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Diabetes Care Policies and Procedures
July 1, 2013

Policies and Procedures

Bayer HealthCare

BHC2013

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INTRODUCTION

This booklet, the **"Bayer HealthCare Diabetes Care Compliance Policies and Procedures,"** contains vital 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 Diabetes Care. The HealthCare Compliance Program includes, among other things, the Policies and Procedures in this booklet, 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 during other interactions between Bayer HealthCare Diabetes Care employees, contractors, consultants or agents and healthcare professionals or institutions.

The definition of healthcare professional is very broad and includes, but is not limited to, any individual who directly interacts with and treats patients such as physicians, nurses, nurse practitioners, physician assistants, certified diabetes educators ("CDE(s)"), medical assistants who treat patients, and other healthcare professionals, such as pharmacists, pharmacist technicians, lab technicians, therapists, interns and office assistants. However, the definition is not limited to these people alone; it also includes any person in a position to recommend or influence the purchase or prescribing of Bayer HealthCare Diabetes Care products. For the purposes of this policy, this definition also includes employees of distributors, mail order companies, purchasing agents, wholesalers, retailers, employees of a health plan administrator, Pharmacy & Therapeutics Committee members, or Formulary Committee members who do not see patients.

The Bayer HealthCare Diabetes Care Compliance Documents are accessible by going to the homepage on the intranet and clicking on the following tabs: Home > Resources > HR Resources > HealthCare Compliance. Alternatively, these documents 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 or state healthcare programs, such as Medicare, Medicaid, the Department of Defense or the Department of Veterans Affairs. Bayer HealthCare Diabetes Care is committed to complying with all applicable laws, regulations and industry codes (including the AdvaMed Code of Ethics) governing the sale and marketing of our devices 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 Diabetes Care's Compliance Policies and Procedures can have direct and severe consequences both to you and to Bayer HealthCare Diabetes Care.

Any Bayer HealthCare Diabetes Care 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 Diabetes Care 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 supervisors, the Law and Patents Department, or the Bayer HealthCare Compliance Officer. Reports may also be made anonymously and confidentially via the Bayer HealthCare 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)" (including for these purposes, Bayer HealthCare Diabetes Care) 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 Diabetes Care 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 Department or Bayer HealthCare Compliance Department.

Anti-Kickback Statute

The CIA puts Policies and Procedures in place to help ensure Bayer HealthCare does not violate the Anti-Kickback Statute. The Anti-Kickback Statute is a federal law that prohibits entities, such as manufacturers of drugs or medical devices, from offering or giving "remuneration" (*e.g.,* anything of value) 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 Bayer HealthCare's commitment to ethical behavior are consistent, and Bayer HealthCare Diabetes Care 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 take precedence.

The Foreign Corrupt Practice Act

Bayer HealthCare Diabetes Care 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 Diabetes Care 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 Diabetes Care employee, contractor, consultant and agent has the responsibility to ensure that his/her dealings with non-U.S. government officials—including state-employed health care 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 Diabetes Care's business.

Questions

It is not expected that every employee, contractor, consultant and agent will have 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 will be 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 generally will 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 reporting to the Bayer IntegrityLine.

THE CONFIDENTIAL DISCLOSURE LOG

Global Compliance Services, Inc. provides two reports to the 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 Resources 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 Diabetes Care 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 Diabetes Care 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 Diabetes Care 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 should 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 Resources 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, Inc. 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 Diabetes Care Law and Patents Department 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 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 Affiliate receives any written report, correspondence, or communication between Bayer HealthCare or any Bayer Affiliate and the FDA that materially discusses Bayer HealthCare, a Bayer HealthCare Affiliate or a Bayer HealthCare Covered Person's actual or potential unlawful or improper promotion of Bayer'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 Diabetes Care 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 Diabetes Care employees, contractors, consultants, and agents.

PROCEDURES

New Hire Self-Disclosure and check against Government websites.

1. The appropriate Human Resources Department Recruiter or the Hiring Manager, prior to hiring a Bayer HealthCare Diabetes Care 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 Diabetes Care 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 Departments 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 Diabetes Care employee, contractor, consultant or agent, Human Resources, Contingent Labor or the Hiring Manager will provide the Self-Disclosure form and the Bayer HealthCare Code of Conduct to the prospective Bayer HealthCare Diabetes Care employee, contractor, consultant or agent. In addition, Human Resources or the Hiring Manager will arrange with their contracted consumer reporting agency to complete the required government exclusion checks for each prospective Diabetes Care employee, contractor, consultant or agent. The government exclusion checks required by the CIA involve checking the prospective employee, contractor, consultant and agent's name against two government exclusion lists: the Department of Health and Human Services/Office of Inspector General's List of Excluded Individuals/Entities at: https://oig.hhs.gov/ and the General Services Administration's List of Parties Excluded from Federal Programs at https://www.sam.gov (formerly ww.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 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 Diabetes Care employee, contractor, consultant or agent is listed on either of the government websites, the Human Resources Representative follows procedures detailed in the following section entitled "Change in Eligibility Status of a Covered Person".

If any potential Bayer HealthCare Diabetes Care employee, contractor, consultant or agent fails to satisfy these requirements or is determined to be an Ineligible Person, Bayer HealthCare Diabetes Care will not hire that person.

The original Self-Disclosure form and results of the government screenings are retained by the Human Resources Department. The Bayer HealthCare Compliance Department retains the fax or electronic copy of the Self-Disclosure 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 WEBSITES 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 Diabetes Care employees. HR//Direct prepares

a report of all active and inactive Bayer HealthCare Diabetes Care 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 Diabetes Care employees, contractors, consultants and agents.

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

All 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 DIABETES CARE EMPLOYEE

The Bayer HealthCare Compliance Officer (or designee) and the appropriate Human Resources Representative must be notified immediately if a Bayer HealthCare Diabetes Care 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 Resources Department will suspend the Bayer HealthCare Diabetes Care 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 Diabetes Care 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 Diabetes Care employee will be terminated or transferred to a position that does not involve responsibility for or involvement with Bayer HealthCare Diabetes Care's business operations related to federal healthcare programs or a position for which the Bayer HealthCare Diabetes Care employee, contractor, consultant and agent's compensation or the items or services

furnished, ordered, or prescribed by the Bayer HealthCare Diabetes Care employee, contractor, consultant or agent 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 EMPLOYEES

Bayer Contingent Labor Program representatives, vendors and agents contracted by Bayer HealthCare must follow similar processes to meet the requirements of determining eligibility. The appropriate Human Resources 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 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's internal HealthCare Compliance database and Human Resources 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 vendor contracts with an effective date prior to November 25, 2008 have been adjusted 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 Diabetes Care 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: Please Print
Bayer HealthCare Diabetes Care

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 or agent as a Covered Person or Arrangements Covered Person in the HealthCare Compliance Program. Supervisors must follow this procedure to ensure that Bayer HealthCare Diabetes Care meets all the HealthCare Compliance Program requirements for Covered or 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 or Arrangements Covered Person in the HealthCare Compliance Program. New Covered and Arrangements Covered Persons also include contractors, consultants and agents (who are 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 Diabetes Care Sponsor.

If an employee contractor, consultant or agent who is not a current HealthCare Compliance Program Covered Person is transferred or promoted into a Covered position, the employee, contractor, consultant or agent must meet the same Compliance training and certification requirements as that of a New Hire covered employee, contractor, consultant or agent. A transfer or promoted employee, contractor, consultant or agent 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 and agents. Covered and Arrangements Covered Persons who do not complete the HealthCare Compliance training or 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 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, 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 Diabetes Care Compliance Policy and Procedures booklet, the Bayer HealthCare Code of Conduct and the Bayer IntegrityLine materials.

The immediate supervisor must ensure that the new Covered Person 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 the due date set by Bayer HealthCare Compliance. 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 Covered Person and their supervisor if training and certifications are not completed.

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 or Contingent Labor. The Bayer Human Resources Department will take the appropriate corrective action which can include 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 Diabetes Care 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 Diabetes Care 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 in 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 contractor, consultant or agent 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's HealthCare 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's 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 Diabetes Care'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 Diabetes Care's 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 Arrangements "refresher" 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 Diabetes Care 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 Bayer HealthCare 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 Compliance 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 Diabetes Care 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 Bayer HealthCare Diabetes Care Compliance Policies and Procedures. Disciplinary action up to and including termination of employment may be taken against any Bayer HealthCare Diabetes Care employee, contractor, consultant or agent who violates applicable federal, state or local laws or regulations, industry guidelines or the Bayer HealthCare Code of Conduct or the Bayer HealthCare Diabetes Care Compliance Policies and Procedures.

NON-RETALIATION

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

DISCIPLINARY ACTION, TERMINATION AND REFERRAL TO LAW ENFORCEMENT

Bayer HealthCare Diabetes Care 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 Diabetes Care 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 Diabetes Care in response to a violation of the Bayer HealthCare Diabetes Care Compliance Policies and Procedures should be commensurate with the severity of the violation as determined in Bayer HealthCare Diabetes Care'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 DIABETES CARE EMPLOYEES, CONTRACTORS, CONSULTANTS AND AGENTS SUBJECT TO DISCIPLINARY ACTION

Disciplinary action may be taken against any Bayer HealthCare Diabetes Care 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 Diabetes Care 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 Diabetes Care 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 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 products. This Policy defines those arrangements and outlines the policies and procedures that Bayer 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 (of referrals or sales) are defined as anything that 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 Education/Continuing Medical Education
- Consultant arrangements
- Advisory board arrangements
- Business Meals outside the recipient's normal working hours
- Promotional funding/Advertising fees
- Disease management programs
- Service agreements with customers
- Data purchases
- Exhibit or display fees
- Educational Items in excess of one (1) per calendar year
- Contracts for discounted product purchase
- Clinical research or clinical trial agreements
- Investigator initiated trials or study grants
- 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 Diabetes Care policy specific to that individual Arrangement.

Bayer 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 Diabetes Care 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 Diabetes Care must send each entity that is a party to the Focus Arrangement a Third Party Personnel Letter, as defined by the CIA, 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 Diabetes Care 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 Diabetes Care 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 and 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 Diabetes Care 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 sheet, slide decks, time sheets or exhibit booth attendance forms), so the Bayer HealthCare Diabetes Care 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 Datasheet

To assist in recording all of the required information into the Focus Arrangements Database, the Focus Arrangement Owner is required to complete an Agreement Request Form which will contain sufficient information to comply with the data entry requirements as outlined below. The completed Form must be submitted to the Law and Patents Department.

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

AUDITS

Bayer 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 Diabetes Care 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 Diabetes Care policy to cooperate fully with federal and/or state government officials or agents who conduct an inquiry, audit or otherwise investigate Bayer HealthCare Diabetes Care. Bayer HealthCare Diabetes Care 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 Diabetes Care 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 Diabetes Care employees, contractors, consultants or agents, (2) presentation of search warrants, (3) on-site visits to or inspections of Bayer HealthCare Diabetes Care's premises by government officials or agents, or (4) visits by government officials to the homes of Bayer HealthCare Diabetes Care employees, contractors, consultants or agents.

CONTACT BY GOVERNMENT INVESTIGATOR

In the event a Bayer HealthCare Diabetes Care 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 Diabetes Care 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 independent 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 Diabetes Care employee, contractor, consultant or agent at his or her home and/or any location which is off Bayer HealthCare Diabetes Care 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 Diabetes Care'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 Diabetes Care will have an attorney or other representative attends such interview.

GOVERNMENT INTERVIEWS

If a Bayer HealthCare Diabetes Care employee, contractor, consultant or agent decides to be interviewed or 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 Diabetes Care 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'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 counsel. Alternatively, Bayer HealthCare Diabetes Care may recommend qualified counsel and, under the appropriate circumstances, will pay for such counsel to represent the Bayer HealthCare Diabetes Care employee, contractor, consultant or agent. If at any time the employee, contractor, consultant or agent feels uncomfortable or uncertain about whether to proceed, or if at any time the employee, contractor, consultant or agent feels the need to consult with his/her own attorney or a Bayer attorney, the employee, contractor, consultant or agent may stop the interview or tell the investigator that he/she wish to consult with counsel.

CORPORATE DOCUMENTS

Bayer HealthCare Diabetes Care 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 Diabetes Care documents. Bayer HealthCare Diabetes Care documents include all documents, whether in paper format or electronically stored that are held or created in connection with your employment at Bayer HealthCare Diabetes Care and/or the operation of Bayer HealthCare's businesses. For example, Bayer HealthCare Diabetes Care 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 Diabetes Care property and is subject to this policy.

In addition, Bayer HealthCare Diabetes Care employees, contractors, consultants or agents must not provide privileged Bayer HealthCare Diabetes Care 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 Diabetes Care'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 Diabetes Care employees, contractors, consultants or 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 Diabetes Care does not authorize you to sign or initial any such documents or statements as a Bayer HealthCare Diabetes Care employee, contractor, consultant or agent unless expressly authorized in writing by the Law and Patents Department. If a Bayer HealthCare Diabetes Care 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 Diabetes Care'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 Diabetes Care's customers may submit information to Bayer HealthCare Diabetes Care on their policies and procedures related to the FCA. Please direct all such submissions to the Bayer HealthCare Compliance Officer.

Bayer HealthCare Diabetes Care has established comprehensive policies and procedures to prevent, detect, and correct violations of law and company policy. Bayer HealthCare Diabetes Care 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 Diabetes Care representatives must follow all institutional access policies pertaining to restricted areas as well as restrictions involving meals and educational items.

Bayer HealthCare Diabetes Care representatives must not sign any documents (hard copy or electronic) or make any representations on behalf of Bayer HealthCare Diabetes Care 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 Diabetes Care 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 the Sales Resource Center on the Diabetes Care Intranet Site: http://moxarj.pitts.bayer.com/SalesAutomation/ResourceCenterContent/Compliance/DCHospitalRegistrationInformation-fieldsales.pdf

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 Diabetes Care 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 Diabetes Care representatives have a legitimate need for access.

REGISTRATION FEES PAID TO CUSTOMERS

In the rare instance where hospital 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 Diabetes Care 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 Diabetes Care 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 Diabetes Care. 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 Diabetes Care 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 on the Focus Arrangements Datasheet that these were sent.

Focus Arrangements Database Procedures

When the executed contract is returned from the hospital, the Bayer HealthCare Diabetes Care Representative forwards it to the Law and Patents Department to be entered into Efilia along with the 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 7 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 8, "Focus Arrangements." Payments must not be made in cash or with a personal check. Once paid, access to the institution must be recorded.

Permissible Activities or Information to Release

Biographical Information

Company Information

- Company name: Bayer HealthCare LLC
- Address: 555 White Plains Road, Tarrytown NY 10591

- Supervisor information
- Tax ID Number: 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 e-mail, debbie.rimel@Bayer.com, with a copy of the healthcare facility's written notice of such requirement 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

Requests for team immunizations at sales meetings must be presented 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, biologics and medical device manufacturers are not generally subject to HIPAA, Bayer HealthCare Diabetes Care 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. If available, 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 LLC insurance certificates can be obtained by contacting Ryan Pierrard at ryan.pierrard@bayer.com in the Insurance and Risk Management Department.

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 Diabetes Care 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 Diabetes Care contains any identifiable patient information.

Bayer HealthCare Diabetes Care 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).

USES OF PRESCRIBER DATA

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

RESTRICTING ACCESS TO PRESCRIBER DATA

Bayer HealthCare Diabetes Care 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 Diabetes Care 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.

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 representatives or others.

You must direct any prescriber wishing to opt-out of the AMA PDRP to contact the AMA.

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 Diabetes Care has added PDRP opt-out flags to the relevant physician profiles in accordance with the process described below.

