pharmaceuticals product discussion or other legitimate business discussion related to Bayer HealthCare Pharmaceuticals products.

- Field sales consultants and their immediate managers may provide business meals only in the healthcare practitioner's office or in the hospital during the healthcare professional's normal working hours. Appropriate places within a hospital include the cafeteria, coffee shop, or a meeting space conducive to an educational discussion (*e.g.*, conference room). The PhRMA Code prohibits field representatives and their managers from providing or offering meals in connection with these informational presentations to healthcare practitioners in restaurants or any location other than the professional's office or the hospital. If a meal is being provided in connection with a promotional speaker program that fully complies with the requirements of Compliance Policy and Procedure 17,

"Fee-for-Service Arrangements," a sales consultant or his/her immediate manager may attend and pay for the meal, as appropriate. Such a meal must comply with the other requirements of this policy.

- All Other Bayer employees (*e.g.*, KAMs, Managed Markets Medical Affairs, Marketing and other applicable home office personnel) 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 HealthCare Pharmaceutical's policy that "occasional" should mean generally no more than **ten** 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 HealthCare Pharmaceuticals personnel to healthcare practitioners prior to and/or after a business meal must be included in the $125 per person limitation. The limit includes food, beverages, tax and tip. 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 (including tax, gratuity, and delivery charge) per person. This per person charge also includes 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 (*e.g.*, if there are 3 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 Bayer HealthCare Pharmaceuticals products.

STATE SPENDING LIMITS

Some states have laws regarding the provision of business meals and other promotional activities that are more restrictive than Bayer HealthCare Pharmaceutical's general policy. Please refer to the Policy and Procedure 29, "State Laws," in this booklet for details of these restrictions. If you interact with healthcare professionals from any of these states, you must consult the relevant Bayer HealthCare Pharmaceuticals procedures **prior** to providing any item of value to those healthcare practitioners.

RETAIL VALUE – AMOUNT TO BE RECORDED

The retail value of a meal, not the amount you or Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals actually paid for it. When listing the value of any meal, you must list its retail value and the amount you or Bayer HealthCare Pharmaceuticals 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 HealthCare does not violate these laws, **Bayer Healthcare Pharmaceuticals employees, contractors, consultants and agents may not provide any business meals or food/drinks of any kind to federal government employees**. For more information on this policy, including who constitutes a federal government employee, consult Policy and Procedure 13, "Special Requirements for Government Employees," in this booklet.

OTHER LIMITS

No Spouses or Guests – Business meals are for legitimate business purposes 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.*, gift certificates, your credit card) 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 HealthCare Pharmaceuticals may only pay for meals of healthcare professionals who actually attend a meeting at which Bayer HealthCare is legitimately sponsoring a meal pursuant to this Policy.
- Meals are only provided to individuals who are necessary for the conduct of Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals representative is not present while the meal is consumed

EXAMPLES

The following are examples of appropriate business meals for field 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 Nexavar
- Providing a physician with a meal in the hospital cafeteria to discuss a newly approved indication for Betaseron

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

- Taking a gynecologist to a modest restaurant around the corner from his/her office for a meal to discuss the use of Essure (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 Kogenate (too expensive to be modest)

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

- Meeting a physician at a "take-out" restaurant and discussing Bayer HealthCare products while waiting for the food (venue/location not conducive to an educational discussion; no Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 (who is not a healthcare professional) to a restaurant dinner in a "foursome" with your spouse (including a spouse or guest is inappropriate)
- Providing a meal for a tumor board (or similar activity) and waiting outside of the meeting room while the meal is consumed (no Bayer HealthCare Pharmaceuticals 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 consultants and their immediate managers, is the setting in either the healthcare practitioner's office or an appropriate hospital venue?
- Is the amount modest?
- Is a Bayer HealthCare Pharmaceuticals representative present?

- Is the frequency of meals provided to this healthcare professional occasional (it is Bayer HealthCare Pharmaceutical's policy that "occasional" means generally no more than ten 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.

FOCUS ARRANGEMENTS

Business meals are items of value provided to a healthcare professional who is a source of referrals or sales of Government Reimbursed Products. The Corporate Integrity Agreement ("CIA") carves out, or excludes, from the definition of Focus Arrangements those business meals that meet certain requirements however such meals must be tracked for state reporting and CIA purposes to ensure accurate data capturing and reporting.

However, any meals that occur outside of the healthcare professional's normal working hours are considered Focus Arrangements. Examples of such meals include dinner speaker programs or any other meals provided outside the healthcare professional's normal working day. Because business meals are not "contractual in nature," Bayer HealthCare Pharmaceuticals is not required to follow Focus Arrangements Procedures for business meals. However, Bayer HealthCare Pharmaceuticals is required to track these meals in the Focus Arrangements Database.

Business meals that constitute Focus Arrangements are tracked through review of T&E reports, information provided by the Meetings and Conventions group, and, in the case of third-party payment, from information provided by third-party vendors. It is critical that you completely and accurately complete your T&E reports or other required documentation of business meals so that Bayer HealthCare Pharmaceuticals can include required information in the Focus Arrangements Database.

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, but may not exceed $125 (including food, beverage, tax and gratuity) per person.

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 under Professional Education Meal. All employees must document the details of business expenses according to IRS rules, Compliance Policies and Procedures and the Corporate T&E Policy. An accurate description (*e.g.*, describes what product you are detailing as well as purpose for the detailing visit to the HCPs office) of the business purpose must be documented. Instructions on how to complete your T&E when providing a business meal to an HCP or Business Guest can be found on the intranet at: http://www.compliance.bayerweb.com/Video20100817/player.html.

Itemized (detailed) receipts and copies of the attendee sign in sheet **must** be included with every professional education meal expense entered into Concur T&E, regardless of the amount. **These two requirements supersede the Corporate T&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 the office, regardless of amount, require an itemized (detailed) receipt and completed sign in sheet which documents the attendance of each individual. If the Bayer HealthCare Pharmaceuticals employee pays for the meal on his/her credit card and will expense the meal through the Concur system, the sign in sheet must be attached to the T&E report. Meals paid on behalf of Bayer HealthCare Pharmaceuticals through a third party vendor also require sign in sheets (*e.g.*, speaker training, advisory boards, investigator meetings, and speaker programs). Sign in sheets used at third party meals (such as speaker programs or advisory boards) must be submitted in accordance with Policy and Procedure 8, "Focus Arrangements."

The sign in sheet must have the following information:

General

- Event date
- Event location (in-office or out of office)
- Event type (education session, dinner speaker program, patient program, ad board, speaker training, etc.)
- Program/Event number (if applicable)
- Event host (Bayer HealthCare Pharmaceuticals employee)
- Signatures of all Bayer HealthCare employees
- Speaker (if applicable) printed and signature
- Contract number (if applicable)
- Name and address of venue
- Number of licensed HCPs, non-licensed HCPs, Bayer HealthCare Pharmaceuticals employees, total attendees

Per Individual HCP

- Contract number (if applicable)
- Printed name
- Title (credentials)
- Affiliated entity or Company
- Full address (address, city, state, zip)
- HCP license number (if applicable) http://hcp.sln.bayernet.com/Login.aspx?ReturnUrl=%2fDefault.aspx
- State of license (if applicable)

- Signature. Bayer HealthCare Pharmaceuticals employees may, if necessary, complete information other than the signature. **Each HCP must sign for himself/herself.** If you are unable to obtain a signature, you must contact the Bayer HealthCare Compliance Department or the Law and Patents Department prior to submitting your expense report.

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 compliance with this policy and proper control of business expenses.

Immediate supervisors are responsible for regularly reviewing T&Es for all employees they oversee to ensure that consistency with this Policy and Procedure and other applicable Bayer HealthCare Pharmaceuticals requirements, including that the limit per person per meal is not exceeded, that the attendees are appropriate, that the venue is appropriate, and that 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 HealthCare Pharmaceuticals 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 Bayer HealthCare Compliance Department. Please refer to Policy and Procedure 7, "Disciplinary Action."

RECORD RETENTION

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

AUDITS

Spending for business meals is subject to auditing by Corporate Audit and Bayer HealthCare Compliance to ensure compliance with this Policy, including proper documentation, spending limits, and company spending policy. The government (*e.g.*, OIG, IRS) may also request to audit or review expense reports.

15. EDUCATIONAL ITEMS FOR HEALTHCARE PROFESSIONALS

Note: Transactions under this Policy are reportable to the federal government under the Patient Protection and Affordable Care Act when implemented. It is each employee, contractor, consultant and agent's responsibility to report accurate, complete and timely data.

Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals product(s) as doing so could lead to a violation of the Federal Anti-Kickback Statute and other relevant state statutes.

SCOPE

The Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals products. Note that the definition of "healthcare professionals" is very broad and includes individuals or entities that directly interact with patients and/or have a role in the diagnosis and treatment of patients. or entities which are involved in the provision of healthcare services and/or items to patient and which may purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe Bayer HealthCare Pharmaceuticals products in the U.S. Generally, this definition includes physicians, nurses, nurse practitioners, physician assistants, medical assistants who treat the patient, and other allied healthcare professionals, such as pharmacists, technicians, 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 administrator, wholesalers, distributors, pharmacies, Pharmacy & Therapeutics Committee members, Formulary Committee members, or other customers who do not see patients.

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 HealthCare Pharmaceuticals does not violate these laws, **Bayer HealthCare Pharmaceuticals 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 13, "Special Requirements for Federal Government Employees," in these Policies and Procedures.

SPENDING LIMITS AND FREQUENCY FOR EDUCATIONAL ITEMS

The retail value of an educational items provided to an HCP in one year may not exceed $100.

Under the PhRMA and AdvaMed Codes, educational items may be offered only "occasionally." In order to ensure that the provision of educational items are not Focus Arrangements as defined by the CIA, it is Bayer HealthCare Pharmaceutical's policy that no more than one educational item be provided to any healthcare practitioner in a calendar year. Textbooks are considered educational items and thus you may give only one item, be it a textbook or another appropriate item, per calendar year. For more information regarding Focus Arrangements, see Policy and Procedure 8, "Focus Arrangements."

Educational items provided to HCPs solely for distribution to and use of 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.

STATE SPENDING LIMITS

Some states have laws regarding the provision of educational items that are more restrictive than Bayer HealthCare Pharmaceuticals' policies. Please refer to the Policy and Procedure 29, "State Laws," in this booklet. You must consult the relevant Bayer HealthCare Pharmaceuticals procedures **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 and not the amount you or Bayer HealthCare Pharmaceuticals paid for it determines whether it is within the $100 limit. Bayer HealthCare often takes advantage of bulk or other discounts such that the retail value of some educational items may be higher than what you or Bayer HealthCare Pharmaceuticals actually paid for them. When listing the value of any educational item, you must always list its retail value and the amount you or Bayer HealthCare Pharmaceuticals paid for the item, if the amounts differ. Retail value must also be used to determine if the cumulative value of educational items or meals is appropriate.

The functional areas responsible for distributing educational items and textbooks must include with each shipment a list that indicates the amount Bayer HealthCare Pharmaceuticals paid for each item and the retail value associated with each item. These amounts may be close estimates if the actual cost and/or an exact retail value are not available.

EDUCATIONAL PURPOSE REQUIRED

You may provide educational items to a 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 HealthCare Pharmaceutical's policy to not provide subscriptions to scientific journals to a healthcare professional. Bayer HealthCare Pharmaceuticals 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, Regulatory 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 HealthCare's Code of Conduct and Bayer HealthCare Pharmaceuticals Compliance Policies and Procedures. Please refer to Policy and Procedure 34, "Materials for External Use," in this booklet 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
- Resident handbook
- Educational materials and/or books on management of disease

EXAMPLES OF UNACCEPTABLE EDUCATIONAL ITEMS

Practice-related "reminder" items such as pens, note pads, mugs, magnets, and similar items with or without the Bayer or product logos are not permissible educational items. 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.

