

Confidential: Proprietary Information
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Consumer Care Policies and Procedures
July 1, 2013



**Clearly
Compliant**

Policies and Procedures



Bayer HealthCare

BHC2013

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INTRODUCTION

This booklet, “**Bayer HealthCare Consumer Care Compliance Policies and Procedures**” (Policies and Procedures), contains rules and procedures that you are required to understand and follow at Consumer Care. These Policies and Procedures are an essential part of the HealthCare Compliance Program for the Consumer Care Division. The HealthCare Compliance Program includes, among other things, the Policies and Procedures in this booklet, the Bayer HealthCare Code of Conduct, and the HealthCare Compliance Training. The program provides employees, contractors, consultants and agents with the knowledge and training to act ethically and with proper judgment in various activities related to sales, and marketing, as well as interactions between Bayer employees, contractors, consultants and agents.

HealthCare Professionals include individuals or entities which are involved in the provision of healthcare services and/or items to patients and which purchase, lease, recommend, use, arrange for the purchase or lease of or prescribe Bayer HealthCare in the U.S. It includes physicians, nurses, nurse practitioners, physician assistants, medical assistants, who treat patients, and other allied healthcare professionals, such as pharmacists, technicians, therapists and others who do not provide services to patients but who are involved in the decision to purchase products such as office staff, purchasing agents at hospitals, practice managers and management within group purchasing organizations (GPOs). In connection with Consumer Care products only, that definition does not include employees of commercial customers (e.g., Walmart, CVS, Walgreens) who are not licensed healthcare professionals.”

Note: All other Bayer HealthCare Consumer Care customers or business guests, who are not “HealthCare Professionals”, including but not limited to employees of retail pharmacies, hospitals, clinics, distributor or wholesalers are “Business Guests” and our interactions with these Business Guests, are governed by Bayer HealthCare Consumer Care’s Corporate Compliance Policy, Bayer’s Gift Policy (for Customers, Vendors, Suppliers and any other entities or persons with whom Bayer HealthCare Consumer Care does or intends to do business with) and Bayer HealthCare Consumer Care’s T&E policy. In fact, under these policies, the same principles which guide our interactions with HealthCare Professionals, may guide our interactions with Business Guests and other entities and their personnel with whom Bayer HealthCare Consumer Care does business and has business relationships. For example, meals, entertainment and gifts generally should be infrequent, reasonable in value, and reasonably related to our business concerns.

The Bayer HealthCare Consumer Care Compliance Documents (e.g., Policies and Procedures, Forms) are accessible via the intranet at: <http://us-wcms01.us.bayer.cnb/apps/BSP/US/BSP-NJ/BSP-NJ.nsf/id/44550041C8BC1607852579B1006813E2?OpenDocument> Questions about specific application of these Policies and Procedures can be referred to Consumer Care Law and Patents, or as noted below.

Importance of Complying with Policies and Procedures

The laws governing our conduct are enforceable by criminal, civil and administrative penalties. Violations may result in jail sentences, fines, or exclusion from federal and state programs including Medicare, Medicaid and Department of Defense. Bayer HealthCare Consumer Care is committed to complying with all applicable laws and regulations governing the sale and marketing of its products. Failure to comply with federal regulations and Bayer HealthCare Consumer Care's Compliance Policies and Procedures can have direct and severe consequences both to you and Bayer HealthCare Consumer Care.

Any Bayer HealthCare Consumer 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 Consumer 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.

Employees, contractors, consultants and agents are required to report suspected violations of the Compliance Policies and Procedures to their supervisors, the Law and Patents Department, the Bayer HealthCare Compliance Officer or via the Bayer IntegrityLine (toll free number, **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.

Bayer AG Global Corporate Compliance Policy

In addition to the **HealthCare Compliance Program**, Bayer (including Bayer HealthCare Consumer Care) operates the Corporate Compliance Policy published by Bayer AG in Germany covers the various Bayer (including Bayer HealthCare Consumer Care) 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 Consumer Care and its employees, contractors, consultants and agents. Although the scope of the compliance programs differs, the concepts reflecting the Company's commitment to ethical behavior are consistent, and Bayer HealthCare Consumer Care employees, contractors, consultants and agents are required to comply with all applicable Bayer HealthCare Consumer Care Compliance Policies and Procedures. The Corporate Compliance Policy can 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, these always take precedence.

The Bayer HealthCare AG Compliance Manual may be found at:

<https://by-margo.bayer-ag.com/view.aspx?id=0912107e8000ca1d>.

The Foreign Corrupt Practice Act

Bayer HealthCare Consumer 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 Consumer 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 Consumer Care employee, contractor, consultant and agent has the responsibility to ensure that his/her dealings with non-U.S. government officials—including state-employed healthcare professionals—comply with the FCPA. Likewise, each employee, contractor, consultant and agents 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 Consumer Care's business.

Questions

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

1. BUSINESS MEALS WITH HEALTHCARE PROFESSIONALS

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

Bayer 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/>.

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

Providing a healthcare professional with a meal solely for "relationship building" is not acceptable. Further, it is not appropriate for Bayer HealthCare Consumer Care to pay for, or reimburse healthcare professionals for, personal meals. Offering meals in any location without a Bayer HealthCare Consumer Care representative present is not allowed, such as dropping off a "take-out" meal, to an HCP's office.

All Bayer HealthCare Consumer Care employees, contractors, consultants and agents must exercise sound judgment and discretion when providing modest food or beverages to HCPs in conjunction with product promotion. The central focus must be the product education provided, with the meal being incidental to that primary purpose. In the event that alcohol is provided, it must accompany a meal, must not be excessive, and the cost must be included in the total cost of the meal. Generally, alcoholic beverages must not be offered because they are not conducive to a scientific, educational exchange or other legitimate business discussions related to Bayer HealthCare products.

Bayer policy prohibits employees, contractors, consultants and agents from offering anything of value, including a business meal, to a healthcare professional or provider to encourage that person to prescribe, purchase, order, refer, use or recommend any of Bayer's government reimbursed products. Offering or providing items of value, including business meals, to encourage healthcare professionals to prescribe, order, or recommend any of Bayer's government reimbursed products including those promoted and distributed by the Medical Care and Pharmaceuticals Divisions could violate the federal Anti-Kickback Statute and relevant state statutes.

SPENDING LIMITS

Out of office 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 Consumer Care personnel to healthcare professionals prior to and/or after a business meal must be included in the \$125 per person limitation. The limit includes food, beverages, tips, and all applicable taxes.

In Office, a modest business meal in-hospital meal typically should consist of sandwiches, pizza, snacks, or soft beverages and thus 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 out-of-office restaurant.

It is important to remember that the Government may view business meals that are provided too frequently or too expensive as an improper inducement to purchase Bayer HealthCare government reimbursed 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 Consumer Care’s general policy. Please refer to the Policy and Procedure 4, “State Laws,” in this booklet for details of these restrictions. If you interact with healthcare professionals who are currently licensed in any of these states, you must consult the relevant Bayer HealthCare Consumer Care procedures prior to providing any item of value to those healthcare practitioners.

RETAIL VALUE – AMOUNT TO BE RECORDED

The retail value of a meal, not the amount you or Bayer HealthCare Consumer 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 Consumer 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 Consumer 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 Consumer 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 government employees (e.g., military and Department of Veterans Affairs). To ensure that Bayer HealthCare Consumer Care does not violate these laws, Bayer HealthCare Consumer 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 3, "Special Requirements for Government Employees," in this booklet.

OTHER LIMITS

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

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

No Cash or Cash Equivalents – You may never give a healthcare professional cash or cash equivalents (e.g., gift certificates, your credit card) to purchase a meal. Further, under no circumstances can this Policy be circumvented by the use of the employee contractor, consultant or agent's own cash or personal credit card.

EXAMPLES

The following is an example of appropriate business meals:

- Taking a customer to a modest lunch to discuss Bayer Products
- Providing breakfast sandwiches, coffee and juice to discuss Bayer products

The following is an example of meals that are **NOT** appropriate:

- Giving your credit card to a customer and telling him/her to "buy lunch" or make some other purchase (credit card provided in this manner is a "cash equivalent"; no Bayer employee present)
- Taking a catered lunch in from a fancy steak house to a customer for a product discussion (too expensive to be modest)

PROCEDURES

Before providing a business meal, ask yourself:

1. Is the venue appropriate?
2. Is the amount modest?
3. Am I reasonably certain that there are no additional considerations, such as whether the customer is a government employee or a state employee who resides in a state with special restrictions or reporting requirements?

The answers to all three questions should be “yes” for the business meal to be appropriate.

Documentation of Business Meals with HealthCare Professionals

Business meals with healthcare professionals and business guests must be recorded through your Travel and Entertainment Expense Report (“T&E”) under Professional Education Meal. All employees must document the details of business expenses according to IRS rules, Compliance Policies and Procedures and the Corporate T&E Policy. An accurate description (e.g., describes what product you are detailing as well as purpose for the detailing visit to the HCP’s office) of the business purpose must be documented. Instructions on how to complete your T&E when providing a business meal to a healthcare professional 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 a completed sign in sheet which documents the attendance of each individual. If the Bayer HealthCare Consumer 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 Consumer Care through a third party vendor (e.g., speaker training, advisory boards, investigator meetings, speaker programs) also require sign in sheets.