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 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 the individual 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, however, 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 Diabetes Care 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 Diabetes Care products, agreeing to put Bayer HealthCare Diabetes Care 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 Diabetes Care 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 representative.

In order to ensure that Bayer HealthCare Diabetes Care complies with this law, it is Bayer HealthCare Diabetes Care policy that Bayer HealthCare Diabetes Care employees, contractors, consultants and agents may not provide educational items (textbooks, anatomical models, does not include "samples") or business meals to federal government employees, regardless of dollar value.

Product samples and products provided for evaluation 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 Diabetes Care, 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.*, ADA conference). In order for the Bayer HealthCare Diabetes Care -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 Diabetes Care -sponsored keynote address at the annual ADA 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 Diabetes Care sponsored limited target audience event (*e.g.*, dinner at a "Bayer HealthCare Diabetes Care table" at the ADA conference) or invite individual government physicians to dinner at an ADA conference or similar event.

Fee for Service Arrangement

Modest business meals may be provided to a federal government employee if there is a f ee-for-service arrangement (consultant or speaker) with the federal employee and the meal is provided in connection with the 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 Diabetes Care follow appropriate procedures when 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 Diabetes Care and its employees from criminal and civil penalties that may result from providing improper gifts 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 Diabetes Care may provide funds to these organizations for various 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 Diabetes Care, determines how the funds are to be 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 Accounts Payable Department must maintain the grant payment request package for a period of 7 years.

AUDIT

Medical education grants are subject to audit by Corporate Auditing and Bayer HealthCare Compliance to ensure compliance with these policies. The government (*e.g.*, OIG, IRS) may also request to audit/review 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 Diabetes Care policy for business meals conforms to guidelines published by the Advanced Medical Technology Association ("AdvaMed Code of Ethics") and 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 Diabetes Care 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/.

The definition of healthcare professional is very broad and includes, but is not limited to, any individual who directly interacts with and treats patients such as physicians, nurses, nurse practitioners, physician assistants, CDE(s), medical assistants who treat patients, and other healthcare professionals, such as pharmacists, pharmacist technicians, lab technicians, therapists, interns and office assistants. However, the definition is not limited to these people alone; it also includes any person in a position to recommend or influence the purchase or prescribing of Bayer HealthCare Diabetes Care products. For the purposes of this policy, this definition also includes employees of distributors, mail order companies, purchasing agents, wholesalers, retailers, employees of a health plan administrator, Pharmacy & Therapeutics Committee members, or Formulary Committee members who do not see patients.

GENERAL RULE

Meals may be provided to healthcare professionals if they are: (1) occasional; (2) modest; (3) take place in a setting conducive to such discussion; (4) are provided connection with a *bona fide* presentation or discussion of Bayer HealthCare Diabetes Care products, disease states relevant to Bayer HealthCare Diabetes Care products, medical education, or other legitimate business discussions related to Bayer HealthCare Diabetes Care products; and (5) involve only individuals who are necessary to conduct Bayer HealthCare Diabetes Care business.

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

All Bayer HealthCare Diabetes Care employees, contractors, consultants and agents must exercise sound judgment 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 should 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 Diabetes Care product discussion or other legitimate business discussion related to Bayer HealthCare Diabetes Care products.

- Field Sales Representatives (DSSs) and their immediate managers may provide business meals to a healthcare practitioner only during the healthcare practitioner's normal working hours. Meals provided to healthcare professionals who provide direct patient care (*e.g.*, physicians, certified diabetes educators (CDEs), pharmacists, technicians, laboratory personnel, nurses, physician's assistants (PAs) and dieticians) must take place in the healthcare practitioner's office or in the hospital where the healthcare practitioner is working. Appropriate places within a hospital to provide a business meal include the cafeteria, coffee shop or meeting space conducive to a business discussion.

- If a field sales representative (DSS) or his/her immediate manager calls on a healthcare professional who does not provide direct patient care *(e.g.*, retail corporate staff, employees of a wholesaler, distributor and/or mail order supplier), a business meal may be provided outside of the professional's office, so long as it otherwise complies with this policy.

- All Other Bayer HealthCare Diabetes Care Employees (including ASMs, KAMs, NAMs, RAMs, FOMs and NSMs) may provide business meals to healthcare professionals in a venue conducive to an educational or product discussion in compliance with this policy.

FREQUENCY OF BUSINESS MEALS

Consistent with AdvaMed Code of Ethics and OIG guidelines, business meals may be provided on an "occasional" basis. It is Bayer HealthCare Diabetes Care's policy that "occasional" generally means 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 Diabetes Care 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 consists of sandwiches, pizza, snacks, or soft drinks 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 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 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 Diabetes Care 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 Diabetes Care'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 Diabetes Care procedures **prior** to providing any item of value to those healthcare professionals.

RETAIL VALUE – AMOUNT TO BE RECORDED

The retail value of a meal, not the amount you or Bayer HealthCare Diabetes Care 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 Diabetes Care 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 Diabetes Care actually paid for it. When listing the value of any meal, you must list its retail value and the amount you or Bayer HealthCare Diabetes Care 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 Diabetes Care does not violate these laws, **Bayer HealthCare Diabetes Care 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 Federal 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 should 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.

ADDITIONAL GUIDANCE

- It is not appropriate to pay or reimburse a healthcare professional for personal meals.
- Bayer HealthCare Diabetes Care may only pay for meals of healthcare professionals who actually attend a meeting at which Bayer HealthCare Diabetes Care is legitimately sponsoring a meal pursuant to this Policy.

- Meals are only provided to individuals who are necessary for the conduct of Bayer HealthCare Diabetes Care 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 Diabetes Care 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:

- Lunch 'n Learn or Dinner 'n Learn (any meal or snack) with a group of physicians and CDEs with food catered from a local deli (modest expense and involving educational discussion)

- Providing breakfast sandwiches, coffee and juice to a physician's office to discuss a new product offering (modest expense and incidental to business)

- An out of office lunch between a DSS or his/her immediate manager and a **customer's mail order rep** at a local Italian restaurant, provided the expense is modest and it involves legitimate business and/or educational discussion. (The customer's mail order rep is classified as a healthcare professional who **does not** provide direct patient care making this a permissible meal. However, the customer's mail order rep is still subject to the Sign-In Sheet requirement more fully detailed later in this Policy.)

- An out of office lunch or dinner between Medical Affairs personnel and a physician to discuss disease states related to Bayer HealthCare Diabetes Care products or other appropriate topics (Medical Affairs personnel are not limited to in-office meals)

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

- Taking a CDE to a modest restaurant around the corner from his/her office for a meal to discuss diabetes education (restaurant is not an appropriate venue)

- Catering a dinner after hours in a physician's office or hospital for a Bayer HealthCare Diabetes Care product discussion (not during the healthcare professionals' working hours) unless the meal is made in conjunction with a speaker program in compliance with Policy and Procedure 18, "Fee-for-Service Arrangements";

- An out of office lunch at a local Italian restaurant with a **customer's mail order rep and healthcare provider** (a DSS or his/her immediate manager may NOT have an out of office meal when a healthcare provider is present)

The following are examples of meals that are NOT appropriate for **any Bayer HealthCare Diabetes Care employee, contractor, consultant or agent**:

- Meeting a physician at a "take-out" restaurant and discussing Bayer HealthCare Diabetes Care products while waiting for the food (venue/location not conducive to an educational or business discussion; no Bayer HealthCare Diabetes Care representative present when meal 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 Diabetes Care employee present; no educational/product discussion)

- Buying a meal for customers who are participants at a trade show for the purposes of relationship building (no educational or business discussion)

PROCEDURES

Before providing a business meal, ask yourself:

1. Will there be a product or scientific discussion, and/or a *bona fide* business and/or educational purpose?

2. Is the location of the meal conducive to an educational discussion and in an appropriate location based on the healthcare professional and/or Bayer HealthCare Diabetes Care employees involved?

3. When required by this policy, is the meal occurring during the healthcare professional's normal working hours?

4. Is the cost of the meal modest?

5. Is a Bayer HealthCare Diabetes Care employee present?

6. Is the frequency of meals provided to this healthcare professional occasional (it is Bayer' HealthCare Diabetes Care s policy that "occasional" means generally no more than ten meals per individual healthcare professional within a calendar year)?

7. Am I reasonably certain that each of the participants in the meal is not a federal government employee?

8. 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 of these 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. Most business meals permitted by this policy are not considered Focus Arrangements for CIA purposes because they meet the "carve-out" definition.

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 Diabetes Care is not required to follow Focus Arrangements Procedures for business meals. However, **Bayer HealthCare Diabetes Care 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 Diabetes Care 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 Travel and 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 of the business purpose (*e.g.,* the product you are detailing and purpose for the detailing visit to the HCP's office) must be documented. Instructions on how to complete your T&E when providing a business meal to an HCP 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, including the Bayer HealthCare Diabetes Care employees who were in attendance. If the Bayer HealthCare Diabetes Care 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 Diabetes Care through a third party vendor also require sign in sheets (*e.g.,* 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 (lunch & learn, dinner speaker program, patient program, advisory board, speaker training, out of office business meal, etc.)

- Program/Event number (if applicable)
- Event host (Bayer HealthCare Diabetes Care employee)
- Signatures of all Bayer HealthCare employees
- Speaker (if applicable) name and signature
- Contract number (if applicable)
- Name and address of venue
- Number of licensed HCPs, non-licensed HCPs, Bayer HealthCare Diabetes Care Employees, Total Attendees

PER INDIVIDUAL HCP/NON-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 Diabetes Care employees may, if necessary, completes 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.

A sample form of the sign in sheet can be found on the Diabetes Care intranet site: http://moxarj.pitts.bayer.com/salesautomation/ResourceCenterContent/Compliance/DCBusinessMealSigninSheet.pdf.

The Corporate T&E Policy can be found on the Intranet at: http://www.bayernet.com/corp/policies/.

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 consistency with this Policy and Procedure and other applicable Bayer HealthCare Diabetes Care requirements, including that the dollar 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 Diabetes Care policy, the supervisor must take appropriate action, including discussing the situation with the employee, documenting corrective action, and notifying the next supervisory level and the Bayer HealthCare Compliance Department.

RECORD RETENTION

T&E documents are retained by the Accounts Payable Department for a period of 7 years.

AUDITS

Spending for business meals is subject to auditing by Corporate Auditing 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

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 Diabetes Care may provide educational items that are modest and designed primarily for the education of patients and healthcare professionals (HCPs). Bayer HealthCare Diabetes Care may also provide educational items in accordance with Policy and Procedure 17, "Drawings and Sweepstakes." Any other items are prohibited, including practice-related and logo "reminder" items. Bayer HealthCare Diabetes Care policy prohibits employees, contractors, consultants and agents from offering anything of value, including an educational item, to a healthcare professional (HCP) to encourage the HCP to prescribe, purchase, lease, order, refer, use or recommend Bayer HealthCare Diabetes Care product(s) as doing so could lead to a violation of the Federal Anti-Kickback Statute or other relevant state statutes.

SCOPE

The Bayer HealthCare Diabetes Care policy for educational items conforms to the AdvaMed Code of Ethics and guidelines published by 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 Diabetes Care products.

The definition of healthcare professional is very broad and includes, but is not limited to, any individual who directly interacts with and treats patients such as physicians, nurses, nurse practitioners, physician assistants, CDE(s), medical assistants who treat patients, and other healthcare professionals, such as pharmacists, pharmacist technicians, lab technicians, therapists, interns and office assistants. The definition also includes any person in a position to recommend or influence the purchase or prescribing of Bayer HealthCare Diabetes Care products. For the purposes of this policy, this definition also includes employees of distributors, mail order companies, purchasing agents, wholesalers, retailers, employees of a health plan administrator, Pharmacy & Therapeutics Committee members, or Formulary Committee members 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 Diabetes Care does not violate these laws, **Bayer HealthCare Diabetes Care 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 government employee, consult Policy and Procedure 13, "Special Requirements for Federal Government Employees," in this booklet.

SPENDING LIMITS AND FREQUENCY FOR EDUCATIONAL ITEMS

Bayer HealthCare Diabetes Care representatives may provide educational items, provided the retail value of each item does not exceed $100. If more than one educational item is provided, the total value of all educational items provided to any healthcare professional may not exceed $100 in a calendar year.

Consistent with AdvaMed Code of Ethics and OIG guidelines, educational items may be distributed on an "occasional" basis. For the purpose of this policy, "occasional" means that no more than five educational items may be provided to any healthcare practitioner in a calendar year. Textbooks are considered educational items.

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 five educational items 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 five items per HCP and cumulative retail value limit of $100.

Any raffle or sweepstake item provided to a healthcare professional must comply with this Policy and Policy and Procedure 17, "Drawings and Sweepstakes." As such, the item must (1) be an educational item; (2) comply with the annual limit of $100; and (3) count towards the annual limit of five items.

STATE SPENDING LIMITS

Some states have separate and very strict laws regarding the provision of educational items that are more restrictive than Bayer HealthCare Diabetes Care's policies. Please refer to the Policy and Procedure 29, "State Laws", in this booklet. You must consult the relevant Bayer HealthCare Diabetes Care 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 Diabetes Care paid for it, determines whether it is within the spending limits. Bayer HealthCare Diabetes Care 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 Diabetes Care 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 Diabetes Care 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 Diabetes Care 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, educational materials (medical booklets, text materials, handbooks), 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 Diabetes Care's policy not to provide subscriptions to scientific journals to a healthcare professional. Bayer HealthCare Diabetes Care may provide transcripts or journal articles or reprints, so long as the value does not exceed $100 per healthcare professional per year.

Medical textbooks may be offered through the Medical and Clinical Affairs Department or the Marketing Department; the textbook, however, must be approved by the Department of Medical and Clinical Affairs.

Bayer HealthCare Diabetes Care plastic bags are not considered educational materials, but you may use them for carrying samples of Bayer HealthCare Diabetes Care products such as meters, strips, lancets or Ketostix, and patient educational materials. Bayer-branded folders may be used in healthcare professional offices, so long as they are used to place approved product and/or promotional material. Using the plastic bags or branded folders in any other manner, such as general distribution to customers, would be considered providing non-educational items to either a healthcare professional or patient, which is not permitted by this Policy.

Other printed medical booklets and text materials, such as review guides, pocket books, brochures and handbooks, etc., may be obtained from the Marketing Department. The Marketing Department is responsible for obtaining approval through the Legal, Medical, Regulatory (LMR) process.

Educational items may only be procured through the Marketing or the Medical and Clinical Affairs Departments. The purchase of any medical books, text materials or other educational items not procured through Marketing or Medical and Clinical Affairs (*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**.**

Adherence to this Policy ensures 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 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.

EXAMPLES OF ACCEPTABLE EDUCATIONAL ITEMS

The following are examples of <u>appropriate</u> educational items for healthcare professionals:

- Anatomical model
- Medical textbook
- Resident handbook
- Educational materials and/or books on management of diabetes

UNACCEPTABLE EDUCATIONAL ITEMS

Practice-related "reminder" items such as pens, note pads, mugs, mouse pads, screen wipes, anti-bacterial sprays, magnets and similar items with or without the Bayer or product logos are <u>not</u> 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 AdvaMed Code of Ethics specifically prohibits 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) gas cards; (c) savings bonds; (d) lottery tickets; (e) airline upgrade coupons; or (f) loans. Items of a personal nature, such as flowers, gift baskets, or holiday items are also not appropriate.

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

PROCEDURES

Before providing an educational item, ask yourself:

1. Is the item intended primarily to educate the healthcare professional?
2. Is the number of educational items provided to the healthcare professional no more than five (5) items within a calendar year?
3. Is the cumulative value of gifts provided to this HCP in this calendar year less than $100?
4. 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?