"Dual-purpose" items, such as DVD players, computer equipment, PDAs, unlocked flash drives and CD players, 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 because they could also be used by the healthcare professional for personal use unrelated to patient education.

Items provided to a healthcare professional may never include payments in cash or cash equivalents, such as (a) gift certificates; (b) loans; (c) savings bonds; (d) lottery tickets; (e) airline upgrade coupons; or (f) gas cards. Items of a personal nature, such as flowers, gift baskets, and holiday 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 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 reasonably 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.

The appropriate company spending policy must be followed when procuring and offering an educational item. Please refer to the Corporate U.S. Signature Authorization Policy 002.20130115.

You may also access the policy through the intranet or use the website address: http://www.bayernet.com/corp/policies/policies_detail.cfm?fileid=236.

Documentation of Educational Items through Impact

All educational items provided by Bayer HealthCare Pharmaceutical sales consultants must be recorded in Impact. Regardless of the source of payment, there is still only a one educational item annual limitation. An accurate description of the business purpose of the educational item (describe the item left with the HCP and what it is used for) must be documented.

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 Impact for a period of 10 years.

AUDITS

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

16. EDUCATIONAL ITEMS AND MEALS PROVIDED TO PATIENTS

Under circumstances described in this Policy, Bayer HealthCare Pharmaceuticals representatives may provide occasional and modest educational, disease or treatment-related items and/or meals to patients. Bayer HealthCare Pharmaceuticals policy prohibits employees, contractors, consultants and agents from offering anything of value, including an educational/treatment item or meal, to a patient to encourage that person to purchase, order, refer, use or recommend Bayer HealthCare Pharmaceuticals product(s).

GENERAL RULE AND LIMITS

Meals

It is generally appropriate for Bayer HealthCare Pharmaceuticals to provide an occasional and modest meal to patients in an appropriate setting conducive to having a Bayer HealthCare Pharmaceuticals product discussion or provide patient education on Bayer HealthCare Pharmaceuticals products or disease states relevant to Bayer HealthCare Pharmaceuticals products. It is not appropriate for Bayer HealthCare Pharmaceuticals to pay for, or reimburse patients for, personal meals. Payment for, or reimbursement of, business meal expenses must be limited to meals for which there is a commercially reasonable business purpose and involve only individuals who are necessary for the conduct of Bayer HealthCare Pharmaceuticals business. As such, 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 HealthCare Pharmaceuticals 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 $25 per person. Such meals should consist of sandwiches, pizza, snacks, or soft beverages. **Providing alcoholic beverages in connection with any patient meal is prohibited.**

Educational, Disease or Treatment Related Items

In accordance with the requirements of this policy, Bayer HealthCare Pharmaceuticals representatives may provide patients with items that are intended to educate patients or are important for patient treatment and/or disease management. These items may only be distributed to patients at health fairs, medical screenings, patient 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 HealthCare Pharmaceuticals may not condition the distribution of such materials in return for a charitable contribution or an educational grant.

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 patients may be no more than $10 and the retail value of any combination of such items given at any one time, not to exceed three such 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 include ice packs, squeeze balls, disease state brochures, calorie counters, pedometers, disposable water bottles at a walk where the water bottles must be intended for single-use only, etc. Such educational and treatment related items may be Bayer branded.

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 use during an educational session/program. However, such items may **not** have a Bayer or brand logo and may only be provided for patient use in conjunction with an educational program.

Examples of inappropriate items include key chains, golf balls, note pads, magnets, pens, cell phone holders, mouse pads, stuffed animals, unlocked flash drives, etc. None of the prohibited items described above may be provided to patients in connection with a product display or exhibit.

All patient education and treatment items must be obtained directly from Marketing and approved by Law and Patents Department. You may not procure items on your own to provide to patients.

Documentation of Patient Meals

Patient meals are recorded through your T&E Expense Report ("T&E"). All employees must document the details of business expenses according to IRS rules, Compliance Policies and Procedures and the Corporate T&E Policy. An accurate description (describes what product you are detailing as well as purpose for the visit with the patient) of the business purpose must be documented.

The Corporate T&E Policy can be found on the intranet at: http://www.bayernet.com/corp/policies/policies_detail.cfm?fileid=229.

The failure to submit for reimbursement for the business expenses does not circumvent this policy. You must account for all "no shows" for events where the meals have been pre-ordered in the attendee screen in T&E.

Due to the Patient Privacy Rule (HIPAA), disclosure of the patient name is not required.

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 they oversee to ensure that consistency with this Policy and Procedure and other applicable Bayer HealthCare Pharmaceuticals requirements, including that the guideline limit per person per educational item or meal is not exceeded, that the attendees are appropriate, that the venue is appropriate, and that the total number and amount of business meals and educational/treatment items provided to any single patient are consistent with this Policy and Procedure.

If the review reveals potential divergence from Bayer HealthCare Pharmaceuticals policy, the supervisor must take appropriate action, to include discussing the situation with the employee, documenting corrective action and notifying consulting with the next supervisory level. If a supervisor determines an employee has not followed this policy, the supervisor must notify the Bayer HealthCare Compliance Department. Please refer to Policy and Procedure 7, "Disciplinary Action."

RECORD RETENTION

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

AUDITS

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

17. FEE-FOR-SERVICE ARRANGEMENTS

Transactions under this Policy constitute Focus Arrangements as defined by the CIA. Prior to initiating a transaction covered under this Policy you must familiarize yourself with Policy and Procedure 8, "Focus Arrangements."

Note: Transactions under this Policy are reportable to the federal government under the Patient Protection and Affordable Care Act when implemented. It is each employee, contractor, consultant and agent's responsibility to report accurate, complete and timely data.

The Personal Services Safe Harbor of the Anti-Kickback Statute allows Bayer HealthCare Pharmaceuticals to enter into certain fee-for-service arrangements with healthcare professionals provided certain criteria are met. Bayer HealthCare Pharmaceutical'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 fees 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 HealthCare Pharmaceuticals products nor should these arrangements be used to reward "high prescribers."

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 HealthCare Pharmaceuticals for services rendered.

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 HealthCare Pharmaceuticals products.

Advisory Board meetings are to obtain expert feedback or advice on commercial or clinical/medical topics. Advisory boards must not be used as a forum for product promotion. 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 HealthCare Pharmaceuticals products.

Consultants are generally healthcare professionals paid by Bayer HealthCare Pharmaceuticals to provide the Company important and needed information about its products, sales and marketing practices, and related issues (*e.g.*, disease states).

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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals in areas that are relevant to its business activities. Bayer HealthCare Pharmaceuticals may not purchase data unless it has established a legitimate need for the data and, in fact, 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 HealthCare 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 over the Internet. 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 HealthCare Pharmaceuticals, in which Bayer HealthCare Pharmaceuticals knows the identity of the participant, are Focus Arrangements. Market research or focus groups where the participants' identities are blinded to Bayer HealthCare Pharmaceuticals are not Focus Arrangements.

Promotional speaker events include speakers who are acting or speaking on Bayer HealthCare Pharmaceutical's behalf. Such events are considered promotional events. Speaker fees must be fair market value and provided pursuant to a written agreement approved by the Law and Patents Department. The total amount of annual compensation to any one healthcare professional in connection with all Bayer HealthCare speaking arrangements across Diabetes Care, Radiology and Interventional, Bayer Dermatology and Bayer HealthCare Pharmaceuticals may not exceed $50,000 annually.

Service agreements with customers are services whereby Bayer pays a fair market value fee to a customer (typically a healthcare organization) to provide certain services in connection with Bayer HealthCare Pharmaceuticals products. Examples include 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 HealthCare Pharmaceuticals product to its formulary, or providing "patient information cards" to patients who may be using a Bayer product for the first time. 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 HealthCare Pharmaceuticals product).

Speaker training provides qualified speakers with training on Bayer HealthCare Pharmaceuticals products as well as FDA regulatory requirements. The content of the training meetings must be designed to develop speakers who will provide a valuable service to Bayer HealthCare. Bayer HealthCare Pharmaceuticals must ensure that the number of speakers trained is closely related to the number of speakers Bayer HealthCare Pharmaceuticals plans to use. All speaker training meetings must be arranged through either the Marketing Department or the Medical Affairs Department and approved through Legal, Medical and Regulatory.

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.
- Speakers or consultants are chosen based upon relevant qualifications, experience and expertise as well as the value their services would provide to Bayer HealthCare Pharmaceuticals, not based on the volume or value of business generated by the speaker or consultant. Field sales personnel may not be involved in selecting members of the speaker bureau or engaging healthcare professionals to serve as consultants. Those responsible for selecting the speaker or consultant must have the expertise necessary to evaluate whether the healthcare professional has the required qualifications.

- The venue and circumstances of consultant meetings must be conducive to the consulting services. Exotic and/or resort locales are prohibited. Bayer HealthCare Pharmaceuticals 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 and Patents 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 and Patents Department **before** it is signed by the speaker or consultant and Bayer HealthCare Pharmaceuticals. No Bayer HealthCare Pharmaceuticals employee may execute any contract or other legally binding document without review and approval from the Law and Patents Department. If a healthcare provider refuses to sign the agreement provided by the Law and Patents 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/Transmittal Form and approved by the requestor's supervisor. The approved request is submitted to the Law and Patents Department for legal review and contract generation. The Agreement Request/Transmittal form must include the following:

- Name and address of the speaker(s), consultant(s), advisory board member(s), etc.;

- Bayer HealthCare Pharmaceutical'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 HealthCare Pharmaceuticals' need or purpose for the services);

- Term of the agreement, including any automatic renewal provisions;

- The proposed fee; and
- Description of the expense to be reimbursed, if any.

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

Before generating the contract, the Law and Patents Departments will determine whether a Master Services Agreement ("MSA") exists for the potential speaker or consultant. If a MSA exists, the Law and Patents 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 $50,000 for speaking engagements annually**. If Bayer HealthCare Pharmaceuticals 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 other fee-for-service arrangement must sign a contract or Letter of Agreement that has been approved by the Law and Patents 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 Focus Arrangement.

THIRD PARTY CONTRACTS

Bayer HealthCare Pharmaceuticals may work with third parties who contract with speakers, moderators, or consultants on behalf of Bayer HealthCare Pharmaceuticals. Third parties are prohibited from entering into contracts with HCPs on Bayer HealthCare Pharmaceutical's behalf. The Law & Patents 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 HealthCare Pharmaceuticals the proposed list of speakers, moderators, or consultants that it plans to use for the event. The Law and Patents Department must verify that each consultant has not exceeded the terms of any applicable MSA or the $50,000 annual limit on speaker fees.

The Law and Patents 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 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 and Patents 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.

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 HealthCare Pharmaceuticals -sponsored clinical trials.

An employee may not receive compensation from Bayer HealthCare Pharmaceuticals if he/she serves in a position of decision-making authority (*e.g.,* formulary committee) in which purchasing or prescribing decisions that might favor or disfavor Bayer HealthCare Pharmaceutical's products are made (other than in the capacity to prescribe drugs /device for patients).

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

FOCUS ARRANGEMENT PROCEDURES

Agreements with speakers, consultants, and advisory board participants as well as data purchases, service agreements with customers, and fees for market research and advertising constitute Focus Arrangements under the CIA because they are actual or potential source of sales or referrals of Bayer HealthCare Pharmaceuticals products.

Law and Patents Review

The Law and Patents 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 and Patents 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 HealthCare. Any deviation from the fair market value methodology and the rationale for such deviation must be approved by the Bayer HealthCare Compliance Officer (or designee) and documented and maintained in the Law and Patents Department.

The Law and Patents Department sends each party to the Focus Arrangement a copy of the approved contract and attaches a copy of Bayer HealthCare's Code of Conduct, the Anti-Kickback Statute Policies and Procedures and, if applicable, a Third Party Personnel Letter 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. Law and Patents must make reasonable efforts to follow up with the speaker or consultant to obtain the Third Party Personnel Letter response and document such efforts.