The sign in sheet must have the following information:

GENERAL

- Event date
- Event location (in-office or out of office)
- Event type (education session, dinner speaker program, patient program, ad board, speaker training, etc.)
- Program/Event number (if applicable)
- Event host (Bayer HealthCare Consumer Care employee)
- Signatures of all Bayer HealthCare Consumer Care employees in attendance.
- Speaker (if applicable) printed and signature
- Contract number (if applicable)
- Name and address of venue
- Number of licensed HCPs, non-licensed HCPs, Bayer 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(s) (if applicable)
<http://hcp.sln.bayernet.com/Login.aspx?ReturnUrl=%2fDefault.aspx>
- State(s) of license (if applicable)

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

Supervisor Review of T&Es

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

Immediate supervisors are responsible for regularly reviewing T&Es for all employees they oversee to ensure that consistency with this Policy and Procedure and other applicable Bayer requirements, including that the limit per person per meal is not exceeded, that the attendees are appropriate, that the venue is appropriate, and that the total number and amount of business meals provided to any single healthcare professional are consistent with this Policy and Procedure.

If the review reveals potential divergence from Bayer HealthCare Consumer Care policy, the supervisor should take appropriate action, to include discussing the situation with the employee, documenting corrective action, notifying the next supervisory level and the Law Patents Department. Please refer to Policy and Procedure 14, "Disciplinary Action."

RECORD RETENTION

T&E reports are retained by the Accounting Department for a period of time as required by law or the Corporate Record Retention Policy.

AUDITS

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

2. EDUCATIONAL ITEMS FOR HEALTHCARE PROFESSIONALS

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

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

STATE SPENDING LIMITS

Some states have separate – and very strict – laws regarding the provision of business meals and other promotional activities that are more restrictive than Bayer's general policy. Please refer to the Policy and Procedure 4, "State Laws", in this booklet for details of these restrictions. If you interact with healthcare professionals who are currently licensed in any of these states, you must consult the relevant Bayer procedures prior to providing any item of value to those healthcare professionals.

SPECIAL SPENDING LIMITS FOR GOVERNMENT EMPLOYEES

There are special rules and limits for educational items provided to Government employees (e.g., military and Department of Veterans Affairs). To ensure that Bayer does not violate these laws, **Bayer employees, contractors, consultants and agents may not provide any business meals or food/drinks of any kind to federal Government employees.** For more information on this policy, including who constitutes a government employee, consult Policy and Procedure 3, "Special Requirements for Federal Government Employees," in this booklet.

EXAMPLES

The following are examples of appropriate educational items:

- Clinical treatment guidelines
- Tracking tools

The following are examples of items that are **NOT** appropriate:

- Note pads; pens; mugs; golf balls; etc. with an approved Bayer logo or slogan
- Cash or cash equivalents. You may never provide cash or cash equivalent to any customer, including government employees. Cash equivalents include, but are not limited to, gift certificates, loans, savings bonds and lottery tickets.
- Office or medical supplies, etc. (anything which could be considered expense relief)
- Any item, regardless of cost, that rewards a customer for purchasing Bayer products

PROCEDURES

Before providing an educational item, ask yourself:

1. Is the amount modest?
2. Will the frequency and the aggregate value for all educational items and business meals to this customer and/or organization be considered modest and reasonable?
3. Am I reasonably certain that the recipient does not require additional considerations, such as whether he/she is a government employee or a state employee who resides in a state with special restrictions or reporting requirements?

The answer to all three questions should be “yes” for the educational item to be appropriate.

Documentation of Educational Items through the T&E

Educational items are recorded on your Travel and Entertainment Expense Report (“T&E”). All employees must document the details of business expenses according to IRS rules, Compliance Policies and Procedures and the Corporate T&E Policy. An accurate description (e.g., describes what product you are detailing as well as purpose for the detailing visit to the veterinarian’s office) of the business purpose must be documented. Instructions on how to complete your T&E when providing an educational item to a healthcare professional or business guest can be found on the intranet at: <http://www.compliance.bayerweb.com/Video20100817/player.html>.

Itemized receipts must be included with every expense report entered into Concur.

The failure to submit for reimbursement for the educational items does not circumvent the educational item policy.

Supervisor Review of T&Es

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

Immediate supervisors are responsible for regularly reviewing T&Es for all employees they oversee to ensure that consistency with this Policy and Procedure and other applicable Bayer requirements, including that the limit per person per meal is not exceeded, that the attendees are appropriate, that the venue is appropriate, and that the total number and amount of business meals provided to any single healthcare professional are consistent with this Policy and Procedure.

If the review reveals potential divergence from Bayer policy, the supervisor should take appropriate action, to include discussing the situation with the employee, documenting corrective action, notifying the next supervisory level and the Law Patents Department. Please refer to Policy and Procedure 14, "Disciplinary Action."

RECORD RETENTION

T&E reports and invoices are retained by the Accounting Department for a period of time as required by law or the Corporate Record Retention Policy.

AUDITS

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

3. 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 individuals. This Policy and Procedure will help you avoid any conduct that presents the appearance of impropriety when conducting business with employees of the federal government.

WHO QUALIFIES AS A GOVERNMENT EMPLOYEE

Federal government employees include anyone (military or civilian) 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, National Institute of Health (“NIH”) or other federal government entities. According to federal law, a government employee includes part-time employees of the government and part-time workers at a government facility.

For example, the following are considered government employees:

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

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

The following is NOT considered a government employee:

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

GENERAL RULE

You may not offer or provide anything of value, regardless of the amount, to a federal government employee in order to influence him or her to purchase, order, or recommend any Bayer HealthCare Consumer Care product(s) or to encourage that employee to take, or not take, any action in his or her official capacity. 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 Consumer 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 Bayer Healthcare Consumer Care sales consultant.

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

Product samples 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 EXCEPTION

Widely Attended Gatherings

Government officials, other than President Obama appointees, are permitted by federal law to attend certain group events of a medical or educational nature, referred to as "widely attended gatherings," sponsored by contractors such as Bayer HealthCare Consumer 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., CHPA conference). In order for the Bayer HealthCare Consumer 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-sponsored keynote address at the annual CHPA convention). Note that the meal itself, not just the conference, must be open to all attendees. Thus, you may not invite government employees to attend a Bayer sponsored limited target audience event (e.g., dinner at a "Bayer table" at a CHPA conference) or invite individual government physicians to dinner at a CHPA conference or similar event.

Fee-for-Service Arrangements

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

4. 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 to entertain or present before 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 use due diligence to determine whether your interaction is with a member of a governmental body. If in doubt, ask the healthcare professional whether he/she is an executive branch official before providing any meal, gift, speaker fee or other fee-for-service payment.

PROHIBITION ON GIFTS TO PUBLIC EMPLOYEES

Under Louisiana's gift law, the only items of value that state employees are permitted to accept are "promotional items" of a nominal value and "food and drink" consumed in the presence of the gift giver. Accordingly, **state employees may not accept medically-related gifts, speaker fees, textbooks, etc.** Bayer's "Educational Items for HealthCare Professionals" policy prohibits the provision of promotional items, regardless of value, to any healthcare professional. Thus, you may not provide any gifts to state employees in Louisiana. You should 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 gift, meal, speaker fee or entering into a fee for service arrangement.

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 Government Affairs employees must register as lobbyists as a requirement of their job.)

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

FEE-FOR-SERVICE EVENTS

Louisiana's Code of Governmental Ethics prohibits a public servant from receiving compensation for services rendered by the public servant if such services are compensated for by an entity from which the public servant may not receive a gift under Louisiana law. Accordingly, you must consult the Law and Patents Department before entering Bayer into a financial arrangement with, reimbursing travel expenses for, and/or engaging any Louisiana health care 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 fields 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 No. 2006-247 (April 18, 2006) and 2006-654 (Sept. 14, 2006) analyzed fee-for-service arrangements between pharmaceutical companies and employees of Louisiana public universities. The Board concluded as follows:

- Although Louisiana law does provide a limited exception for faculty or staff members of a public higher education institution to provide certain consulting services in their field of expertise (provided the consulting arrangement is properly approved according to the process specified by Louisiana law), speaking engagements are not considered consulting services. Therefore, executive branch officials who are employees of public universities in Louisiana **may not** accept compensation or related travel reimbursement for serving as a speaker at a seminar or other speaking engagement.
- Payment of travel expenses and an honorarium from a pharmaceutical company in connection with an executive branch official's participation as a speaker at a seminar or other speaking engagement is not payment for "consulting services." Furthermore, the exception that permits executive branch officials to provide consulting services under certain conditions (discussed immediately below) does not apply. Under certain conditions, executive branch officials employed by Louisiana public universities **may** serve as a paid consultant to a company to serve on an advisory board to assist in product development or advice on other issues particular to the practice of medicine, including developing continuing medical education materials. However, the following conditions must be met first:
 - The services must be related to the executive branch official's academic discipline or area of expertise, 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 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 and the State agency obligates Bayer to pay for all reasonable travel expenses incurred by participating physicians in connection with trial related meetings.
- Executive branch officials may be reimbursed for travel expenses related to a study or clinical research trial only if the contract between Bayer and the State agency obligates Bayer to pay for all reasonable travel expenses incurred by participating physicians in connection with trial-related meetings.

In summary, the Louisiana gift law places significant restrictions on the fee-for-service arrangements a pharmaceutical manufacturer may enter into with Louisiana executive branch officials. The Louisiana statutory provisions are very complex, and are often amended by the legislature or subject to new interpretations by the Louisiana Board of Ethics. Again, you must consult the Law and Patents Department before entering Bayer into a financial arrangement with, reimbursing travel expenses for, and/or engage any Louisiana health care professional as a consultant, advisor or speaker.