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

The appropriate company spending policy must be followed when procuring and offering an educational. 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/

FOCUS ARRANGEMENTS

Educational items 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 educational items if no more than one item is provided per healthcare professional per year and if the retail value of that item is no more than $100.

Bayer HealthCare's Diabetes Care Division permits up to five educational items per healthcare professional per year provided the total limit of all educational items is no more than $100. **Each educational item after the first item in any calendar year IS considered a Focus Arrangement**. Because educational items are not "contractual in nature," Bayer HealthCare Diabetes Care is not required to follow Focus Arrangements Procedures for educational items. However, **Bayer HealthCare Diabetes Care is required to track these educational items** in the Focus Arrangements Database.

Educational items that constitute Focus Arrangements are tracked through Siebel. It is critical that you completely and accurately complete the information in Siebel or other required documentation of educational items so that Bayer HealthCare Diabetes Care can include required information in the Focus Arrangements Database.

Documentation of Educational Items through Siebel

- All educational items must be recorded through the Siebel System in the "Call Detail Screen" under "Products Placed."

Supervisor Review

Complying with the reporting and approval policies is a critical responsibility for managerial employees within the company, ensuring that all compliance obligations are met and ensuring proper control of business expenses.

If the Supervisor reveals potential divergence from this policy, the supervisor must take appropriate action, to include discussing the situation with the employee, documenting corrective action, and notifying the next supervisory level and the Bayer HealthCare Compliance Department.

RECORD RETENTION

Invoices are retained by the Accounting Department for a period of 7 years. The Sales Training Department will retain the distribution of educational items to HCPs in Siebel for a period of 7 years.

AUDITS

Spending for educational items is subject to auditing by Corporate Auditing 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 related spending.

16. EDUCATIONAL ITEMS AND MEALS PROVIDED TO PATIENTS

Under circumstances described in this Policy, Bayer HealthCare Diabetes Care representatives may provide occasional and modest educational, disease or treatment-related items and/or meals to patients. Bayer HealthCare Diabetes Care 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 Diabetes Care product(s).

GENERAL RULE AND LIMITS

Meals

It is generally appropriate for Bayer HealthCare Diabetes Care to provide an occasional and modest meal to patients in an appropriate setting conducive to having a Bayer HealthCare Diabetes Care product discussion or provide patient education on Bayer HealthCare Diabetes Care products or disease states relevant to Bayer HealthCare Diabetes Care products. It is not appropriate for Bayer HealthCare Diabetes Care to pay for, or reimburse patients for, personal meals. Payment for, or reimbursement of, patient meal expenses must be limited to meals for which there is a reasonable educational purpose and involve only individuals who are necessary to conduct Bayer HealthCare Diabetes Care 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 Diabetes Care representative present, or providing "take-out" meals, also 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 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 Diabetes Care employees, contractors, consultants and agents may distribute to patients items that are intended to educate patients or are important for patient treatment and/or disease management. These items may be distributed to patients at health fairs, medical testing events, patient walks, bike events, via on-line web based offers, and patient educational events or programs (*e.g.,* patient events sponsored by American Diabetes Association and Juvenile Diabetes Research Foundation), in connection with a product display or exhibit, or other patient education type events where the items will be distributed directly to the patient. During events which there is a reasonable expectation that both healthcare professionals and patients will attend (*e.g.,* ADA National Convention, JDRF National

Convention, AACE National Convention etc.), educational items may be provided as a raffle and/or sweepstake prize so long as the items are educational or disease or treatment-related items in compliance with this Policy and Policy and Procedure 17, "Drawings and Sweepstakes." Bayer HealthCare Diabetes Care may not condition the distribution of such materials in return for a contribution or a medical 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 pedometers, disease state brochures, CD Rom(s) related to the Know Your program series, meter skins, educational books, calorie counters, diabetes healthy meal cookbooks, health publications, 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 HealthCare Diabetes Care branded.

Supplies, such as pens, folders and paper may be provided for patient use only 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 the 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 Travel and Entertainment Expense Report ("T&E"). All employees must document the details of business expenses according to IRS rules, the Corporate T&E Policy and Compliance Policies and Procedures. 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/

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 Patient Privacy considerations, disclosure of name of the patient 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 Diabetes Care 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 Diabetes Care policy, the supervisor must take appropriate action, including discussing the situation with the employee, documenting corrective action, and notifying 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 7 years.

AUDITS

Spending for patient educational items and meals is subject to auditing by Corporate Auditing 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. DRAWINGS AND SWEEPSTAKES

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.

Educational items may be offered in occasional drawings or sweepstakes to healthcare professionals and/or patients. The items must comply with the requirements of Compliance Policy and Procedure 15, "Educational Items for Healthcare Professionals" and Policy and Procedure 16, "Educational Items and Meals Provided to Patients." For healthcare professionals, all such items must be primarily designed to educate patients or healthcare professionals, and for patients, the items must be related to education, disease and/or treatment. All items provided must also conform to the appropriate spending limits: $100 limit for healthcare professionals and $10 for patients.

The definition of healthcare professional is very broad and includes, but is not limited to, any individual who directly interacts with and treats patients such as physicians, nurses, nurse practitioners, physician assistants, CDE(s), medical assistants who treat patients, and other healthcare professionals, such as pharmacists, pharmacist technicians, lab technicians, therapists, interns and office assistants. However, the definition is not limited to these people alone; it also includes any person in a position to recommend or influence the purchase or prescribing of Bayer HealthCare Diabetes Care products. For the purposes of this policy, this definition also includes employees of distributors, mail order companies, purchasing agents, wholesalers, retailers, employees of a health plan administrator, Pharmacy & Therapeutics Committee members, or Formulary Committee members who do not see patients.

Items offered in drawings and sweepstakes to non-healthcare professionals and/or patients who are not beneficiaries of a federal healthcare program, must comply with all applicable state laws, including but not limited to, applicable sweepstakes and gaming laws. As such, all proposed drawings and sweepstakes must be approved by the Law and Patents Department prior to the event to ensure they comply with applicable federal and state laws.

FOCUS ARRANGEMENTS

Sweepstake prizes may constitute Focus Arrangements under the CIA where the sweepstakes winner is a healthcare professional who is a source of referrals or sales of Government Reimbursed Products.

Because sweepstakes and drawings are not "contractual in nature," Bayer HealthCare Diabetes Care is not required to follow Focus Arrangements Procedures for the sweepstakes and drawings. However, **Bayer** HealthCare Diabetes Care **is required to track these sweepstakes and drawings** for items provided to healthcare professionals in the Focus Arrangements Database.

Sweepstakes and drawings are tracked through Siebel. It is critical that the Bayer HealthCare Diabetes Care employees, contractors, consultants and agents responsible for the sweepstakes accurately document the details of the sweepstakes or drawing so that Bayer HealthCare Diabetes Care can include required information in the Focus Arrangements Database.

18. FEE-FOR-SERVICE ARRANGEMENTS

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.

The Personal Services Safe Harbor of the Anti-Kickback Statute allows Bayer HealthCare Diabetes Care to enter into certain relationships, or fee-for-service arrangements, with healthcare professionals provided certain criteria are met. Bayer HealthCare Diabetes Care's policy on fee-for-service arrangements is consistent with the Personal Services Safe Harbor, 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 Diabetes Care 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, promotional funding programs, medical writing and other activities where individuals (or the companies that employ them) are compensated by Bayer HealthCare Diabetes Care 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 any Bayer HealthCare Diabetes Care 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 or change the prescribing preference of the invited consultants; (2) provide participants merely with an opportunity to meet and mingle with their peers; or (3) have participants passively listen to new information about Diabetes Care products.

Consultants are generally healthcare professionals paid by Bayer HealthCare Diabetes Care 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 Diabetes Care 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 Diabetes Care in areas that are relevant to its business activities. Bayer HealthCare Diabetes Care may not purchase data unless it has established and documented a legitimate need for the data and, in fact, intends to use the data for legitimate business purposes. The purchase of data must not be discussed at the time that Bayer HealthCare Diabetes Care is negotiating price terms or other commercial arrangements with the customer.

Market research is aimed at obtaining information on customer requirements, preferences, product performance, and purchasing options for use by Diabetes Care 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 Market Research Studies may not be selected or compensated by the sales force or others 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 Diabetes Care, in which Bayer HealthCare Diabetes Care knows the identity of the participant prior to the planned research, are Focus Arrangements. Market research or focus groups where the participants' identities are blinded to Bayer HealthCare Diabetes Care are not Focus Arrangements.

Promotional speaker events include speakers who are acting or speaking on Bayer HealthCare Diabetes Care'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 Diabetes Care speaking arrangements across all Bayer HealthCare (including Diabetes Care, Radiology and Interventional, Dermatology and Pharmaceuticals divisions) may not exceed Fifty Thousand Dollars ($50,000) annually.

Service agreements with customers are services where by Bayer HealthCare Diabetes Care pays a fair market value fee to a customer (typically a healthcare organization) to provide certain services in connection with the use of Bayer HealthCare Diabetes Care products – such as disease education and/or management, marketing programs or health compliance programs. Examples include customers calling patients and reminding them to refill their Bayer HealthCare Diabetes Care prescriptions, disease awareness programs, customers mailing physicians information regarding the addition of a Bayer HealthCare Diabetes Care product to its formulary, or providing "patient information cards" to patients who may be using a Bayer HealthCare Diabetes Care 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 as a "Success Fee" 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 Diabetes Care product).

Speaker Training provides qualified speakers with training on Bayer HealthCare Diabetes Care products and includes information about specific disease states and disease management 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 Diabetes Care. Training may be provided via CD/DVD, webcasts or similar methods and, as appropriate, during speaker training meetings. Bayer HealthCare Diabetes Care must ensure that the number of speakers trained is closely related to the number of speakers Bayer HealthCare Diabetes Care plans to use. All speaker training meetings must be arranged through either the Marketing Department or the Department of Medical and Clinical Affairs 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 Diabetes Care, 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 meetings must be conducive to the consulting services. Exotic and/or resort locales are prohibited. Bayer HealthCare Diabetes Care may not provide entertainment, recreational activities in connection with any speaker training event, advisory board meeting 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 Law and Patents Department **before** it is signed by the speaker or consultant and Bayer HealthCare Diabetes Care. No Bayer HealthCare Diabetes Care employee may execute any contract or other legally binding document without review and approval from the Law and Patents Department. If a healthcare professional or other party refuses to sign the agreement provided by the Law and Patents Department **prior** to the initiation of the program or contracted services, he or she cannot be retained to provide the service.

PROCEDURES FOR ALL TYPES OF FEE-FOR-SERVICE ARRANGEMENTS

Initial Written Request

For all Sales Representatives—an initial request for a promotional fee-for-service arrangement must be made in writing and approved by the requestor's supervisor. The approved budgeted promotional and/or educational program request must then be submitted to Marketing for approval. If the Marketing Department approves the request, Marketing will then generate a request for an agreement, as noted below, using the agreement request form, which is submitted to the Law and Patents Department for legal review and contract generation. In the event that a speaker education program is established, Implementation Guidelines will be provided by the Marketing Department. Note that the sales representatives may make requests for non-promotional fee-for-service arrangements using the procedure outlined in the section below.

For the Marketing Department and all Other Bayer HealthCare Diabetes Care Employees, a request for a fee-for service arrangement must be completed on an agreement request form and must include the following:

- Name and address of the speaker(s), consultant(s), advisory board member(s), customer, other party, etc.;
- Bayer HealthCare Diabetes Care'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 Diabetes Care's need or purpose for the services);
- Term of the agreement, including any automatic renewal provisions;
- The proposed fee or contract amount; and
- Description of the expense to be reimbursed, if any.

The necessary information from the request form is included in the contract for all types of fee-for-service arrangements.

No speaker may be paid more than $50,000 for speaking engagements in any given calendar year. If Bayer HealthCare Diabetes Care 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 an agreement, a new agreement 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 Diabetes Care may work with third parties who contract with speakers, moderators, or consultants on behalf of Bayer HealthCare Diabetes Care. Third parties are prohibited from entering into contracts with HCPs on Bayer HealthCare Diabetes Care's behalf. The Law and Patents Department will generate all agreements with HCPs. If the third party engages the consultant or speaker, the third party must send to Bayer HealthCare Diabetes Care the proposed list of speakers, moderators, or consultants that it plans to use for the event. The Third Party must verify that each consultant has not exceeded the terms of any applicable agreement 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 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) entities, Indian Health Service (IHS), the National Institutes of Health (NIH), or other federal or state government entities.

Special rules and limitations apply to fee-for-service arrangements with government employees. Prior to any discussions regarding speaker services or any other fee-for-service arrangement with a federal or state 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 Diabetes Care sponsored clinical trials.

An employee may not receive compensation from Bayer HealthCare Diabetes Care 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 Diabetes Care 's products are made (other than in the capacity to prescribe products for patients).

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

FOCUS ARRANGEMENTS 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 provided to actual or potential source of sales or referrals of Bayer HealthCare Diabetes Care 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 Diabetes Care. 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 generates an approved contract and attaches a copy of Bayer HealthCare's Code of Conduct, Anti-Kickback Statute Policies and Procedures and a Third Party Personnel Letter (if applicable) and documents that these were sent. The 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 written contract may indicate that Bayer HealthCare Diabetes Care will reimburse reasonable expenses for travel, lodging, and meals incurred by the speaker or consultant in connection with the services provided to Bayer HealthCare Diabetes Care, as described in the approved written contract. Bayer HealthCare Diabetes Care will not reimburse incidental expenses, such as gift shop purchases. Bayer HealthCare Diabetes Care will not pay for any additional expenses associated with the spouse or guest of a consultant, such as travel or meals. A spouse or guest may share a hotel room with the consultant, provided Bayer incurs no additional costs.

Proof of Service

The 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 7 years. The contract must permit Bayer HealthCare Diabetes Care 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 from 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 Diabetes Care's policies. The approval process for the payment request package must follow the spending approval levels within Corporate U.S. Authorization Policy 002.20130115.

Focus Arrangements Database Procedures

When the executed contract is returned from the healthcare professional, the Focus Arrangement Owner forwards it to the appropriate Department (*e.g.,* Marketing, Medical, and Scientific Affairs) for processing by the Law and Patents Department to be entered into Efilia along with the information required for the Focus Arrangements Database. Refer to Policy and Procedure 8, "Focus Arrangements," for more information.

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 HealthCare Diabetes Care attendees are invited to an offsite group meeting which is not a patient education event. Please see policy on http://diabetescare.cnb/APPS/DC/US/DC-BDC/DC-BDC.nsf/id/EN_Meetings_Events.

RECORD RETENTION

The Accounting Department will retain the full payment request package according to Procedures for a period of 7 years. For tangible services (*e.g.,* consultant reports), the requestor must retain the proof of service in the department files (organized by contract number) for a period of 7 years.

AUDIT

All fee-for-service arrangements are subject to auditing by Corporate Auditing 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 seven years.

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 Diabetes Care recognizes the need to provide occasional medical practice training to sales representatives and other employees, contractors, consultants and agents to educate them on medical practice and treatment protocols. Group training programs may be arranged through Sales Training. **Bayer HealthCare Diabetes Care does not engage in private practice preceptorship arrangements.**

The Sales Training Department hosts an annual group medical training (such as Phase IV: Diabetes Real World Perspective Training) conducted by a third party organization (such as a recognized research center) for field sales and other employees, contractors, consultants and agents. Requests to attend the annual group medical training must be submitted to your manager.

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 18, "Fee-for-Service Arrangements."**

All medical practice training conducted by a third party organization (such as a recognized research center) must be done pursuant to a written contract. The contract must include the following provisions:

- Training must take place in an environment conducive to education. The training may only occur in a private practice or clinic office only if the third party training organization is solely responsible for selecting the healthcare professional, private practice and/or clinic used for the training with no input from Bayer HealthCare Diabetes Care.
- Any compensation provided to healthcare professionals in connection with the medical practice training must be made by, and at the sole discretion of, the third party training organization.
- As with all consulting arrangements, payment must represent the fair market value of the teaching services provided.