The written contract may indicate that Bayer HealthCare Pharmaceuticals will reimburse reasonable expenses for travel, lodging, and meals incurred by the speaker or consultant in connection with the services provided to Bayer HealthCare Pharmaceuticals, as described in the approved written contract. Bayer HealthCare Pharmaceuticals will not reimburse incidental expenses, such as gift shop purchases. Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals incurs no additional costs.

Proof of Service

The Focus Arrangement Owner must be present or otherwise confirm that the services purchased were performed and/or satisfactorily received before payment is generated. The Focus Arrangement Owner formally confirms proof of service by providing documentation (*e.g.*, a timesheet, slide deck or attendee form) related to services being provided. The Focus Arrangement Owner 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 Focus Arrangement Owner must retain the deliverable as proof that the service was performed. The deliverable must be retained for 10 years. The contract must permit Bayer HealthCare Pharmaceuticals 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 Focus Arrangement Owner generating the initial fee-for-service request is responsible for preparing the payment request documentation package, obtaining necessary approvals, and submitting it to the Law and Patents Department. The "Internal Payment Demand (IPD)," and/or "Invoice" must contain the contract number (formatted as "Contract #123"). On the "Internal Payment Demand (IPD)" the contract must be in the "GL Text Field" in order to match the payment with the contract in the Focus Arrangements Database. The fee-for-service payment request documentation package must include, at a minimum, a copy of the executed contract approved by the Law and Patents Department, the approved "Internal Payment Demand (IPD)" or "Invoice."

The direct supervisor reviews the payment request package and determines if the request complies with Bayer HealthCare Pharmaceutical's policies. The approval process for the payment request package must follow the spending approval levels within Corporate U.S. Signature Authorizations Policy 002.20130115.

Focus Arrangements Database Procedures

When the executed contract is returned from the healthcare professional, Law and Patents completes the required data for the Focus Arrangements Database in Efilia. Refer to Policy and Procedure 8, "Focus Arrangements," for information regarding the Focus Arrangements Datasheet and Focus Arrangements Database Procedures.

PROCEDURES SPECIFIC TO SERVICE TYPES WITH A MEETING

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

The Focus Arrangement Owner must follow the Meetings Department procedures if ten (10) or more external and Bayer attendees are invited to an offsite group meeting. The procedures can be found at: http://us.bsp.cnb/apps/BSP/US/BSP-NJ/BSP-NJ.nsf/id/EN_Meetings_Conventions. The online system to initiate a meeting request can be found at: http://www.cvent.com/EVENTS/Websites/Login.aspx?rwstub=b51e9b00-cd4e-4cd8-9c15-25919cf96aba.

RECORD RETENTION

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

AUDIT

All fee-for-service arrangements are subject to auditing by Corporate Audit and Bayer HealthCare Compliance to ensure compliance with this Policy. The government (*e.g.*, OIG, IRS) may also request to audit or review fee-for-service agreements. The Focus Arrangement Owner 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 Focus Arrangement Owner must keep proof of performance for ten years.

18. 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals to disclose to the committee the existence and nature of his or her relationship with Bayer HealthCare Pharmaceuticals during the period of the contract and two years beyond contract termination. It these healthcare professionals serve as speakers or consultants for Bayer HealthCare Pharmaceuticals, 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 HealthCare Pharmaceuticals contract with the healthcare professional. The specific contract language is as follows:

> "The parties acknowledge that Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals , 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 HealthCare Pharmaceuticals 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 29, "State Laws," in this booklet for details of these restrictions.

19. MEDICAL PRACTICE TRAINING

Transactions under this Policy may constitute Focus Arrangements as defined by the CIA. Prior to initiating a transaction covered under this policy you must familiarize yourself with Policy and Procedure 8, "Focus Arrangements."

Bayer HealthCare Pharmaceuticals recognizes the need to provide occasional medical practice training to sales consultants and other employees, contractors, consultants and agents to educate them on medical practice and treatment protocols. However, Bayer HealthCare Pharmaceuticals 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 17, "Fee-for-Service Arrangements."**

Requests for medical practice training may only be initiated by employees at the District Sales Manager level, Product Manager level, or higher. Requests for medical practice training must be coordinated through the Sales Trainer. Individual sales consultants may not initiate requests for medical practice training.

All medical practice training must comply with the following:

- At least five Bayer HealthCare Pharmaceuticals employees, contractors, consultants or agents must participate; "one-on-one" training sessions are not permitted.
- Training must take place in a meeting room or other similar location; training in a doctor's office is not permitted.
- A medical professional may only use a dummy or model, not a human being for demonstration purposes.
- As with all consulting arrangements, payment must represent the fair market value of the teaching services provided.
- A Bayer HealthCare Pharmaceuticals representative may observe an actual medical procedure only through a viewing room or watch a video.

Bayer HealthCare Pharmaceuticals employees may not:

- Select a healthcare professional to conduct medical practice training to encourage him or her to prescribe or purchase Bayer HealthCare Pharmaceuticals 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 get 15 minutes of a physician's time or pay a physician to critique a "sales pitch."
- Attend a live surgery or medical procedure in an operating room, procedure room, or similar venue under any circumstances.

20. CORPORATE SPONSORSHIPS

Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals may provide general funding for a professional association's, patient or other organization's activities or meetings under appropriate circumstances. The recipient organization must have sole control over the sponsorship funding paid by Bayer HealthCare Pharmaceuticals. 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 HealthCare Pharmaceuticals customers or to entities controlled by or affiliated with Bayer customers, except in limited circumstances, approved by Law and Patents, 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 are considered a Focus Arrangement as defined by the CIA and must comply with all requirements of Policy and Procedure 8, "Focus Arrangements."

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.

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 HealthCare Pharmaceuticals does not expect to receive anything in return and where the primary purpose of the event/activity is fundraising/charity.

- 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 or an opportunity to advertise in the organization's publication. 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, rather than fundraising.

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	No	No	Yes
Bayer HealthCare 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 Diabetes Association for general educational programs regarding diabetes 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 HealthCare Pharmaceuticals 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 impermissible because Bayer HealthCare Pharmaceuticals may not provide funding for entertainment, social, cultural, or recreational activities or items at such meeting or event.

Requirements

The recipient organization receiving Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals products, or to reward any recipient organization for a past purchase, prescription, recommendation, or formulary placement of a Bayer HealthCare Pharmaceuticals 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.

PROCEDURES

Requestor

A medical or professional society or other organization may solicit sponsorship through a website, e-mail, or paper mailing. No Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals customer.

Law and Patents Review of Focus Arrangements

For all requests that are Focus Arrangements, the Law and Patents 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; and
- The requirement that all individuals who meet the definition of Covered Persons shall comply with all applicable elements of Bayer HealthCare's Compliance Program, including applicable training related to the Anti-Kickback Statute.

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 and Patents 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 Bayer HealthCare Compliance Officer (or designee) and documented and maintained in the Law and Patents Department.

Law and Patents Review of Non-Focus Arrangements

The Law and Patents 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 and Patents 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 Corporate Audit and Bayer HealthCare Compliance to ensure compliance with this policy. The government (*e.g.*, OIG, IRS) may also request to audit/review sponsorship payments.

21. PROVIDING FREE PRODUCT FOR CHARITABLE PURPOSES

Bayer HealthCare Pharmaceuticals may provide free Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals products. Bayer HealthCare Pharmaceuticals does not provide free product as price terms or in lieu of price discounts.

SCOPE

This policy covers all free products provided under Bayer HealthCare Pharmaceutical's charitable programs for United States destinations only. For hematology product donations to non-US destinations, please refer to the policy "Hematology Product Donation Policy" retained by the Law and Patents 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 27, "Providing Samples at No Charge."

SPECIFIC PROGRAMS

Bayer HealthCare Pharmaceuticals 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 may register by calling 1-888-84BAYER (1-888-842-2937).

- 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 manages certain Patient Assistance Programs internally. Personnel who are responsible for the internally managed programs approve all medications requested via the Patient Assistance Program and are responsible for

implementing Bayer's written procedures for the programs. Patient Assistance Program Management reviews all programs' requests to ensure compliance with Bayer's procedures.

- In addition, Bayer has contracted with third-party vendors to administer some of our 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.

- The Medical Relief Program ("Missionary Program") provides limited quantities of product for physicians treating patients in underdeveloped countries. Physicians must contact the Reimbursement and Patient Assistance Program at 1-800-288-8370 or 1-888-842-2937. Only "acute care" medication, commercially packaged, with good expiration dating is provided.

The Reimbursement and Patient Assistance Program reviews all applications and determines if the request for the medical donation is in compliance with Bayer's policies. The Medical Communications Department reviews the prescription submitted for donated 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 and Patents 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 Corporate Audit and Bayer HealthCare Compliance to ensure compliance with this Policy. The government (*e.g.*, OIG, IRS) may also request to audit/review free goods transactions.

22. DISPLAYS AND EXHIBITS FOR HOSPITALS AND OTHER CUSTOMERS

Transactions under this Policy may constitute Focus Arrangements as defined by the CIA. Prior to initiating a transaction covered under this policy you must familiarize yourself with Policy and Procedure 8, "Focus Arrangements."

Note: Transactions under this Policy are reportable to the federal government under the Patient Protection and Affordable Care Act when implemented. It is each employee, contractor, consultant and agent's responsibility to report accurate, complete and timely data.

Displays of Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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, 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 HealthCare Pharmaceuticals 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 23, "Displays and Exhibits for Non-Customers."

Questions regarding whether a product exhibit or display request constitutes a Focus Arrangement must be directed to the Law and Patents 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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). 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.

If a healthcare professional asks an off-label question about a Bayer HealthCare Pharmaceuticals product, including questions regarding uses that have not received FDA approval, Bayer Sales or Marketing personnel may not answer the question and must refer him or her to the medical/scientific booth or, if there is no booth, to the Bayer HealthCare Pharmaceuticals Medical Communications Department.

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 HealthCare 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 HealthCare Pharmaceuticals Grant Review Committee will make the appropriate determination regarding whether the grant will be approved and/or whether Bayer HealthCare 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 HealthCare 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 HealthCare product, Bayer HealthCare Pharmaceuticals Sales or Marketing personnel must refer the healthcare professional to the Bayer HealthCare Pharmaceuticals medical/scientific booth. The Bayer HealthCare 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 Healthcare 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.

TRAINING

All Bayer HealthCare staff scheduled to work the exhibit booth must be instructed on this Policy during a pre-convention briefing.

PROCEDURES FOR REQUESTING DISPLAYS/EXHIBITS

Focus Arrangement Owner

The Focus Arrangement Owner, at least six weeks before the product display date, provides Sales Operations or his/her immediate manager the "Request to Exhibit" package 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;
- A completed Display Agreement from the entity hosting the display; and
- A completed Funding Request form.

Fees for displays that are paid to a source of sales or referrals of Bayer HealthCare Pharmaceuticals products (*e.g.*, a hospital or wholesaler) are Focus Arrangements under the CIA. Fees paid to a trade society or medical societies (*e.g.*, National Hemophilia Foundation) are not Focus Arrangements 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 HealthCare Pharmaceutical's policies. If appropriate, the Supervisor approves, then forwards the complete request package to the Law and Patents Department.

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

Law and Patents Review

For all product display requests involving payments to actual or potential Bayer HealthCare Pharmaceuticals customers, the Law and Patents Department generates a written agreement that meets the requirements for Focus 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

- The requirement that all individuals who meet the definition of Covered Persons shall comply with all applicable elements of Bayer HealthCare's Compliance program, including applicable training related to the Anti-Kickback Statute.

The Law and Patents 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 and Patents 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 HealthCare Pharmaceuticals. Any deviation from the fair market value methodology and the rationale for such deviation must be approved by the Bayer HealthCare Compliance Officer (or designee) and documented and maintained in the Law and Patents Department.

