

Bayer HealthCare's Comprehensive Compliance Program Pursuant to Cal Health and Safety
Code §§119400-119402

I. INTRODUCTION

Bayer HealthCare LLC (“Bayer”, including its Diabetes Care Division for purposes of this discussion) is committed to maintaining an effective compliance program in accordance with the California Health and Safety Code §§ 119400-119402 which requires pharmaceutical manufacturers to implement a Comprehensive Compliance Program (“CCP”) consistent with the Compliance Program Guidance for Pharmaceutical Manufacturers issued by the Office of Inspector General, Department of Health and Human Service (“OIG Guidance”) in 2003. The OIG Guidance outlines seven elements that have been identified as fundamental to an effective compliance program:

- (1) implementing written policies and procedures;
- (2) designating a compliance officer and compliance committee;
- (3) conducting effective training and education;
- (4) developing effective lines of communication;
- (5) conducting internal monitoring and auditing;
- (6) enforcing standards through well-publicized disciplinary guidelines; and
- (7) responding promptly to detected problems and undertaking corrective action.

The California Health and Safety Code §§ 119400-119402 also requires pharmaceutical manufacturers to adopt policies that comply with the *PhRMA* Code on Interactions with Healthcare Professionals (“*PhRMA* Code”), and certify compliance with the company’s CCP. The California law also requires the establishment of a specific annual dollar limit on gifts, promotional materials, or items or activities that a pharmaceutical company may give or otherwise provide to a medical or health care professional.

II. OVERVIEW OF BAYER’S COMPREHENSIVE COMPLIANCE PROGRAM

1. Compliance Officer and Compliance Committee

Bayer's Compliance Officer is a member of senior management who oversees all compliance activities. The Compliance Officer is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with federal and state health care programs. The Compliance Officer makes periodic reports regarding compliance activities directly to the President and Chief Executive Officer of Bayer HealthCare Pharmaceuticals Inc. and to the Bayer HealthCare LLC Board of Directors.

The Compliance Officer chairs the Compliance Committee, which is comprised of senior managers from various departments, such as Sales, Marketing, Contracting, Human Resources, Legal and Finance. The Compliance Committee meets regularly and supports the Compliance Officer in all activities of the Compliance Program.

2. Written Standards of Conduct

Bayer has established written standards of conduct, including the Code of Conduct posted on this website, that are designed to ensure compliance with the requirements associated with federal healthcare programs. The Code of Conduct is reviewed annually and updated as necessary. Bayer employees are required to certify on an annual basis that they have read, and understood these written standards. Bayer uses audits to assess and monitor compliance with these written standards, to identify areas of potential concern, and to assist in the reduction of identified problems.

Additionally, Bayer has adopted policies and procedures to address the specific risk areas addressed in the OIG Guidance and to incorporate the principles of the revised P/RMA code and the revised Advanced Medical Technology Association Code of Ethics on Interactions with Healthcare Professionals (“AdvaMed Code”). Examples of some of these areas addressed in the policies are as follows:

A. Policies and Procedures:

- Samples: Evaluation and Demonstration Products:
Bayer employees must comply with the company’s policies on providing evaluation samples, including documentation requirements, when evaluation and demonstration products are provided to physicians for free distribution to patients.
- Reports of Adverse Experiences Involving Bayer Products:
If Bayer employees are told about an adverse experience involving a patient receiving a Bayer product, Bayer employees must report it to Medical Communications as promptly as possible in writing (within 24 hours). Bayer employees must report this information regardless of whether the adverse event appears to have been caused by, or related to, the use of a Bayer product.
- Research and Clinical Study Support:
All research and clinical studies supported by Bayer must promote legitimate research goals and must be conducted pursuant to a written agreement. Support for any research or clinical study will not be provided with the requirement or expectation that Bayer’s support will induce or encourage the prescribing, purchasing or ordering of Bayer products.
- Advertising and Promotion of Bayer Products:
No Bayer employee may promote any company product for uses that are not authorized in the approved product labeling or package insert or otherwise approved.
- Customer Assistance Programs/Product Support Services:
Bayer may support programs that foster increased understanding of scientific or clinical issues in order to improve patient care. No program may be supported in exchange for an agreement to prescribe or order Bayer products or be given in place of a discount on product price.

- Educational Grants:
Bayer provides grants to fund educational activities that foster increased understanding of scientific, clinical, or health care issues that contribute to the improvement of patient care. Grants may not be provided to encourage recipients to prescribe, purchase, order, or recommend Bayer products or provided in place of a product discount.
- Sponsorship of Medical Educational Programs:
Bayer provides financial support for educational programs in accordance with the U.S. Food and Drug Administration (“FDA”) and industry guidelines. Bayer employees may not, directly or indirectly, control or influence the content of a program if that program contains references to unapproved uses. Bayer employees may control and influence the content of a program only when approved uses of Bayer prescription drugs or biologics are discussed.

Bayer may support continuing medical education (CME) or other third-party educational conferences or professional meetings that contribute to the improvement of patient care by providing educational grant funds to the conference sponsor or by contracting with a third-party to plan and execute the event. Bayer does not provide financial support for travel or lodging for non-faculty members at third-party educational events and does not compensate attendees for time spent at the event. Bayer may provide financial support to the event sponsor, which, in turn, can use the money to reduce the overall conference registration fee for all attendees.