In addition, Bayer HealthCare Diabetes Care employees may not:

- Select a healthcare professional to conduct medical practice training to encourage him or her to prescribe or purchase Bayer HealthCare Diabetes Care 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 to 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 Diabetes Care may provide funds for sponsorships to various trade, medical, professional, patient, scientific and community organizations. The recipient organization's mission must 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 Diabetes Care 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 funding paid by Bayer HealthCare Diabetes Care. 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 Diabetes Care customers except in limited circumstances, approved by Law and Patents, where the event is open to all sponsors and provided the same opportunity is given to other similarly situated sponsors. 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."

Sponsorships may not be paid to encourage the recipient organization to purchase, order, refer, use or recommend Bayer HealthCare Diabetes Care products. It is Bayer HealthCare Diabetes Care'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 Diabetes Care 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 a professional, medical or patient association or organization where Bayer HealthCare Diabetes Care 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.

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 Diabetes Care 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 Association of Diabetes Educators (AADE) or a Wi-Fi Café during medical society meetings

- Sponsorship funding to support the annual walk for Juvenile Diabetes Research Foundation (JDRF), if this benefit is also provided to other pharmaceutical or medical device companies who provide a similar level of sponsorship.

- Trade show meetings, conferences, and events held by distributors, retailers and wholesalers (*e.g.*, CVS, Walmart, McKesson, etc.), which may include the opportunity for Bayer to exhibit or display Bayer products.

Examples of Impermissible Sponsorships

- Sponsorship of a hospitality suite at a disease-state awareness program sponsored by the American Diabetes Association (ADA) that is intended specifically for a discussion of a disease state for which Bayer HealthCare Diabetes Care products are not indicated.

- Sponsorship funding for Juvenile Diabetes Research Foundation (JDRF) members to attend a Broadway show one evening during the JDRF meeting. This is impermissible because Bayer HealthCare Diabetes Care 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 Diabetes Care 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 Diabetes Care products, or to reward any recipient organization for a past purchase, prescription, recommendation, or formulary placement of a Bayer HealthCare Diabetes Care 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.

Any employee attending a sponsorship event must be approved by a Vice President or above.

PROCEDURES

Requestor

A medical or professional society or other organization may solicit sponsorship through a website, e-mail, or paper mailing. No Bayer HealthCare Diabetes Care 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 completed on an agreement request form and emailed to: DCCONTRACT@bayer.com**.** The request must specify:

- The purpose of the request;
- The types (levels) 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;
- Whether the organization is affiliated with a Bayer HealthCare Diabetes Care customer; and
- Completed W-9 form;

Supervisor

The Supervisor reviews all documentation and makes an independent judgment as to whether the Corporate Sponsorship is consistent with Bayer HealthCare Diabetes Care's policies. If the Supervisor does not approve the request, he/she informs the Requestor that the proposed request has been denied.

If the sponsorship request is deemed to be complete, within budget and strategic plan, it will be forwarded to the Law and Patents Department for review.

A request must be considered a potential Focus Arrangement if the potential recipient is a source of sales or referrals of Government Reimbursed Products.

Questions regarding whether a request may constitute a Focus Arrangement must be directed to the Law and Patents Department. The Law and Patents Department makes the final determination whether the request is a Focus Arrangement.

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 Diabetes Care 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/project 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 and approves the sponsorship 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 Diabetes Care'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 7 years.

AUDIT

All requests for sponsorship are subject to audit by the Corporate Auditing and Bayer HealthCare Compliance Department to ensure compliance with this policy. The government (*e.g.*, OIG, IRS) may also request to audit/review sponsorship payments.

21. OPEN

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 Diabetes Care products potentially implicate prohibitions on 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 Diabetes Care 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 medical device or similar manufacturers.

The purpose and business need for a product display or exhibit is for Bayer HealthCare Diabetes Care 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 trade groups, professional associations, patient groups, or disease state groups, 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 **onsite-display** is used to display approved Bayer HealthCare Diabetes Care product information at a hospital or non-profit healthcare organization with an educational mission. On-site display opportunities occur within the organization's own facilities.

- An **offsite-display** is used to display approved Bayer HealthCare Diabetes Care product information 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, managed care organizations, or customers 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 Diabetes Care 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 product or unapproved use for an approved 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 Diabetes Care product, including questions regarding uses that have not received FDA approval, Bayer HealthCare Diabetes Care Sales or Marketing personnel may not answer the question and must refer him/her to the medical/scientific booth or, if there is no booth, to the Department of Medical and Clinical Affairs.

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 or charitable contribution or corporate sponsorship that also offers Bayer HealthCare Diabetes Care the opportunity to display or exhibit at the event. Grant and contribution requests should 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 Diabetes Care Grant Review Committee will make the appropriate determination regarding whether the grant will be approved and/or whether Bayer HealthCare Diabetes Care 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 Diabetes Care 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 Diabetes Care product, Bayer HealthCare Diabetes Care Sales or Marketing personnel must refer the healthcare professional to the Bayer HealthCare Diabetes Care medical/scientific booth. The Bayer HealthCare Diabetes Care 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 Department of Medical and Clinical Affairs.
- Only Medical and Clinical Affairs 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 Diabetes Care staff scheduled to work the exhibit booth must be instructed on this Policy during a pre-convention briefing.

PROCEDURES FOR REQUESTING DISPLAYS/EXHIBITS

Each Sales representative is provided a table top display that can be used at regional or local conventions. No other display materials can be used without review and approval by Marketing and Law and Patents. Meetings and Conventions will arrange for exhibits and displays at designated conventions and will publish a list each year of those conventions and procedures for ordering displays.

Focus Arrangement Owner

The Focus Arrangement Owner of the display/exhibit, at least fifteen (15) business days before the product display date, submits an online "Fund Request" through Siebel. It is the Focus Arrangement Owner's responsibility to make sure that (1) his/her manager and (2) Marketing or Field Operations, as appropriate, are aware of the Fund Request and approve it after reviewing the Fund Request submission and all required attachments for accuracy and completion.

Law and Patents Review of Focus Arrangements

For all product display requests involving payments to actual or potential Bayer HealthCare Diabetes Care 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 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 Diabetes Care. 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

After the Focus Arrangement Owner submits the Fund Request for a display and/or exhibit in Siebel, the Law and Patents Department documents his/her review of the Focus Arrangements Database requirements in Siebel. The required information is then extracted from Siebel and uploaded to the Focus Arrangements Database by the Bayer HealthCare Compliance Department.

Proof of Service

The Focus Arrangement Owner must confirm that he/she conducted the display or exhibit. The Focus Arrangement Owner formally confirms proof of service by proving attendance at the event with the product display by completing the Proof of Service box in Siebel. If the Focus Arrangement Owner is unable to confirm Proof of Service (*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 confirms Proof of Service is completed in Siebel, the Sales Force Automation Department sends the completed request documentation to AP or an approved third party vendor (as applicable) to generate payment. 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."

RECORD RETENTION

The Accounting Department retains the payment request package for a period of 7 years.

AUDITS

All displays and exhibits are subject to audit by Corporate Auditing 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 HealthCare Diabetes Care representative attends 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 Diabetes Care products may implicate prohibitions on off-label promotion under the Federal Food, Drug, and Cosmetic Act. This Policy and Procedure is designed to allow you to provide product displays and exhibits 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 an entity that is **not** a customer, potential customer, or source of sales or referrals. Appropriate entities under this policy include trade groups, 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.

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.

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 medical device or unapproved use for an approved device. Only promotional text materials approved for distribution may be located in and distributed from a commercial exhibit booth.

If a healthcare professional asks an "off-label" question about a Bayer HealthCare Diabetes Care product, including questions about uses that have not received FDA approval, Bayer HealthCare Diabetes Care 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 at location, to the Department of Medical and Clinical Affairs.

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 Diabetes Care has both a commercial exhibit and a medical/scientific booth, the commercial exhibit booth

must be physically separated from the medical/scientific booth. This separation helps 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 Diabetes Care'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 to distinguish it from 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 Diabetes Care product, Bayer HealthCare Diabetes Care Sales or Marketing personnel must refer the healthcare professional to the Bayer HealthCare Diabetes Care medical/scientific booth. The Bayer HealthCare Diabetes Care 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 Department of Medical and Clinical Affairs.
- Only Medical and Clinical Affairs personnel may be in or near the medical/scientific booth. Conversely, those individuals must not be in or near the commercial exhibit.

TRAINING

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

PROCEDURES FOR REQUESTING DISPLAYS/EXHIBITS

Each Sales representative is provided a table top display that can be used at regional or local conventions. No other display materials can be used without review and approval by Marketing and Law and Patents. Meetings and Conventions will arrange for Exhibits and Displays at designated conventions and will publish a list each year of those conventions and procedures for ordering displays.

Requestor

The Requestor, at least fifteen (15) business days before the product display date, submits an online "Fund Request" through Siebel. It is the Requestor's responsibility to make sure that (1) his/her manager and (2) Marketing or Field Operations, as appropriate, are aware of the Fund Request and approve it after reviewing the Fund Request submission and all required attachments for accuracy and completion.

Law and Patents Review

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 Diabetes Care's policies. If appropriate, the Law and Patents Department approves the request and generates a written agreement to be signed by all parties.

The Conventions Department

The Conventions Department uses the Bayer Corporate Master Card on behalf of Internal Marketing to pay for convention/conference expenses. The following procedure must be used for payments with the Bayer Corporate Master Card.

Commercial exhibit booths at regional and national conventions are monitored through an annual planning process as follows:

- The Conventions Department provides Marketing, Sales and Finance a budget estimate, prepared in conjunction with the third party exhibit vendor and the exhibit house, for the annual cost of regional and national conventions;
- The Conventions budget for Commercial Exhibits is agreed upon and approved through Marketing Sales and Finance;
- The Marketing and/or Conventions Department obtain proper reviews and approvals of graphic panels from the LMR. Once the approvals to exhibit/display are secured and the exhibit/display fee is paid, the exhibit booth and graphics must be requested;
- The Bayer HealthCare Diabetes Care representative contacts Bayer HealthCare Diabetes Care's designated exhibit house by phone or e-mail;

- The exhibit house ships an exhibit booth with the requested graphic panels for the appropriate product(s), which is returned to the exhibit house at the end of the convention; and

- The exhibit house invoices the Conventions Department per show for the exhibit units. The invoices are processed for payment according to the Corporate U.S. Signature Authorization Policy 002.20130115 website: http://www.bayernet.com/csignature authorizorp/policies/policies_detail.cfm?fileid=236 by the Conventions Department and sent to the Accounting Department for payment according to departmental procedures.

RECORD RETENTION

The Accounting Department retains the payment request package for a period of 7 years.

AUDITS

All displays and exhibits are subject to audit by Corporate Auditing 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 Diabetes Care 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 Diabetes Care participates in corporate memberships with various manufacturing, medical, patient and scientific organizations, as well as legislative policy groups, coalitions 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 Diabetes Care's goodwill in the community.

SCOPE

Trade, distribution, medical, patient and scientific organizations (*e.g.,* National Community Pharmacists Association (NCPA), 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 Diabetes Care wishes to become a member of such an organization, it is the policy of Bayer HealthCare Diabetes Care to establish these memberships for the Corporation or Division and not for individual Bayer HealthCare Diabetes Care employees.

Legislative policy groups offer Bayer HealthCare Diabetes Care relevant industry information, provide Bayer HealthCare Diabetes Care visibility within the device industry, and promote goodwill within organizations that maintain a political voice. Membership in medical and patient organizations allows Bayer HealthCare Diabetes Care 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 Diabetes Care 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 Diabetes Care 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 from 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 Diabetes Care may provide to a patient advocacy group or medical organization. Such payments must comply with Policy and Procedure 26, "Medical Education Grants (Including Accredited Continuing Education/Continuing Medical Education)," and Policy and Procedure 25, "Charitable Contributions (including Product Donation Requests)," respectively. Payment for a corporate membership is not a charitable contribution.

REQUIREMENTS

An organization may solicit membership through a website, e-mail, or paper mailing, or Bayer HealthCare Diabetes Care may seek out an organization and request to become a member. The organization's main focus must 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 Diabetes Care's goodwill in the community. Membership in organizations that primarily consist of healthcare professionals, which are offered to Bayer, must be made available to other device companies.

Membership fees cannot be paid to Bayer HealthCare Diabetes Care customers, entities controlled by or legally affiliated with Bayer HealthCare Diabetes Care customers, or other entities that may purchase, order, refer, use, prescribe, or recommend Bayer HealthCare Diabetes Care products, such as private practice groups, hospitals, managed care organizations or pharmacy benefits managers. Paying membership fees to any organization or basing the level of membership selected (*e.g.*, platinum, gold, silver) may not be contingent on the purchase of Bayer HealthCare Diabetes Care products or used as a price term.

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

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

PROCEDURES

Requestor

The Bayer HealthCare Diabetes Care "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. The approving Supervisor must be at Director's level or above.

Supervisor

The Supervisor reviews all documentation and makes an independent judgment as to whether the Corporate Membership is consistent with Bayer HealthCare Diabetes Care's policies. If the Supervisor does not approve the request, he/she informs the Requestor that the proposed request has been denied.

If appropriate, the Supervisor approves by signing the "Bayer Certification for Corporate Membership" and "Internal Payment Demand" and forwards both documents to 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 Dermatology'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 HealthCare Dermatology 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 Review

The Law and Patents Department reviews all documentation and makes an independent judgment as to whether the contribution is consistent with Bayer HealthCare Diabetes Care'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 Requestor.

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 7 years.

AUDITS

All Corporate Membership payments are subject to audit by Corporate Auditing and Bayer HealthCare Compliance to ensure compliance with these policies. The government (*e.g.*, OIG, IRS) may also request to audit/review corporate memberships.

FORM: BAYER CERTIFICATION FOR CORPORATE MEMBERSHIP FEES

Name of Organization:_____

Amount of Membership Fee: $_____

Indicate by checkmark 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 HealthCare Diabetes Care 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 HealthCare Diabetes Care products.

____ The organization offers the same membership or membership level to other corporations for the same fee.

____ The organization, not Bayer HealthCare Diabetes Care, 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 HealthCare Diabetes Care products.

____ The membership fee is not contingent on lobbying activities on behalf of Bayer HealthCare Diabetes Care.

____ 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 7 years.

25. CHARITABLE CONTRIBUTIONS (INCLUDING PRODUCT DONATIONS)

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 Diabetes Care provides charitable contributions to support legitimate medical research, indigent care programs, patient education, public education, community organizations within a Bayer HealthCare Diabetes Care business community, educational scholarships and other charitable events that directly benefit patients. Provision of charitable contributions can implicate various laws, such as the Anti-Kickback Statute. This policy is designed to enable Bayer HealthCare Diabetes Care 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, including product donations, provided to an IRS tax-exempt charitable organization, for which Bayer HealthCare Diabetes Care does not receive anything of value in return. Charitable contributions include monetary donations, product donations and items contributed for raffles or for fundraising/sponsorship efforts.

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 contribution is funding provided to a non-profit organization to support the organization's activities where Bayer HealthCare Diabetes Care 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 Diabetes Care 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.

Product donations are distinguished from product samples. Products, such as meters, that are provided as part of a patient assistance effort are considered a product donation, and the request must be processed as a request for a charitable contribution in accordance with this Policy and Procedure. Samples, in contrast, are provided for patient or provider evaluation purposes only. For more information on the distribution of samples, refer to Policy and Procedure 27, "Providing Samples at No Charge (Includes No Charge Meters, Sample Reagent Strips and Sample A1C Now Products)."