Law and Patents must send each party to the Focus Arrangement (*e.g.*, the entity hosting the event), along with an approved contract, a (1) copy of Bayer HealthCare's Code of Conduct and (2) 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 and Patents must document that these documents were sent.

Focus Arrangements Database

Law and Patents must complete the required data for the Focus Arrangements Database in Efilia. Refer to Policy and Procedure 8, "Focus Arrangements," for information regarding the Focus Arrangements Database Procedures.

Proof of Service

The Focus Arrangement Owner must confirm that he/she conducted the display or exhibit. The Focus Arrangement Owner or Bayer employee 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 Focus Arrangement Owner is unable to confirm this (*e.g.,* Requestor was unable to attend due to illness), the Focus Arrangement Owner must document the reason that the event did not occur.

Payment Generation

The Focus Arrangement Owner generating the initial display/exhibit request is responsible for preparing the payment request documentation package, obtaining necessary approvals, and submitting it to the Law and Patents Department. The "Internal Payment Demand (IPD)," and/or "Invoice" must contain the contract number (formatted as "Contract #123"). On the "Internal Payment Demand (IPD)" the contract must be in the "GL Text Field" in order to match the payment with the contract in the Focus Arrangements Database. The display/exhibit payment request documentation package must include, at a minimum, a copy of the executed contract approved by the Law and Patents Department, the approved "Internal Payment Demand (IPD)" or "Invoice."

The direct supervisor reviews the payment request package and determines if the request complies with Bayer HealthCare Pharmaceutical's policies. The approval process for the payment request package must follow the spending approval levels within Corporate U.S. Authorization Policy 002.20130115.

RECORD RETENTION

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

AUDITS

All displays and exhibits are subject to auditing by Corporate Audit and Bayer HealthCare Compliance to ensure compliance with these policies. The government (*e.g.,* OIG, 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.

23. DISPLAYS AND EXHIBITS FOR NON-CUSTOMERS

Displays of Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 22, "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 HealthCare Pharmaceuticals employee.

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

If a healthcare professional asks an off-label question about a Bayer HealthCare Pharmaceuticals product, including questions about uses that have not received FDA approval, Bayer Sales or Marketing personnel may not answer the question and must refer him or her to the medical/scientific booth or, if there is no scientific booth at the location, to the Bayer HealthCare Pharmaceuticals Medical Communications Department.

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 HealthCare 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 HealthCare Pharmaceutical'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 HealthCare Pharmaceuticals 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.

TRAINING

All Bayer HealthCare Pharmaceuticals staff scheduled to work the exhibit booth must be instructed on this Policy during a pre-convention briefing.

PROCEDURES FOR REQUESTING DISPLAYS/EXHIBITS

Requestor

The Requestor, at least six weeks before the product display date, provides Sales Operations or his/her manager the "Request to Exhibit" package 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;
- A completed Agreement from the entity hosting the display or exhibit; and
- A completed Funding Request form.

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 HealthCare Pharmaceutical's policies. If appropriate, the Supervisor approves, then forwards the complete request package to the Law and Patents Department.

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

Law and Patents

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

RECORD RETENTION

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

AUDITS

All displays and exhibit are subject to auditing by Corporate Audit and Bayer HealthCare Compliance to ensure compliance with these policies. The government (*e.g.*, OIG, IRS) may also request to audit/review commercial exhibit booth documentation. If a Bayer HealthCare Pharmaceuticals 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.

24. CORPORATE MEMBERSHIPS

Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceutical'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 HealthCare Pharmaceuticals wishes to become a member of such an organization, it is the policy of Bayer HealthCare Pharmaceuticals to establish these memberships for the Corporation or Division and not for individual Bayer HealthCare Pharmaceuticals employees.

Legislative policy groups offer Bayer HealthCare Pharmaceuticals relevant industry information, provide Bayer HealthCare Pharmaceuticals visibility within the pharmaceutical industry, and promote goodwill within organizations that maintain a political voice. Membership in medical and patient organizations allows Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals may provide to a patient advocacy group or medical organization. Such payments must comply with Policy and Procedure 26, "Medical Education Grants (Including Continuing Medical Education)," and Policy and Procedure 25, "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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceutical'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 HealthCare Pharmaceuticals customers, entities controlled or legally affiliated with Bayer HealthCare Pharmaceuticals customers, or other entities that may purchase, order, refer, use, prescribe, or recommend Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals products or used as a price term.

It is Bayer HealthCare Pharmaceutical's policy to pay fair market value for corporate memberships. Thus, Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals.

The membership must be for a Bayer Division or the Corporation, not an individual employee. Individual Bayer HealthCare Pharmaceuticals employees may attend the organization's events to gain knowledge of the subject topic, interact with fellow attendees, demonstrate Bayer HealthCare Pharmaceutical's general support for the advocacy effort and/or the organization's mission, etc.

PROCEDURES

Requestor

The Bayer HealthCare Pharmaceuticals "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 HealthCare Pharmaceutical'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 Public Policy and Government Affairs 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 Public Policy and Government Affairs Department reviews all documentation and makes an independent judgment as to whether the Corporate Membership is consistent with Bayer HealthCare Pharmaceutical's policies. It also confirms that the membership request does not duplicate an existing membership with the same organization. If appropriate, the Public Policy and Government Affairs Department approves by signing the "Bayer Certification for Corporate Membership" form and "Internal Payment Demand" and forwards both documents to the Law and Patents Department.

If the Public Policy and Government Affairs Department does not approve the request, it informs the Requestor that the proposed request has been denied.

Law and Patents Department

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

If the Law and Patents Department does not approve the request, it informs the Requestor that the proposed request has been denied.

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 Corporate Audit and Bayer HealthCare Compliance to ensure compliance with these policies. The government (*e.g.*, OIG, 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:_____

Public Policy and Government Affairs Certification and Approval

Printed name:_____Date:_____

Signature:_____

Law and Patents 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.

25. CHARITABLE CONTRIBUTIONS (OTHER THAN FREE BAYER PRODUCTS)

Transactions under this Policy may constitute Focus Arrangements as defined by the CIA. Prior to initiating a transaction covered under this Policy you must familiarize yourself with Policy and Procedure 8, "Focus Arrangements."

Note: Transactions under this Policy are reportable to the federal government under the Patient Protection and Affordable Care Act when implemented. It is each employee, contractor, consultant and agent's responsibility to report accurate, complete and timely data.

Bayer HealthCare Pharmaceuticals provides charitable contributions to support legitimate medical research, indigent care programs, patient education, public education, community organizations within a Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals does not receive anything of value in return. Charitable contributions include, but are not limited to, cash or cash equivalents (*e.g.*, checks, gift certificates) 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, hospital) 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 HealthCare Pharmaceuticals does not expect to receive anything in return and where the primary purpose of the event/activity is fundraising/charity rather than education.

- A **sponsorship** is funding provided to support the activities of a professional, medical or patient association or organization where Bayer HealthCare Pharmaceuticals receives something of value, such as banners or signage at a conference or an opportunity to advertise in the organization's publication.

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

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 HealthCare Pharmaceuticals customers unless the customer is a non-profit entity and the request is for patient support related programs such as camps for children with diabetes or hemophilia. The Bayer HealthCare Pharmaceuticals 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 a Focus Arrangement as defined by the CIA and must comply with all requirements of Policy and Procedure 8, "Focus Arrangements."

Bayer HealthCare Pharmaceuticals will not make charitable donations to individuals, political parties or causes, or religious groups for religious purposes. In addition, it is Bayer HealthCare Pharmaceuticals policy not to provide charitable donations to Bayer Healthcare Pharmaceuticals customers or physician practice groups, or to non-profit entities controlled by or affiliated with Bayer HealthCare Pharmaceuticals customers or physician practice groups, except in the limited circumstances referenced above.

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 21, "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 HealthCare Pharmaceuticals business community and other charitable events that directly benefit patients which are all considered charitable contributions under Bayer HealthCare Pharmaceutical's 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 HealthCare Pharmaceuticals receives nothing of value in return other than an acknowledgement of Bayer HealthCare Pharmaceutical'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 HealthCare Pharmaceuticals customer (except in the limited circumstances referenced above) or physician practice group, or an organization controlled by or affiliated with a Bayer HealthCare Pharmaceuticals 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 any Bayer HealthCare Pharmaceuticals products.
- Intended to encourage the recipient to order, prescribe, or recommend Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals.

Any questions from a customer regarding a charitable contribution request must be addressed to the Contribution Administrator.

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 HealthCare Pharmaceutical'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 HealthCare Pharmaceuticals may display at the event.

Limited Attendance at Events

Bayer HealthCare Pharmaceuticals, 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 HealthCare Pharmaceuticals employees, as approved by the Vice President for Public Policy and Government Affairs Department (with input from the Compliance Officer, as requested), may be permitted to attend such events in order for Bayer HealthCare Pharmaceuticals to demonstrate support for the patient group. No more than three Bayer HealthCare Pharmaceuticals representatives from sales and marketing may attend. This three-person restriction does not apply to Bayer

HealthCare Pharmaceuticals attendees who are not part of the commercial organization (such as Law and Patents, Government Affairs, Public Policy, Regulatory, or Medical Affairs). The representative(s) of Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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, diabetes testing, blood pressure screening, and mammograms.

Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals may provide disease state brochures to the organization for distribution at the event upon approval of the organization. However, Bayer HealthCare Pharmaceuticals may not provide product-specific information of any type.

- Bayer HealthCare Pharmaceuticals may provide educational, disease or patient treatment related items to support the event in compliance with Policy and Procedure 16, "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 and Patents Department accept a charitable contribution request after the event has occurred.

Contribution Manager

The Charitable Contribution request will first be reviewed by the Contribution Manager. If the request is deemed to be complete, 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 Contribution 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

The Charitable Contribution Review Committee ("Review Committee") is comprised of members from Medical Affairs, Public Policy and State Government Affairs, and Law and Patents. 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, and 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 and Patents representative is not present, Law and Patents must review the charitable contribution before it is approved.

Legal Review of Focus Arrangements

For all charitable contribution requests that are Focus Arrangements, the Law and Patents 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; and
- The requirement that all individuals who meet the definition of Covered Persons shall comply with all applicable elements of Bayer HealthCare's Compliance Program, including applicable training related to the Anti-Kickback Statute.

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 and Patents Department 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 Compliance Officer and documented and maintained in the Law and Patents 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.

Contribution Manager Post Approval Documentation

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

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

Approval of Charitable Contribution Focus Arrangements

For approved charitable contribution requests that are Focus Arrangements, the Contribution Administrator must send the contribution recipient the approved Letter of Agreement, with a copy of Bayer HealthCare's Code of Conduct and 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 Contribution Administrator must document that the documents were sent.

RECORD RETENTION

The Public Policy and Government Affairs Department will retain the payment request package for a period of 10 years.

AUDITS

All charitable contributions are subject to auditing by Corporate Audit and Bayer HealthCare Compliance to ensure compliance with these policies. The government (*e.g.*, OIG, IRS) may also request to audit or review charitable contributions.

26. MEDICAL EDUCATION GRANTS (INCLUDING CONTINUING MEDICAL EDUCATION)

Transactions under this Policy may constitute Focus Arrangements as defined by the CIA. Prior to initiating a transaction covered under this Policy you must familiarize yourself with Policy and Procedure 8, "Focus Arrangements."

Note: Transactions under this Policy are reportable to the federal government under the Patient Protection and Affordable Care Act when implemented. It is each employee, contractor, consultant and agent's responsibility to report accurate, complete and timely data.

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 HealthCare Pharmaceutical'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 HealthCare Pharmaceuticals prohibits offering a medical education grant to encourage the recipient to prescribe, purchase, order, use or recommend Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals products, to encourage off-label use, or reward referrals for Bayer HealthCare Pharmaceuticals products.

Bayer HealthCare Pharmaceuticals 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 grants. 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 HealthCare Pharmaceuticals does not expect to receive anything in return and where the primary purpose of the event/activity is fundraising/charity rather than education.