4. STATE LAWS:

MINNESOTA – Promotional Spending Limits and Cost Reporting

It is the policy of Bayer to follow state laws regarding gifts and business meals even when such laws are more restrictive than Bayer's standard policy. The State of Minnesota limits gifts and business meals provided to any practitioner to an aggregate total of \$50 per year. To ensure that Bayer does **not** exceed the \$50 annual limit, you must **not** provide gifts or meals or other items of value to any practitioner licensed in the State of Minnesota or anyone employed by them.

SCOPE

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

- Doctor Of Medicine (M.D.);
- Doctor Of Osteopathic Medicine (D.O.);
- Dentist (D.D.S.);
- Doctor Of Optometry (O.D.);
- Podiatrist (D.P.M.);
- Physician assistant authorized to prescribe, dispense, and administer drugs;
- Advance practice nurse authorized to prescribe, dispense, and administer prescription drugs.

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

A. PROMOTIONAL SPENDING LIMITS

To ensure that Bayer does not exceed the \$50 annual limit, you must not provide gifts, meals, or other items of value to any practitioner licensed in the State of Minnesota or anyone employed by them. This prohibition does not apply, however, to fee-for-service arrangements and certain other payments described below in the subsection, "Mandatory Reporting of all Payments to Minnesota Practitioners." Payments for "marketing surveys" are interpreted by the Minnesota Board of Pharmacy as "gifts."

EXCEPTIONS TO THE ANNUAL SPENDING LIMIT

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

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

This limit applies to Bayer (the Bayer HealthCare businesses combined), not individual Bayer employees.

APPLYING THE LIMITS

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

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

Textbooks are included in the \$50 limit. Thus, textbooks valued at over \$50 may be provided only to a hospital department or other educational entity and not to individual practitioners (see Policy and Procedure 2, “Educational Items for Healthcare Professionals”).

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

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

B. COST REPORTING

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

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

The internal reporting requirement is for all payments to practitioners licensed in Minnesota, regardless of where the services were rendered. Under the Bayer Code of Conduct, payments for grants, research projects (clinical trials), and to sponsors of medical education programs must be made to an organization rather than to an individual practitioner or a practice group. Payments to entities unrelated to practitioners generally do not need to be reported under the Minnesota statute.

BAYER-SPONSORED MEETINGS PLANNED THROUGH THIRD PARTY VENDORS OR THE BAYER MEETING PLANNERS

Bayer representatives responsible for planning a company-sponsored meeting or program must work with the third party vendors responsible for such meetings to ensure the vendors report the appropriate data to the Disclosure Law & Transparency

Operations Team in order to meet the State reporting laws. If data cannot be collected and reported, then the Bayer representative is responsible for excluding from the invitee list all reportable healthcare professionals licensed in Minnesota, and any other State with similar reporting requirements or spending limits. Also, Bayer representatives contracting with a third party vendor for meeting planning services must also ensure that the vendor make sure the contract clearly states either: 1) that within one month (30 days) from the date of payment or gift to Practitioners, the vendor will provide the appropriate data (providing a description) to the Bayer representative, in order to satisfy the specific reporting requirements; or 2) that the vendor will exclude healthcare professionals licensed in Minnesota and any other State with similar requirements or payment limits.

4. 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.” A marketing code of conduct that incorporates the most recent version of the AdvaMed Code or the PhRMA Code 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 noncompliance 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 noncompliance reports and what corrective actions the company will take in response to noncompliance. Finally, the policies and procedures must require the company to report instances of noncompliance 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.

4. STATE LAWS:

TENNESSEE – Ethics Commissions Act

The Tennessee legislature has enacted an ethics reform bill which requires that, although vendors and their representatives in Tennessee do not have to register as lobbyists, they must, however, comply with provisions which 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. Product samples and product informational materials are not a part of the gift ban and can be given to anyone if otherwise permissible under applicable laws and Bayer policies and procedures. Promotional items (e.g., pens, clocks, pads of paper, etc.) that might otherwise be permitted under Tennessee law are prohibited consistent with Bayer Consumer Care's Compliance Policy and Procedure, "Educational Items for Healthcare Professionals."

APPLICATION OF THE LAW

Sales Representative cannot buy any meal for, or provide any educational items to, any members of the Tennessee legislative or executive branch. This includes state representatives and senators, TennCare officials, Department of Health officials, or anyone directly employed by the state of Tennessee. Also, they may not purchase any meals for physicians appointed to state boards like DUR or PAC committees.

Sales Representatives can buy lunch or other meals in accordance with these policies for county health department officials, First Health employees, and any hospital employed physician unless they are on a board stated above and limited to the extent the provision of the meal is consistent with Bayer HealthCare's Compliance Policy and Procedure, "Business Meals to HealthCare Professionals." (Note: Tennessee does not have any state owned hospitals.)

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

4. 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 drugs, biological and medical devices for human use (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. The Vermont law, according to guidance issued by the Vermont Attorney General, applies to only prescription drugs, biological products, and medical devices for humans. If a company has multiple divisions, however, some of which market prescribed products to Vermont health care providers, and some of which do not, the entire company is bound by the Vermont gift ban and must report allowable expenditures and permitted gifts. Therefore, although the Vermont law does not apply to nonprescription drugs, all Bayer HealthCare employees must follow the Vermont law when interacting with healthcare providers who prescribe prescription drugs or devices for human use.

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. Therefore, although the Vermont law does not apply to nonprescription drugs, all Bayer HealthCare employees must follow the Vermont law when interacting with healthcare providers who prescribe prescription drugs or devices for human use.

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 devices defined in section 201 of the FDCA (21 U.S.C. § 321), a compound drug or drugs, biological products as defined by 42 U.S.C. §262 for human use, or a combination product as defined in 21 C.F.R. §3.2(e). The term

includes prescription drugs, devices, and over-the-counter (OTC) products, but does not include prescription eyewear.

A **"gift"** means:

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

A **"healthcare professional"** means:

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

A **"healthcare provider"** means:

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

A **"sample"** means:

- a unit of a prescription drug, biological product, or medical device that is not intended to be sold and is intended to promote the sale of the drug, product, or device, including starter packs, 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 Prohibition

Bayer HealthCare Consumer Care employees may **not** provide any gift to a Vermont healthcare provider who prescribe drugs, biologicals, or medical devices for humans.

Some “banned” gifts under Vermont law include:

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

Note, this is not an all-inclusive list of banned activities. For further information, please review Vermont state web site, <http://www.atg.state.vt.us>

Each manufacturer of prescribed products must annually disclose for the preceding calendar year the value, nature, purpose and recipient information regarding any allowable expenditures or permitted gifts made to healthcare providers, or to a member of the Green Mountain Care board, or 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.

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 expenditure or permitted gifts, the manufacturer must also report certain information relating to nonprescription medical devices, nonprescription durable medical equipment, medical food, infant formula, and OTC products, provided to Vermont healthcare providers for free distribution to patients during the preceding calendar year. Information on samples and donations to free clinics of prescribed products and of nonprescription medical devices, nonprescription durable medical equipment, medical food, infant formula, and OTC products shall be presented in aggregate form. Donations of prescribed products to free clinics should be included in the samples disclosures form rather than with disclosures of allowable expenditures and permitted gifts. Any public reporting of such information shall not include information that allows for the identification of individual recipients of such items or connects individual recipients with the monetary value of the items provided.

Under Vermont Law, "sample" means: "a unit of a prescription drug, biological product, or medical device that is not intended to be sold and is intended to promote the sale of the drug, product, or device. The term includes starter packs and coupons or other vouchers that enable an individual to receive a prescribed product free of charge or at a discounted price. The term does not include prescribed products distributed free of charge or at a discounted price pursuant to a manufacturer-sponsored or manufacturer-funded patient assistance program."

Samples that are reported to the Department of Health and Human Services (HHS) under Section 6004 of the Patient Protection and Affordable Care Act of 2010 (PPACA) do not need to be reported to the Vermont Attorney General if the Attorney General determines that HHS will collect and provide Vermont with recipient-specific distribution of samples.

The Vermont Attorney General has reported that because it has not been notified whether HHS will provide recipient-specific information, all manufacturers must report directly to the Vermont Attorney General their distribution of all types of samples to all Vermont health care providers.

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

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

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

APPLYING THE REPORTING LIMITS

The law no longer provides a reporting exception for expenditures of \leq \$25. Therefore, all reportable permitted or allowable expenditures, regardless of the dollar amount, must be reported.

COMPLIANCE OFFICER FORM

Bayer HealthCare LLC 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 the 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 LLC 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 (Bayer HealthCare Pharmaceuticals (BHCP) Medical Care and Consumer Care). The Attorney General refers to that person as the "compliance officer."

April 1 of each year: Bayer HealthCare LLC must submit marketing disclosure reports for all covered Bayer entities (BHCP, Medical Care and Consumer Care). The report includes disclosures for the preceding calendar year. The state disclosure will be conducted by the State Reporting 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.

REGISTRATION FEE

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

For further information, please refer to the Laws and the Vermont Office of the Attorney General Guidance which can be found at: <http://www.atg.state.vt.us/issues/pharmaceutical-manufacturer-payment-disclosure.php>

5. RESTRICTIONS ON INTERACTIONS WITH CERTAIN STATE AND LOCAL EXECUTIVE AND LEGISLATIVE OFFICIALS AND STATE AND LOCAL EMPLOYEES (INCLUDING HEALTHCARE PROFESSIONALS)

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

The categories of state 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.

The lobbying and ethics laws are often complex and vary from state to state. Therefore, sales representatives **must, in advance of detailing, providing business gifts 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 or ethics laws in the state 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 4, "State Laws Louisiana – Restrictions on interactions with State Executive Branch Officials (Including HealthCare Professionals)."