The Company spending policy is designed to allow Bayer HealthCare Diabetes Care 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 HealthCare Diabetes Care 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

Generally, charitable contributions may not be provided to Bayer HealthCare Diabetes Care customers. However, recognizing the need for patient-related programs, product donations may be provided to Bayer HealthCare Diabetes Care customers for patient support related programs such as camps for children with diabetes or hemophilia. The Bayer HealthCare Diabetes Care customer requesting product 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 Diabetes Care will not make charitable donations to individuals, political parties or causes, or religious groups for religious purposes. In addition, it is Bayer HealthCare Diabetes Care policy not to provide charitable donations to physician practice groups or to Bayer HealthCare Diabetes Care customers, or entities controlled by or affiliated with Bayer HealthCare Diabetes Care customers, except in the limited circumstances referenced above.

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 Diabetes Care business community or other charitable events that directly benefit patients which are all considered charitable contributions under Bayer HealthCare Diabetes Care's policies. The Review Committee shall be responsible for the review and approval of all Charitable Contributions. In addition, Sales and Marketing are not to be included in any communication regarding status of a request. If Sales or Marketing is approached by anyone regarding a charitable contribution, they are to direct the individual to the website: http://grants-contributions.bayerweb.com/en/home/.

REQUIREMENTS

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

1. The contribution is intended solely for charitable purposes. Bayer HealthCare Diabetes Care receives nothing of value in return, other than acknowledgement of Bayer HealthCare Diabetes Care's support by the charitable organization.

2. The recipient is a qualified 501(c)(3) or otherwise IRS tax-exempt charitable organization.

3. If the organization is a Bayer customer, or an organization that is controlled by a Bayer customer, the request must be for product for patient support-related programs, such as camps for children with diabetes or hemophilia.

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 Diabetes Care products.
- Intended to encourage the recipient to use, purchase, or recommend Bayer HealthCare Diabetes Care 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 fund his/her favorite charity).
- Intended as payment for services or goods.
- Provides a benefit to Bayer HealthCare Diabetes Care.

Any questions from a customer regarding a charitable contribution request must be addressed to the Grant Manager at: diabetes.supportrequests@bayer.com.

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 Diabetes Care'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 HealthCare Diabetes Care Grant Review Committee will determine whether the contribution will be approved and/or whether Bayer HealthCare Diabetes Care may display at the event.

Limited Attendance at Events

Bayer HealthCare Diabetes Care, as a supporter of charitable organizations may be offered tickets to event(s) that were not expected at the time of granting the charitable contribution. If tickets are offered to charitable events sponsored by certain patient support groups (*e.g.,* Juvenile Diabetes Foundation, American Diabetes), designated Bayer employees, as approved by a Vice President or above, may be permitted to attend such events in order for Bayer HealthCare Diabetes Care to demonstrate support for the patient group. The representative(s) of Bayer HealthCare Diabetes Care who attend must not engage in any promotional activity at the event or use the event as a promotional opportunity. Only the designated Bayer HealthCare Diabetes Care 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. However, spouses and/or guests of the employee may attend upon prior approval by a Vice President or above.

Contributions for Health Fairs/Medical Screenings

Under certain circumstances, Bayer HealthCare Diabetes Care may provide charitable contributions to support health fairs and medical screenings/testing events. These events must be offered by charitable organizations free of charge to the general community and promote disease awareness or detect medical conditions. Examples include free prostate exams, blood glucose testing, blood pressure screening, and mammograms.

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

- The request for funds/products must be received from an independent third party that qualifies as a 501(c)(3) or otherwise IRS tax-exempt charitable organization. Bayer cannot provide funds or products to a healthcare professional, private practice group, hospital or any other customer or any charity that is controlled or operated by a healthcare professional, practice group, hospital/clinic or any other customer.

- 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 all community at large (*e.g.*, may not limited to patients of a particular hospital, health organization, members of a certain HMO, etc.).

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

- Bayer HealthCare Diabetes Care may only 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."

If you receive a request for a charitable contribution that does not comply with Bayer HealthCare Diabetes Care's policies, you must inform the person making the request that Bayer HealthCare Diabetes Care's policies do not permit the contribution.

Bayer HealthCare Diabetes Care Employee Initiated Requests

Bayer HealthCare Diabetes Care employee initiated donation requests (*e.g.,* scholarships, product donations, equipment donations, etc.) are considered charitable contributions and must follow the procedures in this Policy and Procedure.

Equipment Donations

The Bayer Corporate U.S. Donation Policy requires Bayer AG approval and confirmation for all equipment donations of $7,500 or more that are charged to a business cost center. Laboratory equipment and supplies must only be donated in justified exceptional cases (for example, previously-used laboratory equipment for schools or universities) and following individual consultation with the responsible tax department. Refer to refer to Bayer Corporate Policy 1980 at: http://www.bayernet.com/corp/policies/policies_detail.cfm?fileid=220 for information regarding donations of used equipment.

NOTE: Used IT equipment such as computers, monitors, etc., must not be donated, but rather disposed of in accordance with the appropriate procedures established by the IT department.

PROCEDURES

Requestor

All Charitable Contribution requests must be received electronically directly from 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) or other tax exempt letter, indicating its status as a tax-exempt charitable organization. Additional backup documentation may also be required (*e.g.,* agenda, budget). The requestor is responsible for providing all Charitable Contribution related documentation.

Under NO circumstances will charitable contribution request be accepted or reviewed after the event has occurred.

Grant Manager

The Charitable Contribution request will first be reviewed by the Grant 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 Review Committee.

If the Grant Manager, after all attempts of obtaining appropriate documentation finds the request incomplete or not aligned with the budget or strategic plan, he/she will inform the requestor of the denial of request.

Review Committee

The Medical Education Grant and Charitable Contributions Review Committee is comprised of members from the Department of Medical and Scientific Affairs, Finance, Communications, Public Affairs, Public Policy and Government Affairs, Law and Patents Department and US Managed Markets. A representative from the Law and Patents Department must be in attendance at all Review Committee meetings and will only have veto power. In situations where Law and Patents cannot attend the meeting, review and comments must be obtained before finalizing any Committee approvals. Sales and Marketing personnel do not vote in the 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. The Review Committee also provides review and comments consistent with the following objectives:

- Each Committee member ensures that there are no legal or compliance issues that would prohibit Bayer' HealthCare Diabetes Care 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 budget.
- The request for support is aligned with Bayer HealthCare Diabetes Care's strategy, community and therapeutic focus.
- The donation will be used solely for charitable purposes and Bayer HealthCare Diabetes Care 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 Charitable Contribution request, the Review Committee will approve or decline in conformance with this Policy and Procedure and its Standard Operating Procedure. If the Law and Patents representative is not present, Law and Patents must review the charitable contribution before it is approved.

Law and Patents Review of Focus Arrangements

For the limited number of charitable contribution requests that are Focus Arrangements, an attorney in 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 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 amount of the charitable contribution may not depend upon or be based on the value or volume of referrals from the charitable contribution recipient.

The attorney also confirms whether the contribution amount represents fair market value in that the proposed amount is fair, reasonable and represents support for necessary expenditures based on the nature and the extent of the event for which the contribution requestor seeks support. Any deviation from the fair market value methodology and the rationale for such deviation must be approved by the Bayer HealthCare Compliance Officer (or designee) and documented and maintained in the Law and Patents Department.

Grant Manager Post Approval Documentation

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

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

No payments will be sent to the Requestor if a signed Letter of Agreement is not returned to Bayer HealthCare Diabetes Care. It is the responsibility of the requestor (or institution-designated staff member) to sign and return the Letter of Agreement to Bayer HealthCare Diabetes Care.

RECORD RETENTION

The Department of Medical and Clinical Affairs will retain the payment request package for a period of 7 years.

AUDITS

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

26. MEDICAL EDUCATION GRANTS (INCLUDING ACCREDITED CONTINUING EDUCATION/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 Diabetes Care's policy conforms to the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, the AdvaMed Code of Ethics, ACCME standards for commercial support and Other Accreditation agencies and relevant industry guidance. Bayer HealthCare Diabetes Care prohibits offering a medical education grant to encourage the recipient to prescribe, purchase, order, use or recommend Bayer HealthCare Diabetes Care 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 HealthCare Diabetes Care to violate the False Claims Act.

DEFINITION OF MEDICAL EDUCATION GRANT

Bayer HealthCare Diabetes Care may provide funding for activities associated with educational conferences, continuing education (CE), continuing medical education (CME) programs, professional meetings or patient education programs if they are sponsored by an organization other than Bayer HealthCare Diabetes Care and 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 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), room rental, 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 Diabetes Care products, to encourage off-label use, or reward referrals for Bayer HealthCare Diabetes Care products.

Bayer HealthCare Diabetes Care 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 Diabetes Care 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 Diabetes Care 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.

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 HealthCare Diabetes Care 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 CE/CME provider for the support, design or development of a medical education program supported by Bayer HealthCare Diabetes Care or in any way seek to influence the content of the program. The Grant Review Committee shall be responsible for the review and approval of all medical education grants (including CE/CME) within Bayer HealthCare Diabetes Care. 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/.

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:

- 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 CE/CME program or scientific meeting. Accreditation for CE/CME credit adds an additional level of evidence that the program is independent of commercial influence.

Bayer HealthCare Diabetes Care supported educational events must conform to the ACCME and/or other applicable accreditation entity's guidelines (such as ACPE).

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

- Bayer HealthCare Diabetes Care's funding of the program and any significant relationships between the vendor and Bayer HealthCare Diabetes Care;
- Financial or other relationships between individual presenters or moderators and Bayer HealthCare Diabetes Care;
- 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 Diabetes Care 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 Diabetes Care product(s).

The following criteria also apply to CE/CME programs:

- Funds from Bayer HealthCare Diabetes Care 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 Diabetes Care representatives may not on their own distribute invitations to a Bayer HealthCare Diabetes Care supported CE/CME event to healthcare professionals. If a CE/CME provider requests Bayer HealthCare Diabetes Care's help in writing (*e.g.*, by letter) to distribute supplemental invitations, Bayer HealthCare Diabetes Care may distribute these invitations on the CE/CME provider's behalf. 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 CE/CME program supported by Bayer HealthCare Diabetes Care must be the scientific nature of the program. Meals provided in conjunction with the program must always be modest, reasonable and secondary to the educational activity. Bayer HealthCare Diabetes Care may not directly provide meals at a CE/CME event. The CE/CME provider at its own discretion may apply the financial support provided by Bayer HealthCare Diabetes Care to provide meals to all program participants.

- Speakers at a Bayer HealthCare Diabetes Care supported CME program must disclose any current or previous relationship with Bayer, (*e.g.*, consultant, paid investigator, member of a Bayer speaker's bureau, etc.).

- Commercial exhibits may not interfere with the CE/CME activities. No promotional materials may be displayed or distributed in the same room as the CE/CME program before, during or after the program. No promotional activities may occur in the CE/CME room. No promotional materials may be displayed within the "obligate path" that attendees must use to enter or exit the room

where the CE/CME activity is taking place. Although not specifically defined by regulation, Bayer HealthCare Diabetes Care interprets "obligate path" to include, for example, paths from the main entry of a hotel to the meeting room or the way to a rest room.

Bayer HealthCare Diabetes Care will not directly provide compensation or reimbursement for registration, travel, lodging or personal expenses for attendees of any CE/CME event. However, pursuant to the AdvaMed Code of Ethics, Bayer HealthCare Diabetes Care may provide support to the CE/CME provider which, in its own discretion, can use the funds to reduce the overall CE/CME registration fee for all participants.

BAYER HEALTHCARE DIABETES CARE 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 products**, regardless of whether or not the event is sponsored in whole or in part by Bayer.

1. Bayer HealthCare Diabetes Care Attendance

    - Medical and Clinical Affairs employees 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 Diabetes Care 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 Diabetes Care Independence

Bayer HealthCare Diabetes Care employees may NOT be involved in the following activities associated with any program supported, even partially, by a medical education grant from Bayer HealthCare Diabetes Care:

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

3. Promoting Bayer HealthCare Diabetes Care or Bayer HealthCare Diabetes Care products

    - Bayer HealthCare Diabetes Care 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 Diabetes Care employees who are not attending the program may conduct appropriate promotional activities outside program meeting rooms, such as at an adjacent exhibit hall, provided that exhibit and display opportunities at the event have also been provided by the event sponsor to manufacturers other than Bayer HealthCare Diabetes Care.

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

    - Event sponsor has provided the opportunity to multiple device companies to display at the event, Bayer HealthCare Diabetes Care employees may display or exhibit at the program. For more information, see Policy and Procedure 22, "Displays and Exhibits for Hospitals and Other Customers," and Policy and Procedure 23, "Displays and Exhibits for Non-Customers."

ACCEPTABLE MEDICAL EDUCATION GRANTS

In summary, a medical education 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 physician practice group; and

- The organization, not Bayer HealthCare Diabetes Care, 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, 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 Diabetes Care may audit or review the use of the grant.
  - Provides a detailed budget describing planned usage of requested grant.
  - Confirms that Bayer HealthCare Diabetes Care'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 unapproved use of Bayer products HealthCare Diabetes Care; or
- Contingent on the purchase of Bayer HealthCare Diabetes Care products; or
- Intended to encourage the recipient to order, prescribe, or recommend Bayer HealthCare Diabetes Care 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 a "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 Diabetes Care by the recipient, with the exception of disclosure in program materials that the program is funded by Bayer HealthCare Diabetes Care; 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 must be covered by fee-for-service contracts as described in Policy and Procedure 18, "Fee-For Service Arrangements"; or
- Conditioned on the receipt of exhibit or display opportunities; or
- Not submitted through the Bayer website.

Invitations for Exhibit Space at the Education 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 HealthCare Diabetes Care 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 HealthCare Diabetes Care Grant Review Committee will make the appropriate determination regarding whether the grant will be approved and/or whether Bayer HealthCare Diabetes Care may display at the event.

PROCEDURES

All medical education grants (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 must be considered a Focus Arrangement if the potential recipient of the grant is a 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. The Law and Patents Department 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 Grant Manager, after attempting to obtain appropriate documentation finds the request incomplete or is not aligned with the budget or strategic plan, he/she will inform the requestor that the request is denied.

Grant Review Committee

The Medical Education Grant and Charitable Contributions Review Committee is comprised of members from the Department of Medical and Clinical Affairs, Finance, Communications, Public Affairs, Public Policy and Government Affairs, Law and Patents Department and US Managed Markets. 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 Review Committee reviews Medical Education Grant Requests from a scientific, educational, regulatory and legal perspective. At the Review Committee meeting, members review the 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 HealthCare Diabetes Care's approval of the grant request (*e.g.* no conflict with government or industry guidelines or Bayer HealthCare Diabetes Care 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 contributes to the improvement of patient care.
- The request for support is within the budget for each business area.
- The request for support is aligned with Bayer HealthCare Diabetes Care'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 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 Review Committee meeting.

Law and Patents Review of Focus Arrangements

For all grant requests that are 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 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 that the grant amount represents fair market value in that it is an amount that 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.

In the event 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. The minutes also list the committee members present at the review meeting.

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

Grant Approval of 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 HealthCare's Compliance program, including applicable training related to the Anti-Kickback Statute.

The Grant Manager must document that these documents were sent and the date they were sent.

Proof of Service

The Grant Manager, or other Bayer HealthCare Diabetes Care employee, must be able to confirm the services or deliverables of the grant. Acceptable proof of performance includes a completed 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 HealthCare Diabetes Care to observe the services rendered or otherwise obtain proof of service. Proof of Service must be retained by the Grant Manager for seven 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 grant recipient is responsible for sending a signed agreement back to the Grant Manager.