- A **sponsorship** is funding provided to support the activities of a professional, medical or patient association or organization where Bayer HealthCare Pharmaceuticals receives something of value, such as banners or signage at a conference or an opportunity to advertise in the association's publication.

- A **medical education grant** is funding provided to support an event where the primary focus is educating the participants/attendees, rather than fundraising. Refer to Policy and Procedure 26, "Medical Education Grants (Including Continuing Medical Education)."

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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals. 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

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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceutical's funding of the program and any significant relationships between the vendor and Bayer HealthCare Pharmaceuticals;
- Financial or other relationships between individual presenters or moderators and Bayer HealthCare Pharmaceuticals;
- Any limitations on information that is presented at the programs, such as data that represent ongoing research, interim analysis, preliminary data or unsupported opinion;
- When a Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals product(s).

The following criteria also apply to CE/CME programs:

- Funds from Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals representatives may not distribute invitations on their own to a Bayer HealthCare Pharmaceuticals supported CME event to healthcare professionals. If the CME provider requests Bayer HealthCare Pharmaceutical's help in writing (*e.g.,* by letter) to distribute supplemental invitations, Bayer HealthCare Pharmaceuticals may distribute these invitations on the CME provider's behalf. 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals may not provide meals directly at a CME event. The CME provider at its own discretion may apply the financial support provided by Bayer HealthCare Pharmaceuticals to provide meals to all program participants.

- Speakers at a Bayer HealthCare Pharmaceuticals supported CME program must disclose any current or previous relationship with Bayer HealthCare Pharmaceuticals, (*e.g.*, consultant, paid investigator, member of a Bayer HealthCare Pharmaceuticals 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 HealthCare 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HEALTHCARE PHARMACEUTICALS 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 HealthCare Pharmaceuticals products,** regardless of whether or not the event is sponsored in whole or in part by Bayer HealthCare Pharmaceuticals.

1. Bayer HealthCare Pharmaceuticals Attendance

    - Medical Science Liaisons may attend such programs.

    - Sales and Marketing personnel may not attend such programs unless the request has been reviewed and approved in writing in advance of the program by their manager after consultation with the Law and Patents Department. Written approval may be made via electronic mail. Separate approval must be obtained for each event.

    - Bayer HealthCare Pharmaceuticals representatives attending such programs may not ask or "plant" questions in the audience that are likely to lead to off-label discussion.

2. Bayer HealthCare Pharmaceuticals Independence

Bayer HealthCare 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 HealthCare Pharmaceuticals or Bayer HealthCare Pharmaceuticals products

    - Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals.

    - If the program includes events which relate to an approved use of Bayer HealthCare Pharmaceuticals products and the

- Event sponsor has provided the opportunity to multiple pharmaceutical companies to display at the event, Bayer HealthCare Pharmaceuticals employees may display or exhibit at the program. For more information, see Policy and Procedure 22, "Displays and Exhibits at Hospitals and Other Customers" and Policy and Procedure 23, "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 HealthCare Pharmaceuticals, 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 HealthCare Pharmaceuticals may audit or review the use of the grant.
  - Provides a detailed budget describing planned usage of requested grant.

- Confirms that Bayer HealthCare Pharmaceutical's 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 Bayer HealthCare Pharmaceuticals products; or
- Intended to encourage the recipient to order, prescribe, or recommend Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals by the recipient, with the exception of disclosure in program materials that the program is funded by Bayer HealthCare Pharmaceuticals; 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 17, "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 grant 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 Focus Arrangement. A grant request should be considered a Focus Arrangement 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 a Focus Arrangement must be directed to the Law and Patents Department, which makes the final determination whether the grant is a Focus Arrangement.

If the grant request is deemed to be complete, within budget and strategic 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 and Patents. Sales and Marketing personnel do not participate in the Grant Review Committee; however, they may provide a strategic plan relating to the subject matter of grants to be considered.

The Grant Review Committee 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 HealthCare 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 and Patents Review of Focus Arrangements

For all grant requests that are Focus Arrangements, the Law and Patents 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; and
- The requirement that all individuals who meet the definition of Covered Persons shall comply with all applicable elements of Bayer HealthCare's Compliance Program, including applicable training related to the Anti-Kickback Statute.

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 and Patents 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 Bayer HealthCare Compliance Officer (or designee) and documented and maintained in the Law and Patents 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

Minutes will be prepared for each Grant Review Committee meeting. The minutes 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 Therapeutic Grant Manager following the meeting. The Grant Manager is responsible for updating the electronic system with the decision.

Grant Approval of Focus Arrangements

For approved grant requests that are Focus Arrangements, the Grant Manager must send the grant recipient the approved Letter of Agreement, with a copy of Bayer HealthCare's Code of Conduct and 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; and
- The requirement that all individuals who meet the definition of Covered Persons shall comply with all applicable elements of Bayer's Compliance program, including applicable training related to the Anti-Kickback Statute.

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. The proof of service must be retained by the Grant Manager for ten years.

Grant Approval of Non-Focus Arrangements

If the approved grant request is not a Focus Arrangement as determined by the Law and Patents 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.

Focus Arrangements Database Procedures

The Grant Manager must complete the required fields for a Focus Arrangement in the Grant database. Refer to Policy 8 "Focus Arrangements" for information regarding the Focus Arrangements Database Procedures.

RECORD RETENTION

The Medical Affairs Department will retain the payment request package for a period of 10 years. Proof of performance 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 Corporate Audit and Bayer HealthCare Compliance to ensure compliance with these policies. The government (*e.g.*, OIG, IRS) may also request to audit/review medical education grant payments.

27. PROVIDING SAMPLES AT NO CHARGE

Bayer HealthCare Pharmaceuticals may provide a limited number of product samples of Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 21, "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:

(1) The identity and quantity of drug samples requested; and

(2) 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

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, 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.

28. PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)

Legislative, regulatory, and enforcement authorities are aggressively pursuing greater disclosure and transparency of financial relationshipsbetween HCPs, HCO's and pharmaceutical, biotech, medical device, and diagnostic companies. On March 23, 2010, the President signed into law what is now known as the Patient Protection Affordable Care Act (PPACA). The final rule for PPACA was published on February 1, 2013. This statute, as amended, sets forth new federal disclosure and transparency requirements including:

- 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.

- 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.

It is the responsibility of each Bayer HealthCare Pharma employee to accurately and completely capture required information and timely report data to the Company. 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 Division's State Law Policies and Procedures governing payments to physicians and other health care professionals and entities, among other topics, to determine what payment information must also be disclosed in certain states.

Physician Payment Sunshine Act

Under the Physician Transparency Provisions of the PPACA, payments and other transfers of value to "covered recipients" must be disclosed unless one of a limited number of narrow exceptions applies. Additionally, physician 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. Under the final rule, the first disclosure to the Federal Government is due March 31, 2014. The disclosure will cover transfers of value made on or after August 1, 2013 thru December 31, 2013. Subsequent disclosures are due annually on the 90th day of each year covering payments made in the prior calendar year. The information disclosed will be made public via a to-be-named website in 2014.

Covered recipients are defined under the Sunshine Act to mean U.S. licensed physicians and teaching hospitals, unless the physician is a physician who is an employee of Bayer HealthCare. 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 of services, stock, stock option, or any other ownership interest, dividend, profit or other return on investment)
- Nature of Payment or transfer of value:
  - Consulting fee
  - Compensation for services other than consulting including serving as faculty or as a speaker at an event other than continuing education program
  - Honoraria
  - Gift
  - Entertainment
  - Food and beverages
  - Travel and lodging
  - Education
  - Research

- Charitable contributions
- Royalty or license
- Current or prospective ownership or investment interest
- Compensation for services as faculty or as a speaker at for an unaccredited and non certified continuing education program.
- Compensation for services as faculty or as a speaker at for an accredited and certified continuing education program.
- Grant
- Space rental of 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);
- For drugs and biological, applicable manufacturers must report the name under which drug is or was marketed and the relevant National Drug Code(s) (NDC);

Excluded Items

There are a limited number of transactions that are excluded from the definition of a covered "payment or other transfer of value," including (among others):

- A transfer of anything valued under $10, unless the total amount transferred to, requested by, or designated on behalf of the physician or teaching hospital in the same calendar year exceeds $100. Importantly, however, Bayer HealthCare will not be able to determine until the end of the calendar year whether it has exceeded the $100 limit. Accordingly, even payments under $10 must be tracked. (Beginning in 2014, the $100 limit will be indexed to inflation);
- Product samples for patient use that are not intended to be sold;
- Educational materials that directly benefit patients or are intended for patient use;
- Short-term loans for a covered device, unless the trial period exceeds 90 days;
- Discounts (including rebates); and
- In-kind items used for charity care.

Prescription Drug Sample Transparency Provision

The Prescription Drug Sample Transparency provision requires Bayer HealthCare to disclose the quantity of drug samples by product name requested by and distributed to practitioners. The information will 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). The first disclosure was submitted to the Federal Government on October 1, 2012. Subsequently disclosures are made annually on or before April 1st each year.

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

29. STATE LAWS – OVERVIEW

		State Law Overviews	Bayer Actions
Limits/Prohibitions	California	Annually declare adherence to compliance program including the annual spend limit of $1,000 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	Bayer has instituted a "NO SPEND" policy
	Vermont	Prohibits gifts, including but not limited to meals and charitable donations to HCPs	No meals, gifts or charitable donations to Vermont HCPs
Annual/Quarterly Disclosure	Connecticut	Adopt compliance program; adopt training program; conduct training and regular audits to monitor compliance	Adopt compliance program
	D.C.	Report payments, fee-for-service, expenses, meals and gifts (greater than >$25), provided to HCPs Additionally report: DTC advertising, salaries of employees	Track and report all relevant spend through internal Bayer Spend Source Systems (*e.g.*, Concur, SAP)
	Massachusetts	Report fees, payments, subsidies or other economic benefit (greater than >$50), and any non-compliance activity	
	Minnesota	Report expenditures including fee-for-service payments and expenses, to consultants and compensation to sponsor of medical conference, professional, meeting, educational program (greater than >$100)	
	West Virginia	Report expenditures, including fee-for-service payments, expenses, meals and gifts provided to HCPs (less than < $100). Additionally report: DTC advertising, direct promotion, payments to pharmacies and patient groups in West Virginia	
	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;
	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	Track and report all "allowable expenditures" and disclose annually.
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 Disclosure	VT 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.
	Maine, New Mexico Texas,	Manufacturers must report AMP and Best Price (BP). TX=AMP & price paid by wholesalers	

29. STATE LAWS:

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

A. COMPLIANCE PROGRAM AND SPENDING LIMITS

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 $1,000.

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://pharma.bayer.com/scripts/pages/en/about_us/healthcare_compliance/index.php 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 MediCal.

29. STATE LAWS:

Connecticut – Compliance Program

COMPLIANCE PROGRAM

Connecticut requires pharmaceutical 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 October 5, 2012, no regulations have been implemented by the Connecticut Department of Consumer Protection, the agency tasked with enforcing the Connecticut compliance program law.

29. 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. The reporting requirements and exemptions are similar to those in the West Virginia marketing disclosure law.

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 through radio, television, magazines, newspapers, direct mail, and telephone communications.

Marketing to D.C. Healthcare Professionals and Entities

The report must also disclose the value, nature, purpose and recipient of the following expenditures 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, hospitals, nursing facilities and clinics):

- Educational or informational programs;
- 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.

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.

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.

Exemptions

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; 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.

APPLYING THE REPORTING LIMITS

The law describes the $25 dollar per day reporting limit as the "value" of the gift, meal, benefit, etc. The value is what the recipient would pay for the item (*e.g.*, retail value).

Fees and payments that must be disclosed include, but are not limited to, payments for grants, speakers, consultants, advisory boards, data purchases, etc. You also must report the value of medical textbooks given to individuals, institutions, departments, or physician practice groups.