6. EDUCATIONAL GRANTS (INCLUDING CONTINUING EDUCATION)

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 educational activities that foster increased understanding of scientific, clinical, or healthcare issues that contribute to the improvement of patient care. Bayer HealthCare Consumer Care prohibits offering a medical education grant to encourage the recipient to prescribe, purchase, order, use or recommend Bayer HealthCare Consumer Care product(s).

DEFINITION OF EDUCATIONAL GRANT

Bayer HealthCare Consumer Care may provide funding for activities associated with educational conferences, continuing education (CE) programs, or professional meetings, if they are sponsored by an organization other than Bayer HealthCare Consumer Care and they will contribute to the improvement of patient care. All CE programs must be sponsored by an accredited medical organization. All educational 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.

Educational grants may only be made to organizations, such as a hospital medical professional society, conference sponsor or continuing education organization. Educational grants may not be provided to individuals or private practice groups. This policy also applies to grants to any governmental agency. The organization may use the grant funds for overall program expenses or specifically for speaker(s), meal(s), reception, etc. Grant funds cannot be used to offset indirect or other expenses not directly related to the educational program nor can they be used for travel expenses of the 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 Consumer Care products, to encourage off-label use, or reward referrals for Bayer HealthCare Consumer Care products.

Bayer HealthCare Consumer 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 provider may include such expenses in their request for financial support and only the CE 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 educational grants. The terminology used by the entity requesting the funding (e.g., "charitable donation," "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 Consumer 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 association or organization where Bayer HealthCare Consumer Care receive something of value, such as banners or signage at a conference or an opportunity to advertise in the association's publication. Refer to Policy and Procedure, "Corporate Sponsorships."
- An education grant is funding provided to support an event where the primary focus is on educating the participants/attendees, rather than fundraising. Refer to Policy and procedure, "Education Grants (Including Continuing Education)."

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

Characteristics	Charitable Contributions	Corporate Sponsorships	Education Grants
Promotional in nature	No	Yes	No
Payee must be a 501(c)(3) or other tax exempt organization	Yes	No	No
Bayer HealthCare Consumer 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

CONTINUING EDUCATION PROGRAMS

The CE programs must be for scientific or educational purposes and not for the purpose of promoting any product. Any discussion of Bayer HealthCare Consumer Care's products must be objective, balanced and scientifically rigorous. The vendor must submit a proposal to Bayer HealthCare Consumer Care describing the specifics of each educational program, including, but not limited to the date, time, location, scope, and budget.

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

Bayer HealthCare Consumer Care supported educational events must conform to the ACCME and/or their Accreditation entity's guidelines.

Under an approved and signed contract (or letter agreement), Bayer HealthCare Consumer Care may provide an education grant to support CE programs sponsored by -accredited providers. There must be a signed contract or letter agreement between Bayer HealthCare Consumer Care and the accredited sponsoring organization. The contract must require that the CE provider disclose the following information to all program participants:

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

Bayer HealthCare Consumer Care representatives may not on their own distribute invitations to a Bayer HealthCare Consumer Care supported CE event to healthcare professionals. If the CE provider requests Bayer HealthCare Consumer Care's help in writing (e.g., by letter) to distribute supplemental invitations, Bayer HealthCare Consumer Care may distribute these invitations on the CE provider's behalf. Such invitations may only be distributed to healthcare professionals who can reasonably prescribe or otherwise use the product for an approved use.

The focus of any CE program supported by Bayer HealthCare Consumer Care must be the scientific and medical program. Meals provided in conjunction with the program must always be modest, reasonable and secondary to the educational activity. They must not be used to influence attendance. Bayer HealthCare Consumer Care may not provide meals directly at a CE event. The CE provider at its own discretion may apply the financial support provided by Bayer HealthCare Consumer Care to provide meals to all program participants.

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

Commercial exhibits may not interfere with the CE activities. No promotional materials may be displayed or distributed in the same room as the CE program before, during or after the program. No promotional activities may occur in the CME room and no promotional materials may be displayed, or sales activities conducted, within the "obligate path" that attendees must use to enter or exit the room where the CE activity is taking place. Although not specifically defined by regulation, Bayer HealthCare Consumer Care interprets "obligate path" to include paths from the main entry of a hotel to the meeting room or the way to a rest room.

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

ACCEPTABLE EDUCATIONAL GRANTS

In summary, a grant is permitted only if:

- It 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 customers in connection with medical education, training, or the improvement of patient care; and
- It is awarded to an organization and not an individual; and
- It is not awarded to an organization that is a private physician practice group; and
- The organization, not Bayer HealthCare Consumer 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 written request that:

- Describes the purpose/intended use of the grant or references other documents attached; such as a brochure, pamphlet, flyer, agenda, memo, or any other supporting documents; that describes the purpose/intended use of the grant. It is not acceptable to list only a generic description (e.g., "educational grant" or "training grant") as the purpose of the expense.
- 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 Consumer Care may audit or review the use of the grant for compliance with guidelines for acceptable educational grants.
- Confirms that Bayer HealthCare Consumer Care's funding and relationship with program provider, presenters, or moderator will be disclosed to attendees.

UNACCEPTABLE 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 of a Bayer government reimbursed product; or
- Intended to encourage off-label use; or
- Contingent on the purchase of Bayer HealthCare Consumer Care products; or
- Intended to encourage the recipient to order, prescribe, or recommend Bayer HealthCare Consumer Care products or reward or compensate the recipient for having ordered, prescribed, or recommended Bayer HealthCare Consumer Care products; or
- Made at the request of a healthcare professional in his/her individual capacity (e.g., a request by a physician to fund his/her "pet project"). A healthcare professional may request a grant in his/her official capacity, such as the head of a hospital department; or
- Made in return for anything of value provided to Bayer HealthCare Consumer Care by the recipient, with the exception of disclosure in program materials that the program is funded by Bayer HealthCare Consumer 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 should be covered by fee-for-service contracts; or
- Conditioned on the receipt of exhibit or display opportunities; or
- Not submitted through the Bayer HealthCare Consumer Care Grants website.

7. CHARITABLE CONTRIBUTIONS (OTHER THAN FREE BAYER PRODUCTS)

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 Consumer Care provides legitimate charitable contributions to support medical research, indigent care programs, patient education, public education, community organizations within a Bayer HealthCare business community 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 Consumer Care and its employees to provide legitimate charitable contributions in a manner that does not create an appearance of impropriety.

SCOPE

It is important to determine whether a request for funding support should be processed as a charitable contribution, corporate sponsorship or educational grant. The terminology used by the entity requesting the funding (e.g., "charitable donation," "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 donation** is funding provided to a non-profit organization to support the organization's activities where Bayer HealthCare Consumer 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 Consumer Care receives something of value, such as banners or signage at a conference or an opportunity to advertise in the association's publication
- An **education grant** is funding provided to support an event where the primary focus is educating the participants/attendees, rather than fundraising.

The Company spending policy is designed to allow Bayer HealthCare Consumer 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 Consumer 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

Charitable contributions may not be provided to Bayer HealthCare Consumer Care customers unless the customer is a non-profit entity. The Bayer HealthCare Consumer Care customer requesting funding for such programs must submit the request for a charitable contribution via the website: <http://grants-contributions.bayerweb.com/en/home/>. If a charitable contribution request is approved for a customer, Law and Patents must be notified for specific instructions.

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

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

EXCLUSION OF SALES AND MARKETING PERSONNEL

Under no circumstances may Sales or Marketing personnel engage in discussions, negotiations or unsolicited requests with an organization for the support of medical research, indigent care, patient education, public education, community organizations within a Bayer HealthCare Consumer Care business community or other charitable events that directly benefit patients which are all considered charitable contributions under Bayer HealthCare Consumer Care's Compliance Policies and Procedures. The Contribution Review Committee is responsible for the review and approval of all Charitable Contributions. In addition, Sales and Marketing may not be included in any communication regarding status of a request. If Sales or Marketing is approached by an organization regarding a charitable contribution, they are to direct the organization to the website: <http://grants-contributions.bayerweb.com/en/home/> and/or customer service telephone number (1-888-84-Bayer or 1-888-842-2937).

REQUIREMENTS

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

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

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

- Intended as a price term or offered in place of a price concession.
- Contingent on the purchase of any Bayer HealthCare Consumer Care products.
- Intended to encourage the recipient to order, prescribe, or recommend Bayer HealthCare Consumer Care products or to reward the recipient for ordering, prescribing, or recommending Bayer HealthCare Consumer Care products.

- Made at the request of a healthcare professional in his/her individual capacity (e.g., a request by a physician to support his/her favorite charity).
- Intended as payment for services or goods.
- Provides a benefit to Bayer HealthCare Consumer Care.

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

Invitations for Exhibit Space at the Charity Event

It is not appropriate to receive exhibit space or advertising space in return for a charitable contribution. It is Bayer HealthCare Consumer 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 Charitable Contribution Review Committee will determine whether the contribution will be approved and/or whether Bayer HealthCare Consumer Care may display at the event.