Focus Arrangements Database Procedures

The Grant Manager must complete the required fields in the grants and contributions database (MicroEdge GIFTS) for Focus Arrangements. Refer to Policy 8 "Focus Arrangements" and the MicroEdge GIFTS User Manual for information regarding the Focus Arrangements Database Procedures.

Reconciliation and Proof of Service

Invoices and final budgets must be reconciled with payments issued by Bayer. Overpayments must be returned to Bayer by the grantee.

RECORD RETENTION

The Department of Medical and Clinical Affairs must maintain the payment request package and Proof of Service for a period of 7 years.

AUDIT

All medical education grants are subject to audit by Corporate Auditing 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 (INCLUDES NO CHARGE METERS, SAMPLE REAGENT STRIPS AND SAMPLE A1C NOW PRODUCTS)

Bayer HealthCare Diabetes Care may provide a limited number of evaluation samples of diabetes care 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 evaluation samples provided (for tests) must not exceed an amount that is reasonably necessary for the intended use of the samples. Samples can include Diabetes Care products such as meters, strips, lancets or Ketostix, and patient educational materials. Bayer HealthCare Diabetes Care logo plastic bags may be used to carry these sample items. Providing evaluation samples in violation of this policy is strictly prohibited.

The provision of evaluation samples to specific customers must be fully documented in Siebel. Such documentation must contain, at a minimum, the number of evaluation samples provided to each healthcare professional, the type of samples provided, and the date the samples were provided. Each representative must maintain accurate records of inventory samples. Guidelines for dispensing evaluation samples may be obtained from the Marketing Department.

Under no circumstances is a sample to be given to a healthcare professional for personal 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 Diabetes Care products.

Recipients of evaluation samples must be advised in writing that no evaluation 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.

Product samples are not the same as charitable product donations. Samples are provided f or 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 25, "Charitable Contributions (including Product Donations)."

VERMONT DISCLOSURE OF SAMPLES OF PRESCRIBED PRODUCTS

If a manufacturer of prescribed products reports other allowable expenditures or permitted gifts, the manufacturer must also report on an annual basis certain information relating to free samples of prescribed products, including prescription drugs, non-prescription medical devices, non-prescription durable medical equipment, and OTC products provided to Vermont healthcare providers for the preceding calendar year, provided that any public reporting of such information shall not include information that allows for the identification of individual recipients of samples or connects individual recipients with the monetary value of the samples provided.

Samples 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. 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 Section 6004 of PPACA.

Regardless of the Attorney General's determination, 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. Vermont's sample reporting requirements apply to coupons and vouchers that allow a patient to receive product free or at a discounted price. Bayer HealthCare Diabetes Care prohibits representatives from providing samples in the state of Vermont to healthcare professionals.

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 Diabetes Care 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 (Includes No Charge Meters, Sample Reagent Strips And Sample A1C Now Products)" 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
	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	
	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.
	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

Bayer HealthCare Diabetes Care is committed to complying with California SB 1765 which requires certain companies to establish:

1. **Compliance Program** – A Comprehensive Compliance Program in accordance with the "Compliance Program Guidance for Pharmaceutical Manufacturers" (April 2003). It is important to note that the OIG has also recommended that medical device companies use this Guidance when developing their compliance programs.

2. **Policies** – Policies that take into account relevant industry guidance on interactions with healthcare professionals, such as the *AdvaMed Code of Ethics on Interactions with Health Care Professionals (AdvaMed Code of Ethics)*.

Limits on Meals, Educational Items and Other Items of Value Provided to Healthcare Professionals – Adopt specific annual dollar limits on meals, educational items and other items of value provided to medical or healthcare professionals. Financial support for continuing medical education and health educational scholarships, along with payment to healthcare professionals for legitimate professional services (*e.g.,* consulting) are specifically exempt from this annual limit provided that such is consistent with fair market value and industry guidance, such as the *AdvaMed Code of Ethics*.

California law defines "medical or healthcare professional" as:

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

Bayer has established an annual dollar limit of $1,000 for all Bayer divisions in a calendar year.

ANNUAL DECLARATION

Bayer HealthCare must annually declare, in writing, compliance with its Comprehensive Compliance Program and the California law. The annual declaration, the Comprehensive Compliance Program, and a toll-free number (1-877-256-3564) where one can obtain copies of both items must be published on the company's website: http://www.simplewins.com/site/Adults/Learn/Pages/The-Bayer-Story/Healthcare-Compliance. The Compliance Department is responsible for ensuring that the annual declaration and publication occurs.

29. STATE LAWS

Connecticut – Compliance Program

COMPLIANCE PROGRAM

Connecticut requires medical device manufacturers to adopt and implement a compliance program that is consistent with and contains, at a minimum, all of the requirements prescribed in the AdvaMed "Code of Ethics on Interactions with Health Care Professionals," as in effect on January 1, 2010. Medical device manufacturers must have adopted a compliance program. Connecticut law also requires medical device manufacturers to adopt a comprehensive compliance program in accordance with the "Compliance Program Guidance for Pharmaceutical Manufacturers" dated April 2003 and developed by the United States Department of Health and Human Services Office of the Inspector general. Manufacturers are also required to conduct training and regular audits of their 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

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 gift or other item of value, including entering into fee-for-service arrangements.

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.** Moreover, Bayer's Policy and Procedure 15, "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 non-educational items to healthcare professionals who are 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.

MEDICAL DEVICE SAMPLES

Medical device demonstration units and samples to state employees may raise issues under federal and Louisiana law. Therefore, you must consult the Law and Patents Department before sampling medical device products to Louisiana state employees.

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 professionals 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 State 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 entering Bayer into a financial arrangement with, reimbursing travel expenses for, and/or engaging 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.
- 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 and 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:

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

- 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.

- In circumstances where Bayer HealthCare Diabetes Care 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 Diabetes Care and the State agency obligates Bayer HealthCare Diabetes Care 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 contact the Law and Patents Department before entering Bayer HealthCare Diabetes Care into a financial arrangement with, reimbursing travel expenses for, and/or engaging 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 prescription drugs or medical devices 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 healthcare providers, healthcare entities and others.

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 Diabetes Care's Policy only allows for in office meals.

KEY DEFINITIONS

The law defines "healthcare practitioner" as a person licensed to provide healthcare, who prescribes prescription drugs for any person, or a partnership or corporation comprised of such persons, or an officer, employee, agent or contractor of such persons 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 (as may be the case with, for example, certified diabetes educators) 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 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 AdvaMed

Code of Ethics on Interactions with Health Care 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, taking corrective action in response to non-compliance and 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:

1. The distribution of peer reviewed academic, scientific or clinical information;
2. The purchase of advertising in peer reviewed, scientific or clinical journals;
3. The provision of reasonable quantities of medical device demonstration and evaluation units to healthcare practitioners for the purpose of assessing the appropriate use and functionality of the product and determining whether or not and when to use or recommend the product at a future time;

4. Compensation for professional or consulting services in connection with a genuine research project or a clinical trial;

5. The reimbursement or payment of reasonable expenses necessary for technical training on the use of a medical device for the purpose of assessing the appropriate use and functionality of the product and determining whether or not and when to use or recommend the product at a future time is part of the vendor's purchase contract for the device;

6. 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; and

7. The provision of product reimbursement information and information designed to offer technical or other support intended to assist in the appropriate and efficient use or installation of products.

The Department's marketing code expressly prohibits:

1. 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 representative or without the sales representative being present; or

   - Are provided to a healthcare practitioner's spouse or other guest.

2. The provision of entertainment or recreational items of any value;

3. Sponsorship or payment for CME that does not meet ACCME standards, or that provides payment directly to a healthcare practitioner;

4. Payment of travel-related expenses for attendees of CME, third-party scientific or educational conferences, or professional meetings, either directly to the attendees or indirectly to the event's sponsor;

5. Compensation for the time spent to attendees of CME, third-party scientific or educational conferences, or professional meetings;

6. Payment made directly to a healthcare professional for meals at any CME event, third-party scientific or educational conference, or professional meetings;

7. Payments in cash or cash equivalents to healthcare practitioners, except as compensation for *bona fide* services; or

8. 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 healthcare 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 healthcare 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 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 that 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 healthcare 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 $2,000 fee.

29. STATE LAWS

Nevada – Marketing Code of Conduct

Nevada law requires each manufacturer that 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 "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 health care professionals." For medical device manufacturers, a code of conduct that incorporates the most recent version of the 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.

Further, the statute 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 reports 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 email 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 will submit to the Governor and the legislature a report which compiles the information from the annual submissions. The Board will 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.

Nevada 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

Tennessee – Ethics Commission Act

The Tennessee ethics reform bill regulates the activities of persons doing business with the state. The legislation does not require vendors or their representatives in Tennessee to register as lobbyists; they must, however, comply with provisions similar to those that govern the conduct of lobbyists.

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 and lodging. 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 HealthCare 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

Bayer employees cannot buy 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.

Bayer employees can buy a meal for 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 Compliance Policy and Procedure 14, "Business Meals to HealthCare Professionals." The Tennessee law applies only to state employees. However, local ordinances could prohibit gifts otherwise permitted by Bayer in a Tennessee county or city. Bayer employees need to check with local governments for those regulations.

29. STATE LAWS

Vermont – Marketing Disclosure Law

SCOPE

The Vermont Prescribed Products Gift Ban and Disclosure Law prohibits certain gifts to healthcare providers and 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.

Under Vermont law, if a company has multiple divisions, some of which market prescribed products to Vermont healthcare 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. The Compliance Officer Form (discussed below) must also be submitted in the name of the manufacturer.

DEFINITIONS

A "**prescribed product**" means:

- Drugs or medical 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 which 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, service provided to a healthcare provider or board member;

- Anything else of value provided to a healthcare provider or board member unless it is reimbursed by the healthcare provider or board member at fair market value or is an allowable expenditure as noted below.

A "**healthcare professional**" means:

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

A "**healthcare provider**" means:

- A healthcare professional, a hospital or nursing home, a pharmacist, health benefit plan administrator or any other Vermont authorized dispenser or purchaser of prescribed products. The term "healthcare provider" does not include a hospital foundation that is organized as a non-profit 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, 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 draft 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 or 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;
- 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 seminars 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 and where there 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 and 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 benefit provided at fair market value.

8. Effective July 1, 2009, the provision of reasonable quantities of medical device demonstration or evaluation units to a healthcare provider to assess the appropriate use and function of the product and determine whether and when to use or recommend the product in the future.

9. ** Effective July 1, 2010, samples of a prescribed product or reasonable quantities of an OTC drug or non-prescription medical device provided to a healthcare provider for free distribution to patients.

10. ** Effective July 1, 2010, free prescription drugs or OTC products, medical devices, biological products, medical equipment or supplies, or financial donations to a free clinic.

11. ** 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.

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

13. 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 healthcare services on behalf of an employee of the manufacturer.

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

15. Effective July 1, 2011, payment for the reasonable expenses necessary for technical training of individual healthcare professionals on the use of a medical device if the commitment to provide such expenses is described in a written agreement between the healthcare provider and the manufacturer.

16. Effective July 1, 2011, loans of medical devices for short-term trial periods, not to exceed 120 days, to permit evaluation of a medical device by a healthcare provider or patient, provided the loan results in purchase, lease, or other comparable arrangement.

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

18. ** 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, 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 expenses on Healthcare Professionals in the appropriate tracking systems (FADb, Concur, etc.).

Continuing Medical Education programs funded by Bayer also must be disclosed. 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 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 non-prescription medical devices, non-prescription durable medical equipment, medical food, infant formula, and OTC products provided to Vermont healthcare providers for free to 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 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.

Vermont's sample reporting requirements apply to coupons and vouchers that allow a patient to receive product free or at a discounted price. Bayer HealthCare Diabetes Care prohibits representatives from providing samples in the state of Vermont to healthcare professionals.

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 requirements.

APPLYING THE REPORTING LIMITS

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

All Diabetes Care employees are responsible for tracking all allowed expenditures within the internal spend source system (*e.g.*, SAP, and Concur) as required by Bayer HealthCare Diabetes Care Compliance Policies and Procedures.

COMPLIANCE OFFICER FORM

Bayer HealthCare must submit a Compliance Officer Form by January 1 of each year. The form identifying the Compliance Officer can be found on the Attorney General's website at: http://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 will become public information.

PENALTIES FOR FAILURE TO REPORT

Civil penalties may be imposed in an amount up to $10,000 per violation. Each unlawful gift, or failure to disclose a gift, 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 1 of each year: Bayer HealthCare must submit marketing disclosure reports for all covered Bayer entities (Bayer HealthCare Pharmaceuticals (BHCP), Bayer Dermatology, Radiology and Interventional, Diabetes Care and Consumer Care). The report includes disclosures 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 (Pharmaceuticals, Dermatology, Radiology and Interventional, Diabetes Care and Consumer Care).

REGISTRATION FEE

Beginning January 1, 2013 and annually thereafter, these manufacturers with 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

DIABETES CARE POLICIES

In all interactions with healthcare providers, relevant Bayer HealthCare Diabetes Care Compliance Policies must be followed. Relevant Bayer HealthCare Diabetes Care Policies outline what is permissible, and what may be restricted, with regard to such items as meals, distribution of educational items, and fee-for-service arrangements. Where state law is more restrictive (*e.g.*, gift ban, prohibitions), Diabetes Care employees must follow the state law requirements.

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 types of 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 representatives **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 representative 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 Diabetes Care recognizes that each customer is solely responsible for the accuracy of any billing and coding used by that customer in obtaining reimbursement. Bayer employees may not advise customers on how to bill or code to obtain reimbursement and must limit any communications relating to billing, coding and reimbursement to communications that comply with this policy.

Written Materials

Bayer HealthCare's Public Policy & Government Affairs Department and/or Diabetes Care Associate Manager, US Reimbursement Strategy, Government Sector is responsible for preparing written communications, brochures, and other materials relating to coverage, procedural and product coding/billing, payment and other reimbursement information for Diabetes Care products. Any materials provided to customers shall be for informational purposes only with the goal of providing materials that can assist them in understanding and complying with CMS and other insurers' reimbursement policies and requirements regarding coverage, coding/billing, and payment.

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.

Literature

You may only provide literature which has been previously approved by the Diabetes Care Associate Manager, US Reimbursement Strategy, Government Sector and the Diabetes Care Law and Patents Department. Approved materials shall clearly reference the source for any such information.

Information Content

Bayer HealthCare Diabetes Care employees may provide insurance coverage, coding/billing, and/or payment information for Bayer HealthCare Diabetes Care products that satisfies the following requirements:

- The coverage, coding/billing, or payment information has been prepared and approved by the Diabetes Care Associate Manager, US Reimbursement Strategy, Government Sector and the Diabetes Care Law and Patents Department and relates to an FDA-approved use of Bayer HealthCare Diabetes Care products.

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

- Bayer HealthCare Diabetes Care 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 HealthCare Diabetes Care, and that Bayer HealthCare Diabetes Care cannot guarantee reimbursement from a third party.

Subject to the requirements above, Bayer HealthCare Diabetes Care 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 Diabetes Care products. The information may include the applicable Medicare Fee Schedule, which publishes the dollar amount for reimbursement assigned to the HCPCS and CPT codes applicable to Bayer HealthCare Diabetes Care products and services.

Bayer HealthCare Diabetes Care employees may not provide personal opinions, comments, or interpretations of coverage, coding/billing, payment or any other reimbursement information published by any insurer or any other source. If a Bayer HealthCare Diabetes Care employee receives a request for reimbursement information or assistance from a customer, the employee may provide the customer with previously approved reimbursement materials and/or direct the customer who has reimbursement questions to the Diabetes Care Associate Manager, US Reimbursement Strategy, Government Sector.