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 Board of Pharmacy. 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, physician consultants, and promotional speakers.**

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. 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/node/185802 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 (for an initial license fee) or $165 (for a biennial renewal fee) made payable to "D.C. Treasurer." Credit card payment will not be accepted;
- Two (2) identical passport type photographs (2x2 inches in size);
- 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 criminal background check results from an outside jurisdiction or, alternatively, an appointment request form for a Livescan fingerprinting appointment. Each new applicant for licensure must obtain a criminal background check, and applicants for renewal of a license must obtain State and FBI criminal background checks.

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. Therefore, the initial licenses of employees who obtained licensure at the time the law took effect expired on February 28, 2010 and will be up for renewal on February 28, 2012. Such employees will receive a renewal notice from the Board. 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:

1. Complete a minimum of fifteen (15) credit hours of approved continuing education during the period preceding the date the license expires;

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

3. 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:

1. Name and address of the sponsor of the program;

2. Name of the program, its location, a description of the subject matter covered, and the names of the instructors;

3. Dates on which the applicant attended the program;

4. Hours of credit claimed; and

5. 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 202-724-8938 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 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 Bayer HealthCare Compliance Officer or the Law and Patents 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 Impact system. Those not on the Impact 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 IMPACT 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 Bayer HealthCare Compliance Officer or the Law and Patents 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

29. 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://www.govengine.com/stategov/louisiana.html. 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" 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 gifts to state employees in Louisiana. 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.

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.

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 Public Policy and State Government Affairs 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 Public Policy and Government Affairs 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 and Patents 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.

1. 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.

2. 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 HealthCare 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 HealthCare Pharmaceuticals and the State agency obligates Bayer HealthCare 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 and Patents Department before Bayer HealthCare Pharmaceuticals enters into a financial arrangement with, reimburses travel expenses for, and/or engages any Louisiana healthcare professional as a consultant, advisor or speaker.

29. 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 to covered recipients as defined below.

Because Massachusetts has not yet issued its final regulations that include the definition and the reporting requirements for "modest" meals, we will not be changing the Policy on out of office meals with MA licensed HCPs at this time. Bayer HealthCare Pharmaceutical's Policy only allows for in office meals.

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 September 19, 2012, the Department passed an emergency rule that temporarily 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.

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; and
- The provision of or payment for modest meals and refreshments to health care practitioners in limited situations, provided that the company satisfies additional requirements, as described below, that are specific to the provision of such meals.

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 October 16, 2012, 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/provider/licensing/programs/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. Pursuant to emergency regulations passed by the Department in September 2012, reporting of such payments is not required under Department regulations after reporting for the calendar year 2012 has closed. Reporting such payments is still required by the applicable Massachusetts statutes, to the extent the disclosures are not required by the federal Physician Payments Sunshine Act or other federal law under which the information disclosed may be obtained by the Department from a federal agency.

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.

FEE

Each disclosure report must be accompanied by a $2000 fee.

29. 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 any practitioner licensed in the State of Minnesota. **To ensure that Bayer HealthCare does not exceed the $50 annual limit, you must not provide gifts or meals or other items of value to any practitioner licensed in the State of Minnesota or anyone employed by them.**

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. To ensure that Bayer does not exceed the $50 annual limit, you must not provide gifts, meals, or other items of value – including textbooks to any practitioner licensed in the State of Minnesota or anyone employed by them. Payments to Minnesota practitioners for "marketing surveys" conducted by Bayer and/or where Bayer pays the healthcare practitioner directly are not permitted because the Minnesota Board of Pharmacy interprets such payments as gifts.

However, 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 Minnesota prohibition does not apply, to fee-for-service arrangements and certain other payments described below in Subsection B, Cost Reporting.

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 HealthCare combined (Bayer HealthCare Pharmaceuticals, Bayer Dermatology and Animal Health), not to individual Bayer employees.

APPLYING THE LIMITS

To ensure that Bayer does not exceed the $50 annual limit, you must not provide gifts or meals or other items of value to any practitioner licensed in the State of Minnesota or anyone employed by them.

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 practitioners for these services must be reported to the State as described below.

Textbooks are included in the $50 limit. Thus, textbooks 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 15, "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

Effective January 1, 2012, the Physician Payment Sunshine Act (PPSA), also known as Patient Protection and Affordable Care Act (PPACA) has preempted any state law that requires a manufacturer to disclose the type of information covered by the federal report. Since the vast majority of the data that is reported under the Minnesota law is information covered by the federal report, the Minnesota Board of Pharmacy has determined that for calendar year 2012 it will not require Manufacturers to report any data. However, the Bayer policy prohibiting meals and gifts in Minnesota remains in effect since the gift ban portion of the law has not been preempted.

Bayer employees must internally report all payments, regardless of dollar amount, to Minnesota practitioners (as defined above) via the appropriate reporting method (*e.g.*, Concur).

Thus, Bayer HealthCare (Bayer HealthCare Pharmaceuticals, Bayer Dermatology, and Animal Health) must report cumulative payments of $100 or more to any Minnesota practitioner. 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.

Note that payments for "marketing surveys" are interpreted by the Minnesota Board of Pharmacy as "gifts." Therefore, Bayer must not utilize Minnesota-licensed practitioners for marketing surveys for which compensation is made by Bayer or a third party vendor administering the survey. Under the Bayer HealthCare 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.

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 Minnesota or any other 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 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 Minnesota or any other State with similar reporting requirements or payment limits.

29. 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 Nevada statutes took effect October 1, 2007. Implementing regulations were promulgated on January 30, 2008. The regulations contain a compliance form that must be completed annually and submitted to the Nevada Board of Pharmacy by June 1 of each year.

29. 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.

29. 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 HealthCare's Compliance Policy and Procedure 15, "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 HealthCare's Compliance Policy and Procedure 14, "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.

29. STATE LAWS:

Texas – Price Disclosure

Manufacturers of prescription drugs sold in Texas must report to the Interagency Council on Pharmaceuticals Bulk Pricing (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 Health 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 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.

29. STATE LAWS:

Vermont – Price Disclosure and 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 payors 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.htm. Please see the sample Short Form at the end of this procedure.

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:* The pharmaceutical marketer must provide the Short Form to the Vermont prescriber. 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.ashp.org/ahfs.

MODEL DISCLOSURE FORMS

Information for Vermont Prescribers of Prescription Drugs (Short Form):

Brand Name (Chemical Name)

- This list does not imply that the products on this chart are interchangeable or have the same efficacy or safety. Please refer to each product's FDA-approved label and indication for further information.
- The prices listed below are Average Wholesale Prices ("AWP") as established and made available to the public by a third party publisher or as calculated from data made available to the public by a third party publisher. The price paid by consumers may be higher or lower than the prices listed below. Information about the AWP of these drugs is being provided to Vermont prescribers pursuant to Vermont law, to give you information about the relative prices of marketed drugs in the same therapeutic class.
- The prices listed here do not necessarily reflect price per dosage, price per course of treatment, or the cost effectiveness of all the products listed. For simplicity, only the smallest package sizes available for each product are included.

Price Comparison: Marketed product and lowest dosage of other products in the same therapeutic class.*

Marketed Products	AWP
Brand Name + dosage	$

Other Products:

	$

Prices shown are for the lowest dosage of each product. Prices for multi-source products have been averaged. Multiple forms of the same product *(e.g.* tabs and caps) have been considered one product, and the prices have been averaged. Chewable forms of the product are not included.

*For additional price comparison information see:
http://www.compliance.bayerweb.com/VermontAWP.htm

_____ *is the source of this information.*

_____ *(date)*

Information for Vermont Prescribers of Prescription Drugs (Long Form)

Brand Name (Chemical Name)

- This list does not imply that the products on this chart are interchangeable or have the same efficacy or safety. Please refer to each product's FDA-approved label and indication for further information.
- The prices listed below are Average Wholesale Prices ("AWP") as established and made available to the public by a third party publisher or as calculated from data made available to the public by a third party publisher. The price paid by consumers may be higher or lower than the prices listed below. Information about AWPs of these drugs is being provided to Vermont prescribers pursuant to Vermont law, to give you information about the relative prices of marketed drugs in the same therapeutic class.
- The prices listed here do not necessarily reflect price per dosage, price per course of treatment, or the cost effectiveness of all the products listed. For simplicity, only the smallest package sizes available for each product are included.

				AWP	
Product Name	Manufacturer	NDC or UPC	Pkg Size	Package	Tablet
Marketed Product (list from lowest to highest dosage)				$	$
Brand Name + dosage	BAYER PHAR				
Other Products (list products in alphabetical order, each from the lowest to the highest dosage)					

_____ *is the source of this information.*

_____ *(date)*

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.

Beginning April 1, 2012, 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, 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.

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 heathcare 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

Effective July 1, 2009, 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, please review the Vermont state link provided in this policy, or contact the Disclosure Law and Transparency Operations Team.

ALLOWABLE EXPENDITURES

Certain expenditures are allowed: *(items with asterisks must be reported to the extent they are not preempted by the federal Physician Payments Sunshine Act,* 42 U.S.C. §1320a-7h)

1. ** Payment to a sponsor of a "significant" educational, medical, scientific or policy-making conference or seminar as long as the 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. Effective July 1, 2010, such payment may be used by the sponsor at its discretion to provide meals and other food for all conference participants.

2. ** 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.

3. ** Certain expenses associated with a bona fide clinical trial, as further detailed in the Vermont law and applicable guidance.

4. ** 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.

5. ** Effective July 1, 2010, 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.

6. 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.

7. ** Certain other reasonable fees, payments, subsidies or other economic benefits provided at fair market value.

8. ** Effective July 1, 2012, 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.

9. ** Effective July 1, 2012, 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. ** Effective July 1, 2011, prescribed products distributed free of charge or at a discounted price pursuant to a manufacturer-sponsored or manufacturer-funded patient assistance program.

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

12. Effective July 1, 2010, 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.

13. Effective July 1, 2010, coffee, snacks and refreshments at a conference or seminar booth.

14. ** 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.

15. ** 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.

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. 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, IMPACT, 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.

DISCLOSURE OF SAMPLES AND OTHER ITEMS PROVIDED TO A HEALTH CARE PROVIDER FOR FREE DISTRIBUTION

Beginning April 1, 2012, and annually thereafter, a manufacturer 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, IMPACT, etc).

COMPLIANCE OFFICER FORM

Bayer HealthCare 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: www.atg.state.vt.us/.

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 HealthCare 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 (BHCP, Bayer Dermatology, Radiology and Interventional, Diabetes Care, and Consumer Care). The Attorney General refers to that person as the "compliance officer."

April of each year: Bayer Pharmaceuticals must submit marketing disclosure reports for all covered Bayer entities (BHCP, Bayer Dermatology, Radiology and Interventional, Diabetes Care, and Consumer Care). Bayer HealthCare will report for the preceding calendar year. The state disclosure will be conducted by the Disclosure Law and Transparency Operations Team.

Beginning April 1, 2012 and every April 1 thereafter: Bayer HealthCare must report samples of prescribed products for the preceding calendar year for all covered Bayer entities (BHCP, Bayer Dermatology, Radiology and Interventional, Diabetes Care, and Consumer Care).

REGISTRATION FEE

Manufacturers of pharmaceuticals who report expenditures above $0 will be required to pay a $250.00 registration fee on January 1, 2012 for the six-month period from July 1, 2011 through December 31, 2011. Beginning January 1, 2013 and annually thereafter, these manufacturers will pay a $500.00 registration fee.

For further information, please refer to the Laws and the Vermont Office of the Attorney General Guidance, which can be found at http://www.atg.state.vt.us/issues/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 drug price disclosure requirement took effect July 1, 2007. 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 beginning on November 1, 2008 and every quarter thereafter 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 Office of Vermont Health Access Program for beneficiaries of federal and Vermont state healthcare programs must pay an annual fee of 0.5 percent of the Office's prescription drug spending from the previous year. The fee is payable to the Vermont Agency for Human Services.