Limited Attendance at Events

Bayer HealthCare Consumer Care, as a supporter of charitable organizations may be offered tickets to event(s) that were not expected at the time of providing the charitable contribution. If tickets are offered involving charitable events sponsored by certain patient support groups (e.g., American Heart Association), designated Bayer HealthCare Consumer Care employees, as approved by the Law and Patents Department (with input from the Bayer HealthCare Compliance Officer, as requested) may be permitted to attend such events in order for Bayer HealthCare Consumer Care to demonstrate support for the patient group. No more than three Bayer HealthCare Consumer Care representatives from sales and marketing may attend. This three person restriction does not apply to Bayer HealthCare Consumer Care attendees who are not part of the commercial organization (such as Law and Patents, Government Affairs, Regulatory, or Medical Affairs). The representative(s) of Bayer HealthCare Consumer Care who do attend approved events must not engage in any promotional activity at the event or use the event as a promotional opportunity. The designated Bayer HealthCare Consumer Care employees may only use the event tickets provided by the event sponsor for admission. Inviting customers, healthcare professionals, or any other non- Bayer HealthCare Consumer Care personnel to these charity events is not permitted.

Contributions for Health Fairs / Medical Screenings

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

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

- The request for funds must be received from an independent third party that qualifies as a **501(c)(3) or otherwise IRS tax-exempt charitable organization**. Bayer HealthCare Consumer Care cannot provide funds to a customer or to any charity that is controlled by, related to, or operated by a customer or physician practice group.
- More than one medical group or more than one healthcare professional, each from different medical groups, must be taking part in the health fair or medical screening.
- The health fair or medical screening must be free and open to the community at large (e.g., may not be limited to patients of a particular hospital, health organization, or physician practice group).
- Any Bayer HealthCare Consumer 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 Consumer Care may provide disease state brochures to the organization for distribution at the event. However, Bayer HealthCare Consumer Care may not provide product-specific information of any type.
- Bayer HealthCare Consumer Care may provide educational, disease or patient treatment related items to support the event.

PROCEDURES

Requestor

All Charitable Contribution requests must be submitted electronically by the requestor through the Bayer website: <http://grants-contributions.bayerweb.com/en/home/>.

The requestor (or institution-designated staff member) shall electronically input all required charitable contribution information and attach a copy of the requestor's organization 501(c)(3) letter, indicating its status as a tax-exempt charitable organization. Additional backup documentation (e.g., agenda, budget) may also be required. The requestor is responsible for providing all Charitable Contribution related documentation.

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

Contribution Manager

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

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

Charitable Contribution Review Committee

The Charitable Contribution Review Committee ("Review Committee") is comprised of members from Global Communications, Public Policy and Government Affairs and Law and Patents. Sales and Marketing personnel do not participate in the Contribution Review Committee; however, they may provide a strategic plan relating to the subject matter of contributions to be considered.

The Review Committee reviews Charitable Contribution Requests with the following objectives:

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

- The request will be used solely for charitable purposes and Bayer receives nothing of value in return.

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

Legal Review of Charitable Contributions involved HCPs and/or Sources of Referrals

For all charitable contribution requests that involve HCPs and or sources of referrals, the Law and Patents attorney participating on the Review Committee must verify that the agreement contains a certification by the parties that the parties shall not violate the Anti-Kickback Statute with respect to the performance or activities related to the contribution. The Law and Patents Department also confirms whether the contribution amount represents fair market value in that the proposed amount is fair, reasonable and represents support for necessary expenditures based on the nature and the extent of the event for which the contribution requestor seeks support. Any deviation from the fair market value methodology and the rationale for such deviation must be approved by the Bayer HealthCare's Compliance Officer (or designee) and documented and maintained in the Law and Patents Department.

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

Contribution Manager Post Approval Documentation

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

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

RECORD RETENTION

The Accounting Department processing the payment must retain the payment request package for a period of time as required by law or the Corporate Record Retention Policy.

AUDITS

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

8. MATERIALS FOR EXTERNAL USE

Bayer HealthCare Consumer Care employee, contractors, consultants and agents s may only distribute promotional and non-promotional materials that are have been approved by the Copy Review Committee process

Bayer HealthCare Consumer Care employees, contractors, consultants and agents may conduct presentations to instruct healthcare professionals and customers on the proper, on-label use of Bayer HealthCare Consumer Care products. However, employees, contractors, consultants and agents must neither solicit questions about nor provide presentations for unapproved uses.

ADVERTISING AND PROMOTIONAL MATERIALS

Advertising and promotional materials include but are not limited to television commercials, radio advertisements, retail displays, digital advertising, letters to physicians, posters, monographs, press materials, consumer materials computer programs and Internet or Internet-based programs and websites.

Self – Created Materials (“Homemade Bread”)

Creating your own 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 or other materials that have not been through the Copy Review process.

Adding to, altering or modifying approved promotional or non-promotional materials, such as by highlighting, deleting, editing or adding notes, stickers or other material, makes those materials unacceptable.

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

9. MATERIALS FOR INTERNAL USE ONLY

Bayer HealthCare Consumer 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, however, be used to promote Bayer HealthCare Consumer Care products, unless specifically approved for such use.

10. INQUIRIES ABOUT OFF-LABEL USES OF BAYER PRODUCTS

If a doctor, pharmacist, or any other individual asks an unsolicited question that is not consistent with the approved labeling of Bayer products, you must direct that person to the appropriate Medical/Regulatory personnel. You may neither answer these questions, nor solicit this type of inquiry.

PROCEDURES

If a discussion is initiated that is not consistent with the approved labeling of Bayer Products, by anyone outside Bayer, employees, contractors, consultants and agents must refer the inquiry to Medical/Regulatory by providing to the requestor the telephone number (1-800-331-4536). Medical/Regulatory will provide relevant information directly to the requestor in private. No discussions can take place in a public forum pertaining to unapproved uses of Bayer HealthCare Consumer Care products.

11. CLINICAL RESEARCH, TRIALS AND STUDY SUPPORT

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, trials and studies supported by Bayer HealthCare Consumer Care must promote legitimate research goals. Any clinical research, trial or study supported by Bayer HealthCare Consumer Care must be conducted pursuant to a written agreement approved by the Law and Patents Department that, at a minimum, includes:

- A statement of the research objectives;
- An outline of the research protocol;
- A written budget detailing the financial and other support to be provided by Bayer HealthCare Consumer Care; and

A REQUIREMENT FOR PROGRESS REPORTS AND, WHERE APPLICABLE, A FINAL WRITTEN REPORT

Bayer HealthCare Consumer Care may sponsor a study, but cannot use a study for the purpose of giving money or anything of value to clinicians or researchers to reward use of a Bayer HealthCare Consumer Care product. Bayer HealthCare Consumer Care cannot seek to further the pre-approval or off-label use of Bayer HealthCare Consumer Care products under the guise of a less-than-adequate study.

Recipients of Bayer HealthCare Consumer Care's financial support for research and studies should be made aware that Bayer HealthCare Consumer Care reserves the right to audit the use of such funds and will expect documentation, such as progress reports, to show that its financial support has been used properly.

Investigators' Meetings, where researchers 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, trial or clinical study.

Payments for clinical research, trials or studies must represent fair market value. It is not appropriate for Bayer HealthCare Consumer 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 any of Bayer HealthCare Consumer Care's government reimbursed products by that clinical investigator.

Support for any clinical research, trial or study cannot be provided with the requirement or expectation that Bayer HealthCare Consumer Care's support will induce or encourage the purchase, order, referral, use or recommendation of any Bayer HealthCare Consumer Care products.

For additional information, please contact the Law and Patents Department for reference to the current departmental SOPs.

12. REVIEW OF COMPLIANCE TEXT MATERIALS

Bayer HealthCare Consumer Care is committed to appropriate and timely communications to all HealthCare Compliance Program employees, contractors, consultants and agents regarding significant changes in the Bayer HealthCare Consumer Care Compliance Policies and Procedures and the Bayer HealthCare LLC Code of Conduct ("Code of Conduct") materials.

Annually, (or more often if necessary), Bayer HealthCare and Bayer HealthCare Consumer Care will review the Code of Conduct, Compliance Policies and Procedures and the Compliance training texts to determine if revisions are appropriate and makes 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 employees, contractors, consultants and agents whose job functions are related to the revised Compliance Policies and Procedures within thirty (30) days of the effective date of the revision.

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

13. 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 Consumer Care's policies, practices, or procedures with respect to any federal health care 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. Global Compliance Services will prepare reports of all disclosure calls. Each report will be assigned a Report Control Number and a PIN code, which will be 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 will be transmitted to the Bayer HealthCare Compliance Officer (or designee) within 24 hours of receipt.

To ensure complete confidentiality, Global Compliance Services will mark any reports that name a designated report recipient or investor (the Bayer HealthCare Compliance Officer or designee) for "Special Handling." Reports marked for "Special Handling" will therefore not be distributed to the designated report recipient or investigator named in the report. If all designated report recipients or investigators are named within the report, the report will be sent to the Special Handling Report Recipient, who is the General Counsel & Sr. Vice President for Bayer HealthCare.

PUBLICATION OF CONFIDENTIAL DISCLOSURE PROGRAM

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

- The toll-free telephone number **(1-888-765-3846)**.
- 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 Consumer Care'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. will provide two reports to Bayer HealthCare Compliance Department each month; one summarizes reporting activity from the prior month and the other lists all open reports. Global Compliance Services, Inc. assigns the Report Control Number to each report which is recorded on all documents that are added to the disclosure file, as well as those that are maintained in the Human Resource and/or Law and Patents Department. This allows the status of any subsequent investigation to be tracked. The reports from Global Compliance Services, Inc. include all disclosures made to the Bayer IntegrityLine. Reports involving federal healthcare programs and/or Bayer HealthCare Consumer Care's Compliance Policies and Procedures will be processed as described below and included in the Annual Report to the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services. Reports that do not involve federal healthcare programs or Bayer HealthCare Consumer Care's Compliance Policies and Procedures, such as those involving employment or human resources issues, will be directed to the Law and Patents or the Human Resources Department within the related Bayer HealthCare business.