Prohibition against Promotion on Reimbursement

It is Bayer HealthCare Diabetes Care's policy to promote products based solely on their efficacy, safety and cost. You must not encourage customers to prescribe or purchase Bayer HealthCare Diabetes Care 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 Diabetes Care products or competitors' products. **You may 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 sources (such as First Databank) where the information may be obtained. You must 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.

Questions

If you have any questions regarding Medicare or Medicaid reimbursement for Bayer HealthCare Diabetes Care products, contact the Diabetes Care Associate Manager, US Reimbursement Strategy, Government Sector and/or the Diabetes Care Law and Patents Department. If you have any questions regarding the advertising and promotion of Bayer HealthCare Diabetes Care products that are reimbursed by Medicare or Medicaid, contact the Diabetes Care US Marketing Department or the Diabetes Care Law and Patents Department.

32. APPROPRIATE TARGET AUDIENCE FOR PROMOTIONAL ACTIVITIES

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

The term "healthcare professional" is very broad and includes, but is not limited to, any individual who directly interacts with and treats patients such as physicians, nurses, nurse practitioners, physician assistants, CDE(s), medical assistants who treat patients, and other healthcare professionals, such as pharmacists, pharmacist technicians, lab technicians, therapists, interns and office assistants. However, the definition is not limited to these people alone; it also includes any person in a position to recommend or influence the purchase or prescribing of Bayer HealthCare Diabetes Care products. For the purposes of this policy, this definition also includes employees of distributors, mail order companies, purchasing agents, wholesalers, retailers, employees of a health plan administrator, Pharmacy & Therapeutics Committee members, or Formulary Committee members who do not see patients.

Audiences for promotional activities must not be selected in such a way as to circumvent the prohibition of off-label promotion of Bayer HealthCare Diabetes Care products.
For example, Bayer HealthCare Diabetes Care representatives cannot:

- 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 Diabetes Care 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 Diabetes Care product.

Questions regarding unapproved, or "off-label" uses, of products must be directed to, the Department of Medical and Clinical Affairs.

33. PROMOTIONAL PRACTICES OUTSIDE THE UNITED STATES

If Bayer HealthCare Diabetes Care 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 AdvaMed Code of Ethics.

ADDITIONAL GUIDANCE

- You may not discuss unapproved uses of a Bayer HealthCare Diabetes Care product with a U.S. physician, or offer prohibited remuneration simply because you are both attending a conference outside of 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 the United States' promotional rules.

- Bayer HealthCare Diabetes Care personnel cannot arrange for the attendance of U.S. healthcare professionals at medical education programs outside the U.S. to discuss uses that are 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 Diabetes Care personnel must adhere to applicable international guidelines (the MEDEC Code of Conduct and Eucomed Code) (Guidelines on Interactions with Healthcare Professionals and Code of Ethics) when interacting with Canadian and European healthcare professionals, respectively, who may prescribe, recommend, purchase or lease medical devices or other medical technology products.

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

34. MATERIALS FOR EXTERNAL USE

Bayer HealthCare Diabetes Care 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 Diabetes Care employees, contractors, consultants and agents may conduct presentations to instruct healthcare professionals on the proper, on-label use of Bayer HealthCare Diabetes Care 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 PROMOTIONAL MATERIALS

Advertising and promotional materials include 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 publicly available materials (internet 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 materials or non- promotional materials, such as by highlighting, deleting, editing or adding notes or other material, makes those materials unacceptable and is also considered "homemade bread."

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 board, investigator meetings, speaker training, etc. are not to 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. Even comparative claims based on competitor's package inserts need to be approved by LMR before the claims can be made.

35. MATERIALS FOR INTERNAL USE ONLY

Bayer HealthCare Diabetes Care permits the distribution among its employees, contractors, consultants and agents of certain educational materials that are intended only for internal use for education or to provide general business information. These materials may not be used externally (*e.g.,* to promote, discuss or reference Bayer HealthCare Diabetes Care 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 Diabetes Care employee, contractor, consultant or agent providing services to or on behalf of Bayer, to ensure that any material distributed is clearly marked in this manner, including material forwarded by electronic mail. Documents marked for internal use only (*e.g.,* for your information only) are not to be distributed to or discussed with customers.

MEDICAL INFORMATION

Under certain limited circumstances, the Law and Patents Department may approve the distribution of specific disease state and management modules and other materials, sales training tools, or medical journal reprints for non-promotional purposes. Such training and documents are for internal use only and not to be shared with customers. Bayer HealthCare Diabetes Care representatives involved in these limited cases are provided written instructions regarding distribution.

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 Diabetes Care employees, contractors, consultants and agents (*e.g.,* 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 lay press (newspapers, magazines, on-line news services, *Gray Sheet,* industry publications, medical journals, medical text books)

- Consumer advertisements (*e.g.*, One Touch Ultra newspaper ad)
- Recall notices

If a Bayer HealthCare Diabetes Care representative or manager shares information with other Bayer employees, contractors, consultants and 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 internal use only, confidential and proprietary information. 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 HEALTHCARE DIABETES CARE PRODUCTS

If anyone, such as a physician, pharmacist, healthcare professional, or individual from a patient group or buying group, asks an unsolicited question about unapproved (or off-label) uses of Bayer HealthCare Diabetes Care products, you must direct that person to Medical Information within the Department of Medical and Clinical Affairs for information. 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, Bayer HealthCare Diabetes employee, contractor, consultant or agent must advise the inquirer that Bayer HealthCare Diabetes Care policy prohibits them from discussing off-label uses. The employee, contractor, consultant or agent must:

- Refer the inquiry to Medical Information within the Department of Medical and Clinical Affairs by providing the requestor the Medical Information email address: DiabetesCare_MedInfo@bayer.com; or
- Complete the Medical Inquiry form, include the name, address and signature of the requesting healthcare professional, scan the form and email to DiabetesCare_MedInfo@bayer.com.

Medical Information within the Department of Medical and Clinical Affairs will then provide appropriate information directly to the requestor. No discussions can take place in a public forum pertaining to unapproved uses of Bayer HealthCare Diabetes Care products.

ADDITIONAL GUIDANCE

Soliciting Discussion: It is against Bayer HealthCare Diabetes Care policy for a sales consultant to ask leading questions intended to encourage discussion of unapproved use. Bayer HealthCare Diabetes Care 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 promotion for unapproved uses.

Requests for Non-Approved Materials: Requests from healthcare professionals or other Bayer HealthCare Diabetes Care customers for product samples for unapproved uses, non-promotional materials, materials discussing off-label uses or materials that are not approved for promotion must be directed to Medical Information, within the Department of Medical and Clinical Affairs. You may not respond to or solicit this type of request or inquiry nor provide such information.

37. ADVERSE EVENTS INVOLVING BAYER HEALTHCARE DIABETES CARE PRODUCTS

REPORTING REQUIREMENTS

Bayer HealthCare Diabetes Care, as a medical device manufacturer, is required to report adverse information to the FDA. Certain customers, such as hospitals and nursing homes, have separate obligations to report suspected medical device-related deaths to both the FDA and the manufacturer, and medical device-related serious injuries to the manufacturer. If you become aware of adverse information involving a Bayer product, you must report this information to the Customer Services Department at 1-800-348-8100 as promptly as possible, as but no later than twenty-four (24) hours after becoming aware of the information.

WHAT TO REPORT

Adverse event information that you must report includes:

- Information, from any source, that reasonably suggests that one of Diabetes Care Division's products may have caused or contributed to a death or serious injury; and
- Information, from any source, that reasonably suggests that a malfunction of a Bayer HealthCare Diabetes Care Division product has occurred and, if a malfunction were to recur in the same or a similar product, it could cause or contribute to a death or serious injury.

Bayer Healthcare Diabetes Care must report this information to FDA.

NOTE: You must report adverse event information regardless of whether you believe that the facility at which the event occurred will report the information to Bayer HealthCare Diabetes Care or FDA. You must report adverse event information involving a Bayer HealthCare Diabetes Care product to the Customer Services Department regardless of whether the adverse event appears to have been caused by, or related to, the use of the Diabetes Care Division product. The appropriate personnel will determine whether the Bayer HealthCare Diabetes Care product may have caused or contributed to the adverse event and whether the information must be reported to FDA.

38. CLINICAL RESEARCH

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 clinical research and clinical studies conducted by Bayer HealthCare Diabetes Care must promote legitimate research goals. Bayer HealthCare Diabetes Care may enter into an arrangement for clinical research or clinical studies for the purpose of developing clinical information concerning Bayer HealthCare Diabetes Care products, both pre- and post-market, or research related to the diagnosis and treatment of diabetes or other related clinical presentations, provided that the clinical information sought is reasonably necessary to achieve a commercially reasonable business purpose. Payment for any research or clinical study cannot be provided with the requirement or expectation that such support will induce or encourage the prescription, purchase order, refer, use or order of Bayer HealthCare Diabetes Care products. Any research or clinical study conducted by Bayer HealthCare Diabetes Care must be pursuant to a written agreement approved by the Law and Patents Department that, at a minimum, includes:

- A statement of the research or clinical objectives;
- An outline of the research or clinical protocol;
- A written budget detailing the payments to be provided by Bayer HealthCare Diabetes Care; and
- A requirement for progress reports and/or, a final written report as applicable.

It is not appropriate for Bayer HealthCare Diabetes Care to enter into an arrangement for clinical research that is not intended to, or otherwise does not, develop clinical information and/or develop clinical information concerning Bayer HealthCare Diabetes Care products that is reasonably necessary to achieve a commercially reasonable business purpose (such as, to demonstrate the safety or efficacy of a Bayer HealthCare Diabetes Care product). It is also not appropriate for Bayer HealthCare Diabetes Care 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 Diabetes Care by that clinical investigator.

Under no circumstances may Sales or Marketing personnel engage in discussions, negotiations or unsolicited requests with an investigator, including a research organization or institution, involved in clinical research studies supported by Bayer HealthCare Diabetes Care or in any way seek to influence the study protocol. In addition, Sales and Marketing are not to be included in any communication regarding the status of a request by an investigator or an institution for any type of support, including funding or the supply of product, to conduct clinical studies. If Sales or Marketing is approached by an investigator or institution requesting support for a clinical study, they are to direct the investigator or institution to the Department of Medical and Clinical Affairs at 1-800-348-8100.

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

ADDITIONAL GUIDANCE

- Bayer HealthCare Diabetes Care may not seek to further the pre-approval or off-label use of Bayer HealthCare Diabetes Care drug products under the guise of a less-than-adequate clinical study.
- Recipients of Bayer HealthCare Diabetes Care's financial support for clinical research and clinical studies must be made aware, and the respective contract(s) will so reflect, that Bayer HealthCare Diabetes Care 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.
- All requests by an independent researcher to approve publishing of a Bayer HealthCare Diabetes Care sponsored clinical research and/or clinical trial (pursuant to the written agreement) must be sent directly to the Office Medical and Clinical Affairs who shall obtain final approval from the Law and Patents Department.
- For additional information, please contact the Office of the Chief Medical Officer at 914 333-6290 or the Law and Patents Department.

Some agreements for research may constitute Focus Arrangements under the CIA. An agreement for 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 a source of sales or referrals of Bayer HealthCare Diabetes Care products.

Law and Patents Review of Focus Arrangements

For all clinical research agreements 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 arrangements; 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 Diabetes Care. 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 Diabetes Care 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 HealthCare Diabetes Care must document that the documents were sent.

Approval of Focus Arrangements

For approved clinical research agreements that are Focus Arrangements, the Bayer HealthCare Diabetes Care employee who initiated the request, or the "Focus Arrangement Owner," must send each party to the Focus Arrangement, (*e.g.*, the recipient of the funds), a copy of Bayer HealthCare's Code of Conduct and Anti-Kickback Statute Policies and Procedures. The Focus Arrangement Owner must document that these documents were sent.

Approval of Non-Focus Arrangements

If the approved request for clinical research agreement is not a Focus Arrangement as determined by the Law and Patents Department, the Focus Arrangement Owner will send the approved agreement to the funds recipient (or institution-designated staff member). The Focus Arrangement Owner is responsible for sending a signed agreement back to the Law and Patents Department.

THIRD PARTY CONTRACTS

Bayer HealthCare Diabetes Care may work with third parties who contract with hospitals, research sites, or other entities on behalf of Bayer HealthCare Diabetes Care. In order to ensure that third party contracts comply with the Anti-Kickback Statute and Bayer HealthCare Diabetes Care'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 the reviewing attorney's name must be documented.

The third party contract must include a maximum value for the research or clinical studies support based on information from a database of fair market values or other relevant sources.

The contract provided to the third party must contain:

- A certification by the parties that the parties shall not violate the Anti-Kickback Statute with respect to the performance 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 to Bayer HealthCare Diabetes Care that these were sent.

Proof of Service

The Focus Arrangement Owner, or other Bayer HealthCare Diabetes Care employee, must be able to confirm that the study was performed. Documents confirming proof of service, such as study results or publications, must be retained by the Medical and Clinical Affairs Department for a period of seven years.

Focus Arrangements Database Procedures

The Focus Arrangement Owner or other Bayer HealthCare Diabetes Care employee must provide the Focus Arrangements Datasheet to the Bayer HealthCare Diabetes Care personnel responsible for entering information into the Focus Arrangements Database. Refer to Policy 8 "Focus Arrangements" for information regarding the Focus Arrangements Datasheet and Focus Arrangements Database Procedures.

RECORD RETENTION

The Medical and Clinical Affairs Department will retain the payment request package for a period of seven years. The Medical Communications Department will also retain proof of the services provided, such as a report on the clinical trials, for a period of seven years.

39. PRICE REPORTING

It is Bayer HealthCare Diabetes Care's policy to report, completely and accurately, cost, price and sales information about Bayer HealthCare Diabetes Care 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.

DEFINITIONS

Government Health Care 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, U.S. Department of Health and Human Services Pharmacy Affairs Branch, TRICARE, Department of Defense, 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 such as Pharmacy Benefit Managers (PBMs) and Managed Care Organizations (MCOs).

GENERAL LIMITS

All information that Bayer HealthCare Diabetes Care must report or generate, directly or indirectly, about costs, prices and sales for Bayer HealthCare Diabetes Care products for submission to or use by a Government Health Care Program or a Price Reporting Entity must be accurate, complete and not intentionally misleading. Additionally, as a government contractor on the Federal Supply Schedule (FSS), Bayer HealthCare Diabetes Care must report quarterly sales as detailed in the FSS contract. Bayer HealthCare Diabetes Care must establish a "Tracking Customer" for which Bayer HealthCare Diabetes Care must monitor all price discounting, price-related promotional offers, special pricing incentives and any other terms or conditions. All material changes in terms, pricing and promotions of the "Tracking Customer" must be reported to the federal government.

REPORTING PRICE INFORMATION

When applicable all Bayer HealthCare Diabetes Care reports of price information provided directly or indirectly to Government Health Care Programs or a Price Reporting Entity must accurately reflect 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; (6) promotions and (7) other price concessions or similar benefits.

PROCEDURES

Submission Process

Any Bayer HealthCare Diabetes Care employee, contractor, consultant or agent who receives a survey or request for pricing information from any Governmental Healthcare Program or Price Reporting Entity or any submission made on behalf of Diabetes Care to any Price Reporting Entity (such as First Databank) must be submitted to the Director of Strategic Contracting for completion and approval. Strategic Contracting will review all submissions with Finance prior to approval. The requests and/or submissions for pricing information will then be sent to the Law and Patents Department for approval prior to submitting the responses to such entities.

Any Bayer HealthCare Diabetes Care 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 Strategic Contracting for approval prior to submitting that information to such entity. The Director of Strategic Contracting or designee must approve all pricing information prior to its submission to such entity after consulting with the Law and Patents Department.