29. STATE LAWS:

West Virginia – Promotional Cost Reporting

Manufacturers of prescription drugs dispensed in West Virginia who employ direct or use marketing representatives must report their advertising costs to the Governor's Office of Health Enhancement and Lifestyle Planning ("GOHELP"). Under the Prescription Drug Advertising Expense Reporting 210-01 which became effective April 30, 2010 manufacturers must report all expenditures for advertising and direct promotion of prescription drugs that are made through radio, television, magazines, newspapers, direct mail or telephone communications to consumers, prescribers, pharmacies, patient support or advocacy groups within West Virginia.

West Virginia regulations specify the exact information that must be annually reported to "GOHELP" and contain reporting forms on which the information must be submitted. Information includes:

- The total number of West Virginia prescribers to whom the manufacturer has provided, directly or indirectly, gifts, grants, or payments of any kind in excess of $100.00 for the purpose of advertising prescription drugs. Annual payments that total more than the amount on the reporting form must be reported in increments of $2,500 until all payments of any kind to prescribers have been reported;

- Direct-to-consumer (DTC) advertising reaching or targeting West Virginia consumers to include the type of advertising used (*e.g.*, radio, magazine, direct mail, etc.) and the total amount expended for advertising; and

- Payments to West Virginia consumers, prescribers, pharmacies and patient support and advocacy groups will be included in the total amount spent on advertising and promotion during the calendar year.

To the extent that pharmaceutical manufacturers do not maintain separate records of expenditures for advertising prescription drugs within West Virginia, manufacturers may calculate the advertising expenditures by dividing the West Virginia population (as determined in accordance with data available from the United States Census Bureau) receiving the DTC advertising by the national or regional population for which the manufacturer maintains records. The quotient obtained by this calculation must then be multiplied by the total amount the manufacturer spent on advertising nationally or in a specific region. Manufacturers are required to attach the calculations to the disclosure form.

The following are exempt from the reporting requirements:

- Free drug samples intended for free distribution to patients;

- Payments for "bona fide" clinical trials;

- Scholarship funds or other support for medical students, residents or fellows to attend a significant educational, scientific or policy-making conference of a specialty medical or other professional association if the recipient of the scholarship or support is selected by such association;
- All marketing items of a value less than $100; and
- Any data that identifies any specific drug, individual, physician, or pharmacy.

DEADLINE FOR SUBMITTING INFORMATION

Annual reports are due on April 1 covering the previous calendar year.

Reports must be submitted in the format specified by "GOHELP." The form must be signed by a company official and notarized.

30. 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. 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 Vice President of Public Policy and Government Affairs 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 Vice President of Public Policy and Government Affairs 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 29, "State Laws: LOUISIANA – Restrictions on Interactions with State Executive Branch Officials (Including HealthCare Professionals)."

31. PROMOTION AND GOVERNMENT REIMBURSEMENT

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

Written materials must not direct any customer in 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 shall clearly reference the source for any such information. Any materials provided to customers shall be informational only with a goal of providing materials that can assist them in understanding and complying with CMS and other insurer's billing, coding and reimbursement policies and requirements.

Bayer HealthCare Pharmaceuticals employees, contractors, consultants and agents may only provide insurance coding, coverage or payment information for Bayer HealthCare Pharmaceuticals products that satisfies the following requirements:

- The coding, coverage or payment information has been prepared and approved by the Managed Markets Department and relates to FDA-approved uses of Bayer HealthCare Pharmaceuticals products.

- Bayer HealthCare Pharmaceuticals provides equal access to the same reimbursement information to all purchasers or potential purchasers of Bayer HealthCare Pharmaceuticals products.

Bayer HealthCare Pharmaceuticals does not in any way add to, delete, or modify third party information and includes a disclaimer that the information was obtained from a third party, is not advice from Bayer Pharmaceuticals HealthCare, and that Bayer HealthCare Pharmaceuticals cannot guarantee reimbursement from a third party. Subject to the requirements above, Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals products. The information may relate to published dollar reimbursement amounts assigned to a CPT code from the current Medicare Durable Medical Equipment for Prosthetics, Orthotics and Supplies and/or Clinical Laboratory Fee Schedule.

You may not offer comments regarding the amount of reimbursement a customer may receive for a Bayer HealthCare Pharmaceuticals product or procedure. Bayer HealthCare Pharmaceuticals employees, contractors, consultants and agents may not provide personal opinions or interpretations of coding, coverage or reimbursement information. If a Bayer HealthCare Pharmaceuticals employee, contractor, consultant or agent receives a request

for reimbursement information or assistance from a customer, the employee, contractor, consultant or agent may provide the customer with previously approved reimbursement materials 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 HealthCare Pharmaceutical's policy to promote products based solely on their efficacy, safety and cost. You must not encourage customers to prescribe or purchase Bayer HealthCare Pharmaceuticals 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 receives in reimbursement from government programs, such as Medicare or Medicaid. The Anti-Kickback Statute 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 Anti-Kickback Statute.

You may not offer comments regarding the amount a customer might receive in reimbursement from Medicare or Medicaid for Bayer HealthCare Pharmaceuticals products or competitors' products. **You must also not provide customers with values for Average Wholesaler Price ("AWP") or other prices on which government reimbursement is based. If a customer requests that information, you must suggest the customer consult the Centers for Medicare and Medicaid Services' (CMS) website, the state Medicaid office, or other publicly available source (such as First Databank) where the information may be obtained. You should also not set or discuss a non-published Average Wholesaler Price ("AWP") and/or non-published Wholesale Acquisition Costs ("WAC") with customers or other prices on which government reimbursement is based.**

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 and Patents Department.

32. APPROPRIATE TARGET AUDIENCE FOR PROMOTIONAL ACTIVITIES

Promotion of Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals sales consultants 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 HealthCare Pharmaceuticals product in question for an approved use.

The term "healthcare professionals" is very broad and includes individuals who directly interacts with patients and/or have a role in the diagnosis and treatment of patients or 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 HealthCare Pharmaceuticals 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, technicians, 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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.

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

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

33. PROMOTIONAL PRACTICES OUTSIDE THE UNITED STATES

If Bayer HealthCare Pharmaceuticals 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 HealthCare 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals personnel 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 HealthCare Pharmaceuticals personnel 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 HealthCare Pharmaceuticals products.

- The US meal and travel policies must be followed when interacting with a US HCP who is outside the US. Please refer to Policy and Procedure "Business Meals with HealthCare Professionals."

34. MATERIALS FOR EXTERNAL USE

Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals employees, contractors, consultants and agents may conduct presentations to instruct healthcare professionals on the proper, on-label use of Bayer HealthCare Pharmaceuticals 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.

ADVERTISING AND PROMOTION 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.

SELF-CREATED MATERIALS ("HOMEMADE BREAD")

Creating your own promotional materials – also known as "homemade bread" – IS STRICTLY PROHIBITED. Self-created materials not only includes 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 EDUCATION MATERIALS

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 HealthCare Pharmaceuticals products or of competitor's products.

35. MATERIALS FOR INTERNAL USE ONLY

Bayer HealthCare Pharmaceuticals 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 to externally (*e.g.,* to promote, discuss or reference Bayer HealthCare Pharmaceuticals products), unless specifically approved for such use.

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 HealthCare Pharmaceuticals employee, contractor, consultant or agent providing services to or on behalf of Bayer HealthCare Pharmaceuticals 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.

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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals representative 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 to marketing and sales training for Legal, Medical, Regulatory review before it is disseminated. Together, these departments will formulate appropriate educational materials for the field.

36. 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 HealthCare 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 HealthCare Pharmaceuticals, the Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceutical products.

ADDITIONAL GUIDANCE

Soliciting Discussion: It is against Bayer HealthCare Pharmaceuticals policy for a sales consultant to ask leading questions intended to encourage discussion of unapproved uses (*e.g.*, "What was new at ASCO?"). Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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.

37. ADVERSE EVENTS INVOLVING BAYER PRODUCTS

All Bayer HealthCare Pharmaceuticals 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.
- Device Incident (DI) - any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labeling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or user or other persons or to a serious deterioration in their state of health.
- 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 product in its quality (including the identity, durability, reliability, safety, efficacy or performance) or suspect counterfeit. The complaint may or may not represent a potential risk to the customer.

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

- Identifiable Patient (*i.e.*, gender, age or age range, DOB, patient initials, name, etc.)
- Description of the AE/DI/PTC (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 safety related information:

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

In addition, the employee should provide his/her own contact information including date and time they first knew about the report, in the event that GPV-US needs to follow up to obtain additional information.

38. CLINICAL RESEARCH AND CLINICAL STUDY SUPPORT

Transactions under this Policy may constitute Focus Arrangements as defined by the CIA. Prior to initiating a transaction covered under this policy you must familiarize yourself with Policy and Procedure 8, "Focus Arrangements."

Note: Transactions under this Policy are reportable to the federal government under the Patient Protection and Affordable Care Act when implemented. It is each employee, contractor, consultant and agent's responsibility to report accurate, complete and timely data.

All research and clinical studies supported by Bayer HealthCare Pharmaceuticals must promote legitimate research goals. Bayer HealthCare Pharmaceuticals may enter into an arrangement to sponsor or authorize clinical research or clinical studies for the purpose of developing clinical information concerning Bayer HealthCare Pharmaceuticals products and/or Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceutical's support will induce or encourage the prescription, purchase, order, referral, use or recommendation of Bayer HealthCare Pharmaceuticals products. Any research or study supported by Bayer HealthCare must be conducted pursuant to a written agreement approved by the Law and Patents 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 HealthCare 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals by that clinical investigator.

Agreements to fund clinical trial or research may constitute focus arrangements under the CIA. An agreement to fund clinical research or clinical studies must be considered a potential focus arrangement 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 HealthCare Pharmaceuticals products.

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

Law and Patents Review of Focus Arrangements

For all requests for clinical research or study support that are potential focus arrangements, the Law and Patents 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 or activities related to the arrangement; and
- The requirement that all individuals who meet the definition of Covered Persons shall comply with all applicable elements of Bayer HealthCare's Compliance program, including applicable training related to the Anti-Kickback Statute.

The Law and Patents 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 the assessment was conducted.

The Law and Patents 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 HealthCare Pharmaceuticals. Any deviation from the fair market value methodology and the rationale for such deviation must be approved by the Bayer HealthCare Compliance Officer (or designee) and documented and maintained in the Law and Patents Department.

Bayer HealthCare Pharmaceuticals must send each party to the Focus Arrangement a copy of Bayer HealthCare's 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 the documents were sent.

Focus Arrangements Database Procedures

When the executed contract is returned from each party to the contract specialist, from the Department of Monitoring & Study Management, the contract specialist completes the Focus Arrangements Upload Template. Refer to Policy and Procedure 8, "Focus Arrangements," for information regarding Focus Arrangements Database Procedures.

Law and Patents review of Non-Focus Arrangements

If the approved request for clinical research or clinical study support is not a Focus Arrangement as determined by the Law and Patents Department, the Department of Monitoring & Study Management will send the approved agreement to the funds recipient (or designated staff member).

THIRD PARTY CONTRACTS

Bayer HealthCare Pharmaceuticals may work with third parties who contract with hospitals, research sites, or other entities on behalf of Bayer HealthCare Pharmaceuticals. In order to ensure that third party contracts comply with the Anti-Kickback Statute and Bayer HealthCare's Compliance Policies and Procedures, the Law and Patents 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 assesses compliance with relevant Safe Harbor(s). This assessment, the date it was conducted, and his/her name it 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 or activities related to the grant; and
- The requirement that all individuals who meet the definition of Covered Persons shall comply with all applicable elements of Bayer HealthCare's Compliance program, including applicable training related to the Anti-Kickback Statute.