PROCEDURE UPON RECEIPT OF DISCLOSURE REPORT

Upon receipt of a disclosure report, involving federal healthcare program and/or Bayer HealthCare Consumer 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 must be conducted.

An internal review is initiated to investigate any disclosure that is sufficiently specific so that it reasonably permits a determination of the appropriateness of the alleged improper practice and provides an opportunity for taking corrective action. The Compliance Officer (or designee) initiates the investigation by providing a summary of the allegation, including the Report Control Number, to the Law and Patents Department and/or the applicable Human Resource Department, as appropriate.

By the follow up date, Bayer HealthCare Compliance Officer (or designee) will provide a statement of closure or a request for additional information to Global Compliance Services to be provided to the caller. Once all necessary information is obtained and the investigation is finalized the disclosure report will be documented as closed by Global Compliance Services, Inc.

A final written report is maintained in the Bayer HealthCare Compliance Department and will include, as appropriate, the results of the investigation and corrective actions taken.

Corrective actions may include, but are not limited to, the following:

- Modifications to appropriate policies or procedures.
- Additional or remedial training.
- Disciplinary action, up to and including termination.

14. DISCIPLINARY ACTION

GENERAL RULE

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

NON-RETALIATION

Bayer HealthCare Consumer Care will not retaliate, or tolerate retaliation, against any Bayer HealthCare Consumer Care employees, contractors, consultants or agents for reporting in good faith any alleged compliance issue or other inappropriate activity involving applicable federal, state or local laws or regulations, industry guidelines, the Bayer HealthCare Code of Conduct or the Bayer HealthCare Consumer Care Compliance Policies and Procedures.

DISCIPLINARY ACTION, TERMINATION AND REFERRAL TO LAW ENFORCEMENT

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

Disciplinary action may be taken against any Bayer HealthCare Consumer Care employee, contractor, consultant or agent who: (1) authorizes or participates in a violation of any applicable federal, state or local law or regulation, industry guidelines or the Bayer HealthCare Consumer 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 Consumer 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.

15. INTERACTIONS WITH GOVERNMENT INVESTIGATORS

GENERAL RULE

Bayer HealthCare Consumer Care may be contacted 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)), Federal Bureau of Investigation (FBI), Federal Trade Commission (FTC) or other regulatory agency. It is Bayer HealthCare Consumer Care's policy to cooperate fully with federal and/or state government officials or agents who conduct an inquiry, audit or otherwise investigate Bayer HealthCare Consumer Care. Bayer HealthCare Consumer 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 Consumer 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 Consumer Care 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 Consumer Care's employees, contractors, consultants and agents, (2) presentation of search warrants, (3) on-site visits to or inspections of Bayer HealthCare Consumer Care's premises by government officials or agents, or (4) visits by government officials to the homes of Bayer HealthCare Consumer Care employees, contractors, consultants or agents.

CONTACT BY GOVERNMENT INVESTIGATOR

In the event a Bayer HealthCare Consumer Care employee, contractor, consultant or agent is contacted by a federal or state investigator with respect to Bayer HealthCare Consumer Care related activities, the employee, contractor, consultant or agent must obtain proper identification from the government investigator prior to answering questions. Bayer HealthCare Consumer 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 legal counsel – either their own or Bayer HealthCare Consumer Care 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 Consumer Care employee, contractor, consultant or agent at his or her respective home and/or any location which is off Bayer HealthCare Consumer Care premises with respect to Bayer

HealthCare Consumer Care 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 Consumer Care's premises during regular business hours or at an alternate time and place that is otherwise convenient or to have independent legal counsel present during questioning by a government agency. If so requested by the employee, contractor, consultant or agent, Bayer HealthCare Consumer Care will have an attorney or other representative attend such interview.

GOVERNMENT INTERVIEWS

If a Bayer HealthCare Consumer Care employee, contractor, consultant or agent decides to be interviewed or to respond to questions from a government investigator with respect to Bayer HealthCare Consumer Care related activities, the employee, contractor, consultant or agent must answer all questions completely, accurately and truthfully. Bayer HealthCare Consumer 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 should refuse to discuss any communications he or she may have had, or of which he or she may be aware, involving the Law and Patents Department or Bayer HealthCare Consumer Care's outside legal counsel. If the employee, contractor, consultant or agent does not know whether the information being asked to discuss is privileged, the employee, contractor, consultant or agent should consult with the Law and Patents Department for a determination as to whether that information is privileged to ensure that no unauthorized disclosures of privileged information are made.

If you do not know with certainty the answer to any question, it is appropriate to say that you do not know the answer to the question. If an employee, contractor, consultant or agent would like to consult with an attorney, the employee, contractor, consultant or agent may request the presence of Bayer HealthCare Consumer Care counsel. Alternatively, Bayer HealthCare Consumer Care may recommend qualified counsel and, under the appropriate circumstances, will pay for such counsel to represent the Bayer HealthCare Consumer 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 HealthCare Consumer Care 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 Consumer Care employees, contractors, consultants and agents should contact the Law and Patents Department if asked by a government investigator for Bayer HealthCare Consumer Care documents. Bayer HealthCare Consumer 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 Consumer Care.

For example, Bayer HealthCare Consumer 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 Consumer Care property and is subject to this policy.

In addition, Bayer HealthCare Consumer Care employees, contractors, consultants and agents must not provide privileged Bayer HealthCare Consumer Care documents to the government without specific authorization from the Law and Patents Department. Privileged documents include any documents involving the Law and Patents Department or Bayer HealthCare Consumer 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 should 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 Consumer 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 Consumer Care does not authorize you to sign or initial any such documents or statements as a Bayer HealthCare Consumer Care employee, contractor, consultant or agent unless expressly authorized by the Law and Patents Department. If a Bayer HealthCare Consumer Care employee, contractor, consultant or agent is asked to sign such a document, the employee, contractor, consultant or agent should decline to do so and inform the government investigator of Bayer HealthCare Consumer Care's policy.

16. ADVERSE EVENTS INVOLVING BAYER CONSUMER CARE PRODUCTS

REPORTING REQUIREMENTS

Bayer HealthCare Consumer Care is required to report to FDA adverse drug experience information associated with the use of products manufactured and/or marketed by Bayer HealthCare Consumer Care. If you become aware of adverse drug experience information involving a Bayer HealthCare Consumer Care product, you must report this information as promptly as possible, but no later than twenty-four (24) hours after becoming aware of the information, to the Consumer Relations Department at 1-800-331-4536 or email to CC-CONSRELDEPT@bayer.com.

What to Report

You must report information about an adverse experience, which is any adverse event associated with the use of a product in humans, whether or not considered related, including the following: an adverse event occurring in the course of the use of a product; an adverse event occurring from an overdose whether accidental or intentional; an adverse event occurring from product abuse; an adverse event occurring from product withdrawal; and any failure of expected pharmacological action.

You must report adverse experience information associated with the use of a product manufactured and/or marketed by Bayer HealthCare Consumer Care, whether or not you consider the event to be related to the product.

The following information is necessary when reporting an adverse event;

1. **Identifiable Reporter** (name, and contact information).
2. **Identifiable Patient** (name, DOB, gender)
3. Bayer HealthCare Consumer Care **Product**
4. Description of the **adverse event**

NOTE: You must provide as much detail as possible about the event so that the Pharmacovigilance Department can identify you as the initial reporter and can identify the patient, the Bayer HealthCare product involved, and the adverse event.

17. DETERMINING INELIGIBLE PERSONS

Bayer HealthCare Consumer Care 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.

SCOPE

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

PROCEDURES

New Hire Self-Disclosure and check against Government websites.

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

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

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

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

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

The original Self-Disclosure Form and results of the government screenings and exclusion checks are retained by the Human Resources Department. The Bayer HealthCare Compliance Department retains the fax or electronic copy of the Self-Disclosure in a binder in the Bayer HealthCare Compliance Department. The certifications will be retained for a period of 10 years from the date they are completed. Records are subject to review and audit by Bayer HealthCare and the OIG.

ANNUAL CHECK AGAINST GOVERNMENT WEBSITE FOR ALL BAYER HEALTHCARE CONSUMER CARE 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 Consumer Care employees. HR//Direct prepares a report of all active and inactive Bayer HealthCare Consumer Care employees and submits the report to the Bayer HealthCare Compliance Department to utilize in conducting the government screenings. Upon completion, HR//Direct generates a report and submits the report to the Bayer HealthCare Compliance Department. The Bayer HealthCare Compliance

Department will complete the annual exclusion process by February 23rd of each year for all Bayer HealthCare employees, contractors, consultants and agents.

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

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

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

The Bayer HealthCare Compliance Officer (or designee) and the appropriate Human Resource Representative must be notified immediately if a Bayer HealthCare Consumer 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 Resource Department or Contingent Labor will suspend the Bayer HealthCare Consumer 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 Consumer 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 Consumer Care employee, contractor, consultant or agent will be terminated or transferred to a position that does not involve responsibility for or involvement with Bayer HealthCare Consumer Care's business operations related to federal healthcare programs or a position for which the Covered Person's compensation or the items or services furnished, ordered, or prescribed by the Covered Person are not paid in whole or part, directly or indirectly, by federal healthcare programs or otherwise with federal funds.

INDIVIDUALS WHO ARE NOT BAYER HEALTHCARE CONSUMER CARE EMPLOYEES

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

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

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

HEALTHCARE COMPLIANCE PROGRAM SELF DISCLOSURE*Bayer HealthCare employees, contractors, consultants and agents***Self-Disclosure Certification**

I, _____, represent that I:

- have never been convicted of a crime under Section 306(a) or 306(b) of the Generic Drug Enforcement Act of 1992 or as defined or included within 42 U.S.C. section 1320a-7(a) or (b), 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 Bayer HealthCare Code of Conduct booklet and certify that I have read, understand, and agree to abide by this code.