Completion of Requests for Pricing Information

All prices reported for use by or reported to any Governmental 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"), including Section 340B, must be completed and submitted to the Director of Strategic Contracting or designee for approvals 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.
- The Law and Patents Department is contacted to obtain its approval after the documentation is approved by the Director of Strategic Contracting.

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 Diabetes Care 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

Strategic Contracting will maintain copies of all price submissions to any agency of the federal or a state government or foreign government or Price Reporting Entity as well as documents (*e.g.*, contracts) supporting those submissions. Documents will 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 Director of Strategic Contracting or the Law and Patents Department.

40. PROVIDING DISCOUNTS AND REBATES

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." You must also follow the procedures as outlined in Policy and Procedure 41, "Reviewing and Approving Customer Purchase Contracts," as they provide for appropriate compliance with Focus Arrangements Procedures.

The Federal Anti-Kickback Statute provides that the terms of all price reductions must be disclosed in written agreements that notify recipients of their obligations to report the arrangement to government payors, such as Medicare and Medicaid, or to other payors and insurers as appropriate. All discounts, rebates, or other price concessions must be included in written contracts and processed in accordance with this policy and Policy 41, "Reviewing and Approving Customer Purchase Contracts." "Side deals," or price concessions, whether oral or written, offered outside of written contracts, are not allowed.

GENERAL LIMITS

Discounts. Discounts are typically provided at the time of invoice. Bayer HealthCare Diabetes Care 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 discount to payors and insurers.

Rebates. The terms of any rebate must be fixed and disclosed in writing to the purchaser at the time of the sale. A rebate may only be furnished based upon products actually sold and purchased. A rebate may not be paid or earned prior to the provision and purchase of the Bayer HealthCare Diabetes Care products to which the rebate applies without the prior written approval of the Law and Patents Department. Each rebate paid must clearly indicate to the purchaser those Bayer HealthCare Diabetes Care products to which the rebate is to be applied. A rebate on any Bayer HealthCare Diabetes Care product(s) may not exceed the sum total of the actual purchase price(s) for the Bayer HealthCare Diabetes Care product(s) to which the rebate is to be applied. Bayer HealthCare Diabetes Care must fully and accurately disclose rebates, if known, on the invoice or other statements submitted to the healthcare professional at the time or the sale and inform the customer of its potential obligation to report such rebates to payors and insurers, as appropriate, or to the government, as a reduction in price on the Bayer HealthCare Diabetes Care products purchased. Bayer HealthCare Diabetes Care may not pay rebates to customers in cash.

Price Concessions

All price concessions, rebates and/or prompt pay discounts offered to customers directly by Bayer HealthCare Diabetes Care must be approved by Finance and Strategic Contracting, with final approval by Law and Patents.

Bayer HealthCare Diabetes Care must fully and accurately list all discounts or other price concessions in the contract. For example, if the customer is entitled to a flat 10% discount on all products, this must be included in the contract. Bayer HealthCare Diabetes Care must also make clear in the contract if there are any contingencies involving formulary placement (*e.g.*, if earning rebates on one product is contingent on another product(s) being placed on formulary).

Invoices and Credit Memos

Invoices must accurately reflect all discounts known at the time of sale (*e.g.*, "up front" discounts). Invoices must contain language notifying customers of their potential obligation to report all discounts and other price concessions to the government. If the value of a price concession is not known at the time the contract is signed and/or another statement is provided to the customer at the time the rebate is provided, Bayer HealthCare Diabetes Care must provide credit memos that accurately explain the reason for the credit and reflect the true value of the credit.

"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 on one product contingent on the purchase or formulary placement of another product or a different type of the same product. Any discount potentially involving "bundled goods" must be approved in advance and in writing by the Law and Patents Department.

Free Product

When free product is provided as a form of a discount or price term (*e.g.*, "buy 10, get 1 free"), the promotional material and the invoices must accurately reflect the discounts provided. Invoices must also contain language notifying customers of their potential obligation to report all discounts and other price concessions to the government.

QUESTIONS

All questions regarding discounts or other price concessions must be referred to the Director of Strategic Contracting, the Finance Department or the Law and Patents Department.

41. REVIEWING AND APPROVING CUSTOMER PURCHASE 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."

All contracts must be requested through the Request for Contract ("RFC") process, which includes:

- Contracts for business models offered on current contract templates;
- Contracts for business models offered on current contract templates with certain modifications; or
- Contracts for business models which will require a new contract template.

Each 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; 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.

PROCEDURES

Approval Process for Template and Non-Template Agreements

1. The Bayer HealthCare Diabetes Care employee handling the account sends the Request for contract to the Strategic Contracting group for approval.
2. For contract templates, Bayer HealthCare Diabetes Care employee handling the account sends the Request for Contract ("RFC") to his/her respective manager via the RFC process. Once the manager has reviewed and approved the RFC, it is forwarded on to the Strategic Contracting group for review and to create an executable copy of a current contract template or a redline document to be reviewed by the account.
3. When an RFC comes in with a requested modification to a current contract template, or a contract that would require a new contract template, the Strategic Contracting group will evaluate one or more of the following factors:

- A financial analysis has been performed, if applicable.

- Business justification has been made, if applicable.
- Competitive information is included, if applicable.
- Past performance and contract compliance is documented, if applicable.
- 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.

4. For non-template contracts, upon evaluating one or more of the above factors, the Director of Strategic Contracting will seek approval from the US Country Division Head and the US Finance Controller. Once approved, Strategic Contracting will request written approval from the Law and Patents Department.
5. Law and Patents reviews the proposed contract for compliance with the Anti-Kickback Statute and relevant Safe Harbor(s) before it is signed by Bayer HealthCare Diabetes Care. The reviewing attorney must document that this review and assessment was conducted, his/her name, and the date it was conducted.
6. Law and Patents also confirms that the proposed payment represents fair market value. The methodology used to determine fair market value will be based on fair market values, or other relevant sources available to Bayer HealthCare Diabetes Care. 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) documented and maintained in the Law and Patents Department.
7. With the exception of volume-based purchase contracts, payment must not depend upon or be based on the value or volume of sales.
8. If approved, a contract is created with the appropriate approved language and terms.
9. Strategic Contracting sends the contract, along with a copy of the Bayer HealthCare Code of Conduct and Anti-Kickback Statute policies and procedures either to the Account Manager to present to the customer for signature or directly to the customer for signature. These documents may be sent electronically or via hard copy and may be provided as an attachment to the contract or as a separate document. Strategic Contracting must document that these documents were sent.

10. The customer signs the contract and returns it to the Strategic Contracting for counter signature by Bayer HealthCare Diabetes Care and awarding of the contract.

Awarding the Contract

Upon receipt of the final contract, it is subsequently entered into the Focus Arrangements Database.

Contract Dating

Bayer HealthCare Diabetes Care general policy is not to backdate contracts. The effective date for a contract for the purchase of Bayer HealthCare Diabetes Care 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 Diabetes Care'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 Diabetes Care 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, the need to replace a damaged or missing document, or such other circumstances as approved by the Law and Patents Department.

Proof of Performance/Service

Information confirming proof of product shipment and payment of rebates is maintained by Strategic Contracting and/or BHC Contracting either in a database (*e.g.*, Vistex) or in hard copy, as appropriate. Strategic Contracting and/or BHC Contracting also maintains copies of proof of performance/service related to dispensing data, administrative fees or other service fees included in contacts for product purchase for a period of seven years.

RECORD RETENTION

Strategic Contracting and/or BHC Contracting will maintain copies of all contracts and related documentation (*e.g.*, price concessions, rebate payments, chargeback information) for 7 years.

42. 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 Diabetes Care's policy conforms to the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 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 Diabetes Care must promote legitimate research goals. Research grants must be selected based solely on the credentials and the merits of the research proposals. Bayer HealthCare Diabetes Care may not provide an investigator sponsored study grant to induce or reward an investigator for prescribing or purchasing a Bayer HealthCare Diabetes Care product or to familiarize an investigator with a Bayer HealthCare Diabetes Care 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
- Investigator intends to either publish the study results in a journal or use the results for legitimate research purposes.

Investigator sponsored study grants must **not** be provided directly to the individual 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 HealthCare Diabetes Care Personnel

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

The ISS Review Committee is responsible for the review and approval of all investigator sponsored grants within Bayer HealthCare Diabetes Care. Sales and marketing personnel must not:

- Select or recommend recipients;
- Discuss Bayer HealthCare Diabetes Care's provision of investigator sponsored grants 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.

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://grants-contributions.bayerweb.com/en/home/.

Disclosure of Bayer HealthCare Diabetes Care 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 Diabetes Care must accurately disclose Bayer HealthCare Diabetes Care's financial support.

UNACCEPTABLE INVESTIGATOR SPONSORED STUDY 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 Diabetes Care products; or
- Intended to encourage the investigator to order, prescribe, or recommend Bayer HealthCare Diabetes Care products or reward or compensate the recipient for having done so; or
- Primarily provided to fund salaries of hospital nurses, residents, or other healthcare professionals, or routine administrative costs; or
- Provided to pay for activities that must be covered by fee-for-service contracts as described in Policy and Procedure 18, "Fee-For Service Arrangements;" or
- Not submitted through the Bayer website.

Agreements in which Bayer HealthCare Diabetes Care retains an institution for clinical trials or medical research are **not** considered "investigator sponsored" for purposes of this policy and instead must comply with Policy and Procedure 38, "Clinical Research."

PROCEDURES

All requests for grant funds for investigator-initiated studies must be submitted to the Bayer website: http://grants-contributions.bayerweb.com/en/home/. Requestors may submit either a full proposal if the research is clearly within the areas of interest described on the website or a letter of inquiry if the research is outside the defined areas of interest. A letter of inquiry must provide an overview of the research proposal, goals, and introductory material about the investigators. A request for a full proposal in response to a letter of inquiry is not a guarantee of approval of the request. The full proposal must:

- State what the applicant is requesting (funds, products, both) and how it will be used;
- Identify and attach *curriculum vitae* of all investigators;
- Identify the name of the IRB that will approve protocol and Informed Consent;
- Describe the purpose/intended use of the grant or reference other documents attached, such as a study protocol or investigator's brochure or memo that describes the purpose/intended use of the grant. The description must include the study design and objectives; a background section reviewing the significance of the grant and a review of previous work in the area; a brief description of the study facility; inclusion-exclusion criteria; a description of how adverse events will be handled and good clinical practice will be assured; and a statistical section

justifying sample size and describing how data will be managed and analyzed. It is not acceptable to list only a generic description (*e.g.*, "investigator-initiated study") as the purpose of the expense;

- Include a detailed budget;
- Include a W-9 for the organization; and
- Describe a publication plan for the study results.

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, or not aligned with the budget or strategic plan, he/she will inform the requestor that the request is being denied.

Investigator Sponsored Studies (ISS) Review Committee

The ISS Review Committee is comprised of members from Medical and Clinical Affairs and Law and Patents representatives serve as the Legal Advisor. Sales and Marketing personnel do not vote in the ISS Review Committee meetings.

The ISS 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 HealthCare Diabetes Care'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 HealthCare Diabetes Care's strategy and therapeutic focus.

If the ISS 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 by the voting members present will be made in conformance with this Policy and Procedure and its Standard Operating Protocol.

Law and Patents Review

The Law and Patents attorney participating on the 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). 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 Diabetes Care. 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.

If the reviewing attorney is not present at the 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 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. The minutes also identify the attendees at the meeting.

A letter documenting the 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.

For approved grants, the Grant Manager must send approved agreement and 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 HealthCare Diabetes Care must document that these documents were sent.

No payments or products will be sent to the requestor without a fully executed agreement in place. It is the responsibility of the requestor (or institution-designated staff member) to sign and return the agreement to Bayer HealthCare Diabetes Care. Milestone payments (if any) will not be sent without receipt of verification of milestone completion and proof of service.

Proof of Service

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

RECONCILIATION

Invoices and final budgets must be reconciled with payments issued by Bayer. Overpayments must be returned to Bayer by the grantee.

RECORD RETENTION

The Medical and Clinical Affairs Department will retain the payment request package for a period of 7 years. Proof of service documents are retained electronically for a period of 7 years.

AUDIT

All grants, including investigator sponsored studies grants, are subject to audit by Corporate Auditing and Bayer HealthCare Compliance to ensure compliance with these policies. The government (*e.g.*, OIG, IRS) may also request to audit/review grant payments.

43. ADMINISTRATIVE FEES

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."

Administrative fees are payments made to an administrator of a contract, such as a Group Purchasing Organization ("GPO"), Pharmacy Benefits Manager ("PBM") or wholesalers to compensate for legitimate administrative services provided to Bayer HealthCare Diabetes Care as defined in the Administrative Services Agreement.

TREATMENT OF ADMINISTRATIVE FEES

All Administrative Fees must be specifically approved in advance and in writing by the Law and Patents Department to ensure consistency with fair market value (in coordination with the BHC Compliance Department), as well as in compliance with any applicable statutory requirements, including safe harbors and/or industry guidance.

The Law and Patents Department will also review the Agreement to ensure that:

1. The Administrative Fee has been identified in the Agreement;

2. The Agreement includes a statement that, "to the extent required by law, discounts, rebates, credits, and administrative fees must be appropriately disclosed and fully and accurately reported to the government."

All written agreements for payment of administrative fees must be signed by the parties prior to the performance of services and payment.

Administrative Fees for Non-Possession Takers – Group Purchasing Organizations (GPOs) and Pharmacy Benefit Managers (PBMs)

Pursuant to the GPO Safe Harbor to the Anti-Kickback statute, it is generally Bayer HealthCare Diabetes Care's policy to pay administrative fees of 3% or less to non-possession takers, such as GPOs and PBMs, upon approval by the Law and Patents Department in advance and in writing. Any administrative fees that exceed 3% must be approved by the Law and Patents Department in advance and in writing. Any such approval will be granted only where there is a documented justification based on the services provided by the specific GPO or PBM.

The written agreement to pay administrative fees must be approved in advance and in writing by the Law and Patents Department to ensure that the Agreement complies with the elements above and the GPO Safe Harbor including that:

1. The GPO/PBM must represent that it has a written agreement with each member on whose behalf it acts as a purchasing agent.

2. The GPO/PBM must disclose in such membership agreements that it receives administrative fees from Bayer HealthCare Diabetes Care of 3% or less, or, if more than 3%, the amount it receives from Bayer HealthCare Diabetes Care.

3. The GPO/PBM must disclose annually in writing the actual amount of administrative fees received from Bayer HealthCare with respect to purchases made by the GPO/PBM on behalf of each member.

The Law and Patents Department is responsible for ensuring that all the elements of the applicable safe harbor, including those above, have been met.

Administrative Fees for Possession Takers – Wholesalers and Health Maintenance Organizations (HMOs)

The payment of administrative fees to possession takers, such as wholesalers and HMOs, is permitted so long as such fees represent fair market value, as determined by the Law and Patents Department and the BHC Compliance Department in advance and in writing.
PROCEDURES

Because administrative fees are Focus Arrangements, Focus Arrangements Procedures must be followed. Thus, a provision for administrative fees must either be included in a written product purchase contract that complies with the review and approval procedures in Policy and Procedure 41, "Reviewing and Approving Customer Purchase Contracts" or must be in a separate contract that is processed in accordance with Policy and Procedure 41.

PROCEDURES

Because administrative fees are Focus Arrangements, Focus Arrangements Procedures must be followed. Thus, a provision for administrative fees must either be included in a written product purchase contract that complies with the review and approval procedures in Policy and Procedure 41, "Reviewing and Approving Customer Purchase Contracts" or must be in a separate contract that is processed in accordance with Policy and Procedure 41.

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