The third party must send to each party to the Focus Arrangement, in addition to a copy of the approved contract, a copy of (1) Bayer HealthCare's Code of Conduct and (2) applicable 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 Contract Upload Template. Refer to Policy and Procedure 8, "Focus Arrangements," for information regarding the Focus Arrangement Database Procedures.

ADDITIONAL GUIDANCE

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

Proof of Service

The Department of Monitoring & Study Management or Medical Communications Department will retain documents confirming proof of the services provided, such as a report on the clinical trials, for 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 Corporate Auditing to ensure compliance with this Policy. The government (*e.g.*, OIG, IRS) may also request to audit/review clinical research and clinical study payments.

39. INVESTIGATOR SPONSORED STUDIES

Transactions under this Policy constitute Focus Arrangements as defined by the CIA. Prior to initiating a transaction covered under this policy you must familiarize yourself with Policy and Procedure 8, "Focus Arrangements."

Note: Transactions under this Policy are reportable to the federal government under the Patient Protection and Affordable Care Act when implemented. It is each employee, contractor, consultant and agent's responsibility to report accurate, complete and timely data.

This policy describes the appropriate use of grants to fund independent investigator sponsored studies that foster increased understanding of scientific, clinical, or healthcare issues that contribute to the improvement of patient care. Bayer HealthCare Pharmaceutical'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 sponsored studies provided by Bayer HealthCare Pharmaceuticals must promote legitimate research goals. Investigators must be selected based solely on their credentials and the merits of their research proposals. Bayer HealthCare Pharmaceuticals may not provide an investigator sponsored grant to induce or reward an investigator for prescribing or purchasing a Bayer product or to familiarize an investigator with a Bayer HealthCare Pharmaceuticals product. Elements of a bona fide study include:

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

Investigator sponsored 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 HealthCare Pharmaceuticals -supported clinical studies must be written primarily by the investigator. Bayer HealthCare Pharmaceuticals employees, contractors, consultants and agents may not write a protocol for an independent investigator. However, upon request by the investigator, Bayer HealthCare 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 ISS Grant Review Committee, as described below.)

The Investigator Sponsored Study ("ISS") Grant Review Committee is responsible for the review and approval of all investigator sponsored grants within Bayer HealthCare Pharmaceuticals. ***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 HealthCare Pharmaceutical's provision of investigator sponsored studies 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 sponsored studies.

If Sales and Marketing personnel are approached by a customer or potential investigator regarding a grant, they must direct the customer to the website: *http://stream.bayerhealthcare.com/* 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 HealthCare Pharmaceuticals must accurately disclose Bayer HealthCare Pharmaceutical's financial support.

UNACCEPTABLE INVESTIGATOR SPONSORED 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 Bayer HealthCare Pharmaceuticals products; or
- Intended to encourage the investigator to order, prescribe, or recommend Bayer HealthCare Pharmaceuticals 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 17, "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 sponsored" for purposes of this policy and instead must comply with Policy and Procedure 38, "Clinical Research and Clinical Study Support."

PROCEDURES

All requests for grant funds for investigator sponsored studies must be submitted to the Bayer website: http://stream.bayerhealthcare.com/. 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 sponsored study.

Grant Requestor

The investigator (or designated staff member) must electronically input all required grant information. The investigator 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 strategic plan, it will be placed on the agenda for review by the ISS 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 and Patents. 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 and Patents Review

The Law and Patents 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 Focus Arrangement; and
- The requirement that all individuals who meet the definition of Covered Persons shall comply with all applicable elements of Bayer HealthCare's Compliance Program, including applicable training related to the Anti-Kickback Statute.

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 and Patents 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 Compliance Officer (or designee) and documented and maintained in the Law and Patents 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

Minutes will be prepared for each Grant Review Committee meeting. The minutes 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 HealthCare's Code of Conduct and 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.

Focus Arrangements Database Procedures

When the executed agreement is returned from the investigator, the Grant Manager, or other Bayer employee, completes the required Focus Arrangement fields in the ISS database. Refer to Policy 8 "Focus Arrangements" for information regarding the Focus Arrangements Database Procedures.

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 Corporate Auditing to ensure compliance with these policies. The government (*e.g.*, OIG, IRS) may also request to audit/review grant payments.

40. PRICE REPORTING

It is Bayer HealthCare Pharmaceutical's policy to report, completely and accurately, cost, price and sales information about Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 and Patents 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 LIMITS

All information that Bayer HealthCare Pharmaceuticals must report or generate, directly or indirectly, about costs, prices and sales for Bayer HealthCare Pharmaceuticals products for submission to or for use by a Government Healthcare Program or a Price Reporting Entity must be accurate, must be complete and not intentionally misleading.

REPORTING PRICE INFORMATION

All Bayer HealthCare Pharmaceuticals reports of price information provided directly or indirectly to Government Healthcare Programs or a Price Reporting Entity must accurately take into account all pricing information, including, to the extent they exist: (1) price reductions; (2) discounts; (3) free goods contingent upon a purchase agreement; (4) rebates; (5) up-front payments; and (6) other price concessions or similar benefits offered to some or all purchasers.

PROCEDURES

Submission Process

Any Bayer HealthCare Pharmaceuticals 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 via facsimile to the Director of Contracting for completion. In addition, a copy of all such requests for pricing information must be sent to the Law and Patents Department prior to submitting responses to any such entity.

Any Bayer HealthCare Pharmaceuticals employee, contractor, consultant or agent who reports prices to any agency of the federal or state government or any Price Reporting Entity must submit that pricing data, along with any information pertaining to that request (*e.g.,* instructions for calculating prices) to the Director of Contracting for approval prior to submitting that information to such entity. The Director of Contracting or designate will approve all pricing information prior to its submission.

Completion of Requests for Pricing Information

All prices reported to any Government Healthcare Program or Price Reporting Entity must be accurate.

All responses to requests from the federal or state government for pricing related to Medicaid, Medicare, Department of Defense ("DOD"), Department of Veterans Affairs ("VA"), or Public Health Service ("PHS") must be completed as follows:

- Submit complete responses, with detailed annotations if necessary. For example, if the request is for "wholesaler" pricing, include, as appropriate, all classes of wholesalers.
- Report any discounts offered to an entire class of trade, such as prompt pay discounts.
- Always include the lowest class of trade price at which Bayer HealthCare Pharmaceuticals sells a product to a commercial customer, even if this information is not specifically requested.

Updates to Pricing Information

Some government and Price Reporting entities request pricing updates when prices change or on a time-specific basis (*e.g.*, once a year). Bayer HealthCare Pharmaceuticals must provide these updates within the time requested by such entity. If no time is specified, you must provide updated information within 30 days of the event that necessitated a change (*e.g.*, price increase). You must state the effective date the price change took effect. All updates to pricing information must be routed through the same review and approval process as the initial response.

RECORD RETENTION

Contracting will maintain copies of all price submissions to any agency of the federal or state government or foreign government or Price Reporting Entity as well as documents (*e.g.*, contracts) supporting those submissions. Documents must be maintained for 10 years following the date of their submission to the agency, or longer as required by law.

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 and Patents Department.

41. REVIEWING AND APPROVING CUSTOMER CONTRACTS

Transactions under this Policy constitute Focus Arrangements as defined by the CIA. Prior to initiating a transaction covered under this policy you must familiarize yourself with Policy and Procedure 8, "Focus Arrangements."

Bayer HealthCare Pharmaceuticals 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 and Patents 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals products to which the rebate applies without the prior written approval of the Vice President of Business Planning and Administration or designee and the Law and Patents Department. Each rebate paid must clearly indicate to the purchaser those Bayer HealthCare Pharmaceuticals products to which the rebate is to be applied. A rebate on any Bayer HealthCare Pharmaceuticals product(s) may not exceed the sum total of the actual purchase price(s) for the Bayer HealthCare Pharmaceuticals product(s) to which the rebate is to be applied. Bayer HealthCare Pharmaceuticals 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 r ebate to payors and insurers, as appropriate, as a reduction in price on the Bayer HealthCare Pharmaceuticals products purchased. Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals must disclose the existence of the price concession in the contract. For example, if Bayer HealthCare Pharmaceuticals offers

tiered market share performance rebates, the amount of various tiers and the market share required to attain each tier must be disclosed in the contract.

Administrative Fees It is Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceuticals policy to provide free product as a discount or price term (*e.g.*, "buy 10, get 1 free").

PROCEDURES

Approval Process

1. The Bayer HealthCare Pharmaceuticals employee handling the account sends the proposed Request for Contract ("RFC") to Customer Business Strategies[1] (Managed Markets) 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.

[1] 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.

- 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 Executive Pricing Committee (EPC) once the above items have been reviewed, Customer Business Strategies presents the proposed custom contract to Contracting (BPA) which will confirm that the above criteria are met.

3. As determined by the Director of the Contracting (BPA) 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 HealthCare Pharmaceutical's standard legal language (addition, revision, or deletion of standard language), as determined by the Law and Patents 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 (BPA) or designee function presents any custom contract with applicable justification to the Contract Review Committee (CRC) which is composed of:

    - Director, Controlling Director or designee;
    - Director of Contract Generation or designee;
    - Director, Customer Business Strategies or designee;
    - Brand Lead or designee; and
    - Law and Patents Department.

The CRC reviews the custom contract and recommends revision, rejection, or approval of the custom contract. As part of its consideration of a requested contract, the CRC representative from the Law and Patents Department will consider the applicability of Robinson-Patman.

The CRC may act upon a custom contract by e-mail. The Director of Contracting or the CRC representative from the Law and Patents 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 there is not unanimous CRC approval, if a new contracting strategy is proposed or as otherwise required by the EPC. The EPC members include:

    - Vice President, Managed Markets;
    - Vice President, Law and Patents; and
    - Vice President of Business Planning and Administration (BPA).

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 the customer for signature. 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, the requirement that all individuals who meet the definition of Covered Persons, as defined in the CIA, shall comply with all applicable elements of Bayer HealthCare's Compliance Program, including applicable training related to the Anti-Kickback Statute; that the other party has and enforces a code of conduct and compliance program for its personnel substantially comparable to Bayer's Code of Conduct and Bayer HealthCare Compliance Program; or that the other parties will make copies of a description of Bayer's Code of Conduct and a description of Bayer HealthCare's Compliance Program will be made available to personnel who are directly involved in performance of the agreement.
    - Where applicable, Contracting must send the customer a copy of Bayer HealthCare's 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 contract or sent as separate documents. Contracting must document on the Focus Arrangements Datasheet that the documents were sent.

Law and Patents Review and Approval

The contract signed by the customer is returned to Law and Patents, who reviews the proposed contract for compliance with the Anti-Kickback Statute and relevant Safe Harbor(s) before it is signed by Bayer HealthCare Pharmaceuticals. The reviewing attorney must document that this assessment was conducted, his/her name, and the date it was conducted.

Law and Patents also confirms that the proposed payment of any service, data, or administrative fee 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 HealthCare Pharmaceuticals. Any deviation from the fair market value methodology and the rationale for such deviation must be approved by the Compliance Officer (or designee) and documented and maintained in the Law and Patents Department.

With the exception of volume-based purchase contracts, payment must not depend upon or be based on the value or volume of sales.

Awarding the Contract

Upon receipt of the final contract, it is stamped by the Law and Patents Department and signed by the Director of Contracting, the Vice President BPA or designee, or the Chief Executive Officer of Bayer HealthCare, as appropriate, based on the value of the contract.

Bayer HealthCare Pharmaceutical's general policy is not to backdate contracts. The effective date for a contract for the purchase of Bayer HealthCare Pharmaceuticals 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 HealthCare Pharmaceutical'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 HealthCare Pharmaceuticals, with the approval of Law and Patents 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 and Patents Department, no contract may have an effective date more than one hundred and eighty days prior to the date of execution by Bayer HealthCare Pharmaceuticals. Any deviations from this policy must be approved by the Compliance Officer (or designee) and documented and maintained in the Law and Patents 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.

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