Signature_____
Date_____
Printed name**For Internal Use Only:
Bayer HealthCare Consumer 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.

18. CORPORATE PONSORSHIPS

Bayer HealthCare Consumer Care may provide funds for sponsorships to various trades, medical, professional, patient, scientific and community organizations. The recipient organization's mission should be to increase understanding of scientific, clinical, or healthcare issues that contribute to the improvement of patient care or continuing education of professionals.

Sponsorship funds may not be paid to sources of referrals for Bayer HealthCare Consumer Care products except in limited circumstances, approved by Law and Patents, where the event is open to all members and provided the same opportunity is given to other similarly situated members. This type of transaction would be considered a Focus Arrangement as defined by the CIA and must comply with all requirements.

Sponsorships may not be paid to sources of referrals (other than wholesalers) or to entities controlled by or affiliated with sources nor can they be paid to encourage the recipient organization to purchase, order, refer, use or recommend Bayer HealthCare Consumer Care products. It is Bayer HealthCare Consumer Care's policy to pay the same fee as other corporate sponsors for the same level or type of sponsorship.

Bayer HealthCare Consumer 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 Consumer 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 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 educational grants. The terminology used by the entity requesting the funding (e.g., "charitable donation," "grant") is not the determining factor because organizations may submit funding requests using inconsistent or incorrect terminology. The key factors are the type of entity requesting the funding (e.g., non-profit, patient organization, and 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 Consumer 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 an organization where Bayer HealthCare Consumer Care receives something of value, such as banners or signage at a conference or an opportunity to advertise in the organization's publication. The sponsorship opportunity is offered to other similarly situated industry members and not just Bayer HealthCare Consumer Care.
- An **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 Consumer 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 Heart Association (AHA) for general educational programs.

- Sponsorship funding of appropriate, non-educational activities, such as a modest hospitality suite at national meetings of medical societies or organizations, such as the AHA or a Wi-Fi Café during medical society meetings.
- Accepting a seat on an advisory council to the AHA, if this benefit is also provided to other OTC, pharmaceutical or medical device companies who provide a similar level of sponsorship.

Examples of Impermissible Sponsorships

- Sponsorship of a hospitality suite at a disease-state awareness program sponsored by the American Heart Association that is intended specifically for a discussion of a disease state for which Bayer HealthCare Consumer Care products are not indicated.
- Sponsorship funding for pharmacists employed by CVS to attend a Broadway show one evening during a national pharmacists meeting. This is impermissible because Bayer HealthCare Consumer 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 Consumer 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 products, or to reward any recipient organization for a past purchase, prescription, recommendation, or formulary placement of a Bayer HealthCare Consumer 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.

PROCEDURES

Requestor

A medical or professional society or other organization may solicit sponsorship through a website, e-mail, or paper mailing. No Bayer HealthCare Consumer 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 made in writing from the requesting organization on its letterhead and must include a completed W-9 form.

The request must specify:

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

Law and Patents Review

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

RECORD RETENTION

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

AUDIT

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

19. FEE-FOR-SERVICE 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 Consumer Care to enter into certain fee-for-service arrangements with healthcare professionals provided certain criteria are met. Bayer HealthCare Consumer Care's policy on fee-for-service arrangements is consistent with the Personal Services Safe Harbor, the PhRMA Code on Interactions with HealthCare Professionals, 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 market research, or advertising space may never be used to encourage the recipients to purchase, order, refer, use or recommend Bayer HealthCare Consumer Care products.

CLARIFICATION OF TERMINOLOGY AND PROGRAMS

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

Advisory Board meetings must be to gain expert feedback or advice on commercial or clinical/medical topics -- not to provide a forum for product promotion. Bayer HealthCare Consumer Care representatives should ensure that advisory board participants clearly understand that they are being retained to provide a service and not merely to passively receive promotional presentations. An advisory board meeting cannot be designed to (1) influence the invited consultants or to change their prescribing preferences; (2) provide participants with an opportunity to meet and mingle with their peers; or (3) have participants merely listen to new information about Bayer HealthCare Consumer Care products.

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

Fee-for-service transactions include, but are not limited to, arrangements with healthcare professionals for speaker agreements, consulting, advisory board participation, data purchases, customer programs, patient education programs, medical writers and other activities where individuals (or the companies that employ them) are compensated by Bayer HealthCare Consumer Care for services rendered.

Market research is aimed at obtaining information on customer requirements, preferences, product performance, and purchasing options for use by Bayer HealthCare Consumer 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 Marketing Research Studies may not be selected or compensated by the sales force or other employees, contractors, consultants or agents involved in direct promotion. For example, it is not appropriate for sales personnel to design marketing research questionnaires for physicians or to pay physicians for completing these surveys.

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.
- Consultants are chosen based upon relevant qualifications, experience and expertise as well as the value their services would provide to Bayer HealthCare Consumer Care, not based on the volume or value of business generated by the speaker or consultant. Field sales personnel may not be directly involved in selecting choosing consultants. Those responsible for selecting the consultant must have the expertise necessary to evaluate whether the healthcare professional has the required qualifications.
- The venue and circumstances of consultant meetings must be conducive to the consulting services. Exotic and/or resort locales are prohibited. Bayer HealthCare Consumer Care may not provide entertainment or recreational activities in connection with any speaker training event, advisory board, or consultant meeting.
- Consultant meetings and advisory board meetings must be approved by the Law and Patents Department **before** invitations are sent and **before** venues are booked.
- The number of participants, speakers, advisors and/or consultants chosen must be consistent with the business need.
- The written contract must specify the nature of the services and the basis of payment for those services. The contract must be approved by the Law and Patents Department **before** it is signed by the speaker or consultant and Bayer

HealthCare Consumer Care. No Bayer HealthCare Consumer Care employee may execute any contract or other legally binding document without review and approval from the Law and Patents Department. If a healthcare provider refuses to sign the agreement provided by the Law and Patents Department **prior** to the initiation of the program, he or she cannot be retained to provide the service.

PROCEDURES FOR ALL TYPES OF FEE-FOR-SERVICE ARRANGEMENTS

Initial Written Request

The initial request for a fee-for-service arrangement must be made using the Agreement Request/Transmittal Form and approved by the requestor's supervisor. The approved request is submitted to the Law and Patents Department for legal review and contract generation. The Agreement Request/Transmittal form must include the following:

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

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

Before generating the contract, the Law and Patents Departments will determine whether a Master Services Agreement ("MSA") exists for the potential speaker or consultant. If a MSA exists, the Law and Patents Department determines whether the new arrangement conforms to the terms of the MSA, including any limit on the number of engagements or maximum amount paid annually. If Bayer HealthCare Consumer 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 a MSA, a new MSA that identifies a maximum value and type of services to be provided must be created.

Contents of the Contract

Each healthcare professional retained as a speaker, consultant or other fee-for-service arrangement must sign a contract or Letter of Agreement that has been approved by the Law and Patents Department and that includes 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 contract provision that the arrangement with the parties shall not violate the Anti-Kickback Statute.

THIRD PARTY CONTRACTS

Bayer HealthCare Consumer Care may work with third parties who interact with speakers, moderators, or consultants on behalf of Bayer HealthCare Consumer Care. Third parties are prohibited from entering into contracts with HCPs on Bayer HealthCare Consumer Care's behalf. The Law and Patents Department will generate all agreements with HCPs in accordance with the procedures described above.

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).

Special Rules for Contracting with a Federal Government Employee

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

Special rules and limitations apply to fee-for-service arrangements with federal government employees. Prior to any discussions regarding speaker services or any other fee-for-service arrangement with a federal government employee you must contact the 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 Speaker Agreements and Consultant Agreements entered into with VA employees. It is, therefore, **mandatory** that any Speaker or Consultant Approval Form requesting Law and Patents Department approval for activities to be undertaken by a VA employee (e.g., speaking at a Bayer HealthCare Consumer Care-sponsored event) **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 services 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 Consumer Care-sponsored clinical trials.

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

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

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 Law and Patents Department also confirms that the proposed payment represents fair market value.

The written contract may indicate that Bayer HealthCare Consumer 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 Consumer Care, as described in the approved written contract. Bayer HealthCare Consumer Care will not reimburse incidental expenses, such as gift shop purchases. Bayer HealthCare Consumer 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 HealthCare Consumer Care incurs no additional costs.

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
- The direct supervisor reviews the payment request package and determines if the request complies with Bayer HealthCare Consumer Care's policies. The approval process for the payment request package must follow the spending approval levels within Corporate U.S. Authorization Policy 001.20100901.

RECORD RETENTION

The Accounting Department will retain the full payment request package for a period of time as required by law or the Corporate Record Retention Policy.

AUDITS

All fee-for-service arrangements are subject to audit by Corporate Audit and HealthCare Compliance to ensure compliance with this Policy, including proper documentation, spending limits, and company spending policy. The government (e.g., IRS) may also request to audit/review expense reports.

20. PROVIDING FREE PRODUCT FOR CHARITABLE PURPOSES

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

SCOPE

This policy covers all free products provided under Bayer HealthCare Consumer Care's charitable programs for United States destinations only.

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

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

APPROVALS

Free product provided under this policy must be approved by the Law and Patents Department.

RECORD RETENTION

The Medical Affairs Department will retain all documents relating to free goods transactions for a period of time as required by law or the Corporate Record Retention Policy.