- Ineligible Persons:
It is Bayer’s policy not to hire Ineligible Persons -- individuals who are excluded, suspended, debarred or otherwise ineligible to participate in Government reimbursement programs or who have been convicted of a criminal offense related to federal health care programs -- for positions involving marketing, selling, contracting for or reporting prices for Bayer products. If an individual becomes an Ineligible Person while employed with Bayer, Bayer will, at a minimum, remove the employee from work involving Government reimbursement programs.

Interactions with Healthcare Professionals:

- “Educational Items” and “Meals”:
As required by the revised PhRMA and AdvaMed Codes, all gifts or educational items must primarily benefit patients or serve a genuine educational function. Bayer may provide occasional modest meals to healthcare professionals in connection with informational presentations and discussions that occur in a healthcare professional’s office or hospital setting in a manner that is conducive to educational and scientific communication.

- Consultants:
Bayer may engage healthcare professionals as consultants or advisors to furnish important and needed information to Bayer. Bayer selects consultants based on their relevant qualifications, experience, and expertise and pays them fair market value for their legitimate services, pursuant to written contracts.
- Incentives to Prescribe or Use Bayer Products:
No Bayer employee may offer any remuneration -- that is, anything of value -- to induce or encourage prescriptions or purchases of Bayer products. Certain discounts and other price concessions may be provided in conformance with the PhRMA and AdvaMed Codes and the Discount Safe Harbor to the Anti-Kickback Statute.

Government Price Reporting:

- Promotion and Government Reimbursement:
Bayer employees must comply with all applicable laws and federal health care program requirements in marketing and promoting medical device, drug and biologic products. It is Bayer's policy not to promote based on the "spread" -- or the difference between what a customer pays for a product and the amount the customer receives in government reimbursement.
- Reporting Product Prices to the Government:
It is Bayer's policy to comply with all applicable laws and regulations in determining the way products are priced and how prices are reported to the Government. Everything that could affect the net pricing of Bayer products, including discounts, rebates, and all other price concessions, must be taken into account in reporting prices to the Government in accordance with the laws and regulations of Medicare, Medicaid and other Government reimbursement programs.

California Annual Spending Limit:

Bayer currently has established a \$1,000 annual dollar limit on business meals, and educational items that Bayer may provide to an individual healthcare professional. This annual dollar limit represents an upper limit and is not reflective of the actual value of meals, educational items, or activities that Bayer may provide to a medical or healthcare professional. Bayer reserves the right to adjust this annual limit as appropriate.

3. Education and Training

Bayer provides Bayer employees with training to assist them in meeting the responsibility of conducting Company business in an ethical manner. Each employee is required to certify that he/she has completed this training program. The publication of our policies is not intended to alter the employment-at-will relationship in any way.

Employees receive annual training that covers Bayer policies and procedures and the legal rules that apply to those programs including, but not limited to, arrangements with healthcare providers (e.g. consulting agreements, speaker programs), establishing or reporting prices for Government reimbursed products (e.g. reporting of accurate pricing information; the obligation to ensure that prices are accurately reported; and examples of proper and improper product price reporting and marketing/sales practices). Employees must certify completion of all training.

4. Internal Lines of Communication

Bayer maintains an “Integrity Line” to enable employees with a confidential call number to make anonymous complaints regarding accounting or auditing misconduct or violations of the company’s Code of Conduct Guidelines and to promote a positive work environment. Bayer is committed to a confidential, to the extent allowed by law, and non-retaliation disclosure process.

A. Confidential Disclosure Program

All Bayer employees have a responsibility to comply with all legal requirements and must report suspected violations of our compliance programs and related policies to their supervisors, the Law and Patents Department, the Human Resources Department, the Ombudsman or the Compliance Officer through the Confidential Disclosure Program. Reports to the Confidential Disclosure Program may be made anonymously. Any employee who reports a suspected violation, or raises any compliance matter, will not be subject to any retaliation or adverse action based upon such reports.

Bayer maintains a confidential disclosure program, which includes a toll-free telephone line, which allows employees to report to the Compliance Officer suspected violations of federal or state health care program requirements or of Bayer’s policies and procedures. Reports may be made anonymously. The Compliance Officer (or designee) will make a good faith inquiry into any reported violation. It is Bayer’s policy not to retaliate against any employee for, good faith reporting of suspected violations.

5. Auditing and Monitoring

Bayer’s auditing and monitoring practices include activities to monitor, audit, and evaluate compliance with the company’s policies and procedures. The approach involves an assessment of identified and prioritized risk areas, which may change depending on new regulatory requirements, business considerations, and other factors. The extent and frequency of the auditing and monitoring of activities may vary based upon these factors.

6. Discipline

Violations of Bayer’s compliance policies and procedures subject employees to disciplinary action. Employees who fail to comply with these policies, or who negligently or willfully fail to detect and report violations of these policies, will be subject to a variety of sanctions, up to and including termination.

7. Corrective and Preventative Procedures

This CCP is designed and enforced to prevent and detect unlawful and unethical behavior. However, as recognized in the OIG Guidance, no compliance program can completely eliminate the possibility that an individual employee or employees may engage in conduct that would be considered improper. As part of Bayer's compliance program an internal investigation and corrective action processes has been established to include corrective action and preventive measures and are implemented as appropriate.

III. CONCLUSION

Bayer is committed to an ongoing assessment of ethical conduct and compliance with the laws. This CCP is designed, implemented, and enforced with the goal of preventing and detecting unlawful and unethical behavior. A description of Bayer's Compliance Program, including the Company's written declaration and certification of compliance with Cal Health and Safety Code §§119400-119402, can be requested toll-free by calling 1-877-256-3562.