AUDITS

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

21. CORPORATE MEMBERSHIPS

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

SCOPE

Trade, distribution, medical, patient and scientific organizations (e.g. Consumer Health Products Association), as well as legislative policy groups, may require payment of a fee as a condition of membership. To the extent Bayer HealthCare Consumer Care wishes to become a member of such an organization, it is the policy of Bayer HealthCare Consumer Care to establish these memberships for the Corporation or Division and not for individual Bayer HealthCare Consumer Care employees.

Legislative policy groups offer Bayer HealthCare Consumer Care relevant industry information, provide Bayer HealthCare Consumer Care visibility within the pharmaceutical industry, and promote goodwill within organizations that maintain a political voice. Membership in medical and patient organizations allows Bayer HealthCare Consumer 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 Consumer 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 Consumer 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 of your supervisor, individual professional organization memberships must be submitted through Concur T&E.

This policy does not cover educational grants or charitable contributions Bayer HealthCare Consumer Care may provide to a patient advocacy group or medical organization. Such payments must comply with Policy and Procedure, "Education Grants (Including Continuing Education (CE))," and Policy and Procedure "Charitable Contributions (Other than Free Bayer Product)," 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 Consumer Care may seek out an organization and request to become a member. The organization's main focus should be to increase understanding of scientific, clinical, or healthcare issues that contribute to the improvement of patient care, including support for advocacy groups and/or Bayer HealthCare Consumer Care's goodwill in the community. Membership in organizations that primarily consist of healthcare professionals which are offered to Bayer HealthCare Consumer Care must be open to other pharmaceutical companies.

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

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

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

PROCEDURES

Requestor

The Bayer HealthCare Consumer Care "Requestor" must be entitled to complete the "Bayer HealthCare Consumer Care 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 HealthCare Consumer Care Certification for Corporate Membership" form.
- Generate an internal spending request by completing an "Internal Payment Demand (IPD)."
- Include any supporting documentation.
- Forward the completed payment request package to the Supervisor.

Supervisor

The Supervisor reviews all documentation and makes an independent judgment as to whether the Corporate Membership is consistent with Bayer HealthCare Consumer Care's policies. If appropriate, the Supervisor approves by signing the "Bayer HealthCare Consumer Care Certification for Corporate Membership" and "Internal Payment Demand" and forwards both documents to the Public Policy and Government Affairs Department.

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

Public Policy and Government Affairs Department

The Public Policy and Government Affairs Department reviews all documentation and makes an independent judgment as to whether the Corporate Membership is consistent with Bayer HealthCare Consumer Care'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 Consumer Care Certification for Corporate Membership" form and "Internal Payment Demand" and forwards both documents to the Law and Patents Department.

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

Law and Patents Department

The Law and Patents Department reviews all documentation and makes an independent judgment as to whether the contribution is consistent with Bayer HealthCare Consumer Care's policies. If appropriate, the Law and Patents Department approves by signing the

"Bayer HealthCare Consumer Care Certification for Corporate Membership" form and "Internal Payment Demand" and forwards both documents to the Accounting Department.

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

RECORD RETENTION

The Accounting Department must maintain the payment request package for a period of time as required by law or the Corporate Record Retention Policy.

AUDITS

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

FORM: BAYER HEALTHCARE CONSUMER CARE 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 Consumer 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 Consumer Care products.
- ☐ The organization offers the same membership or membership level to other corporations for the same fee.
- ☐ The organization, not Bayer HealthCare Consumer Care, controls the disbursement of the membership fees.
- ☐ The membership fees are not charitable contributions or educational grants.
- ☐ The membership fee is not contingent on the price or purchase of Bayer HealthCare Consumer Care products.
- ☐ The membership fee is not contingent on lobbying activities on behalf of Bayer HealthCare Consumer 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 time as required by law or the Corporate Record Retention Policy.

22. PROVIDING SAMPLES AT NO CHARGE

Bayer HealthCare Consumer Care may provide a limited number of samples of products to customers and healthcare professionals at no charge. The quantities of product samples provided must not exceed an amount that is reasonably necessary for the intended use of the samples. Providing product samples in violation of this policy is strictly prohibited.

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 products. The government may see the sample as a form of remuneration given to the physician to influence physician referrals—an action that violates the Anti-Kickback Statute.

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

23. PATIENT PROTECTION AND AFFORDABLE CARE ACT (PPACA)

Legislative, regulatory, and enforcement authorities are aggressively pursuing greater disclosure and transparency of financial relationships between 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 Consumer 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” for more information on sample distribution. Also, guidelines for dispensing product samples may be obtained from the Sales Operations Department.

24. DRAWINGS AND SWEEPSTAKES

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, "Educational Items for Healthcare Professionals." 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.

HealthCare Professionals include individuals or entities which are involved in the provision of healthcare services and/or items to patients and which purchase, lease, recommend, use, arrange for the purchase or lease of or prescribe Bayer HealthCare Consumer Care products in the U.S. It includes physicians, nurses, nurse practitioners, physician assistants, medical assistants, who treat patients, and other allied healthcare professionals, such as pharmacists, technicians, therapists and others who do not provide services to patients but who are involved in the decision to purchase such as office staff, purchasing agents at hospitals, practice managers and management within group purchasing organizations (GPOs).

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.

25. INVESTIGATOR SPONSORED STUDIES

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 Consumer Care's policy conforms to the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, the PhRMA Code on Interactions with Healthcare Professionals, 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 Consumer Care must promote legitimate research goals. Investigators must be selected based solely on their credentials and the merits of their research proposals. Bayer HealthCare Consumer Care may not provide an investigator sponsored study grant to induce or reward an investigator for purchasing a Bayer HealthCare Consumer Care product or to familiarize an investigator with a Bayer HealthCare Consumer 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
- Bayer HealthCare Consumer Care and/or the investigator intend to publish the study or submit the results to the FDA.

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

Involvement of Bayer HealthCare Consumer Care Personnel

Protocols for Bayer HealthCare Consumer Care-supported clinical studies must be written primarily by the investigator. Bayer HealthCare Consumer Care employees, contractors, consultants or agents may not write a protocol for an independent investigator. However, upon request by the investigator, Bayer HealthCare Consumer 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 IIS Grant Review Committee, as described below.)

The Investigator Sponsored Studies ("ISS") Grant Review Committee is responsible for the review and approval of all investigator sponsored grants within Bayer HealthCare Consumer Care. Sales and Marketing may not be included in any communication regarding the status of a grant request, nor may Sales and Marketing personnel be involved in the provision of a grant. Sales and marketing personnel must not:

- Select or recommend recipients;
- Discuss Bayer HealthCare Consumer Care's provision of investigator sponsored studies with a customer or assure a customer about participation in a prospective study;
- Discuss ideas for potential research protocols with customers; or
- Assist in drafting a research protocol.
- Sales and Marketing may not be involved directly or indirectly in the selection of potential sites for investigator sponsored studies.

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

Disclosure of Bayer HealthCare Consumer 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 Consumer Care must accurately disclose Bayer HealthCare Consumer 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 Consumer Care products; or

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

Grants for clinical trials or medical research that are initiated or controlled by Bayer are not considered "investigator sponsored" for purposes of this policy and instead must comply with Policy and Procedure, "Clinical Research, Trials and Study Support."

PROCEDURES

All requests for grant funds for investigator sponsored studies must be submitted to the Bayer/ Bayer HealthCare website: <http://grants-contributions.bayerweb.com/en/home/investigator-sponsored-studies/consumer-care-investigator-sponsored-studies/>. The initial request must:

- Describe the purpose/intended use of the grant or reference other documents attached, such as a study protocol, or memo that describes the purpose/intended use of the grant. It is not acceptable to list only a generic description (e.g., "investigator sponsored study") as the purpose of the expense;
- Include a budget; and
- Confirm that the grant will be used to support an investigator sponsored study.

Grant Requestor

The investigator (or designated staff member) must electronically input all required grant information. The investigator is responsible for providing any requested grant-related documentation.

Grant Manager Review

A Grant Manager initially reviews the grant request. If the grant request is deemed to be complete, within budget and strategic plan, it will be placed on the agenda for review by the ISS Grant Review Committee at the next scheduled meeting.

If the Grant Manager, after attempting to obtain appropriate documentation, finds the request incomplete, he/she will inform the requestor that the request is being denied due to insufficient documentation.

Grant Review Committee

The Grant Review Committee is comprised of members from Medical Affairs, Medical Education and Law and Patents. Sales and Marketing personnel do not participate in the Grant Review Committee.

The Grant Review Committee reviews grant requests from a scientific, educational, regulatory and legal perspective consistent with the following:

- Each Committee member certifies that, to the best of his/her knowledge, there are no legal or compliance issues that would prohibit Bayer HealthCare Consumer 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 Consumer Care's strategy and therapeutic focus.

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

Law and Patents Review

The Law and Patents attorney participating on the Grant Review Committee must verify that the agreement contains provisions that the arrangement satisfies the requirements of the Anti-Kickback Statute and assesses compliance with relevant Safe Harbor(s).

Grant Manager Post-Meeting Documentation

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

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

The Grant Manager or other Bayer HealthCare Consumer Care employee must send the grant recipient, along with the approved agreement, a copy of Bayer HealthCare's Code of Conduct and Anti-Kickback Statute Policies and Procedures attached. These documents may be sent electronically or by hard copy, and can be included as an exhibit to the agreement or sent as separate documents.

RECORD RETENTION

The Medical Affairs Department will retain the payment request package for a period of time as required by law or the Corporate Record Retention Policy.

AUDIT

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