

Bayer U.S. LLC Comprehensive Compliance Program Pursuant to California Health and Safety Code §§119400-119402

I. INTRODUCTION

Bayer U.S. LLC, including Bayer U.S. Pharmaceuticals, which includes the Radiology Business (collectively referred to as “Bayer”), 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. 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 healthcare professional.

II. OVERVIEW OF BAYER’S COMPREHENSIVE COMPLIANCE PROGRAM

1. Compliance Officer and Risk & 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 healthcare programs. The Compliance Officer makes periodic reports regarding compliance activities directly to the heads of the Bayer businesses.

2. Written Standards of Conduct

Bayer has established written standards of conduct, including the Bayer U.S. Pharmaceuticals Compliance Policies and Procedures posted on this website, that are designed to ensure compliance with the requirements associated with federal healthcare programs. The Compliance Policies and Procedures are reviewed annually and updated as necessary. Bayer employees, contractors, consultants, and agents 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 PhRMA Code. Examples of some of these areas addressed in the policies are as follows:

Policies and Procedures:

- Samples:
Bayer employees must comply with the Prescription Drug Marketing Act (“PDMA”), including documentation requirements, when distributing drug samples 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 as promptly as possible (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 administration of the 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, purchase, recommend or order Bayer products or be given in place of a discount on product price.

- Educational Grants:
Bayer may provide grants to support educational activities that foster increased understanding of scientific, clinical, or healthcare issues that contribute to improving patient care. Grants may not be provided to encourage recipients to prescribe, purchase, order, or recommend Bayer products or be provided in place of a product discount.
- Sponsorship of Medical Educational Programs:
Bayer may provide financial support for educational programs in accordance with applicable 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, who, 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 healthcare 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 Code, appropriate educational items must primarily benefit patients or be primarily associated with a healthcare professional's work. 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, recommendations or purchases of Bayer products. Certain discounts and other price concessions may be provided in conformance with the PhRMA Code and applicable law.

Government Price Reporting:

- Promotion and Government Reimbursement:
Bayer employees must comply with all applicable laws and federal healthcare program requirements in marketing and promoting 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. Discounts, rebates, and other types of price concessions that could affect the net pricing of Bayer products must be taken into account when 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 \$2,500 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 healthcare professional. Bayer reserves the right to adjust this annual limit as appropriate.

3. Education and Training

Bayer provides relevant employees, including contractors, consultants and agents, with training to assist them in meeting the responsibility of conducting Bayer business in an ethical manner. Each employee is required to certify that they have 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 drug price reporting and marketing/sales practices).

4. Internal Lines of Communication

Bayer maintains a “Compliance Hotline” to provide employees with a toll-free number to make anonymous reports or complaints regarding misconduct or violations of the company’s Code of Conduct or policies and to promote a positive work environment. Bayer is committed to the confidentiality of such a call, to the extent allowed by law and the circumstances of such call, and a non-retaliation policy for such calls.

Confidential Disclosure Program

All Bayer employees are responsible for complying with all legal requirements and must report suspected violations of our compliance programs and related policies to their supervisors, the Law, Patents and Compliance Department, 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 in good faith will not be subject to any retaliation or adverse action based upon such reports.

Bayer maintains a toll-free telephone line (the Bayer “Compliance Hotline,” 1-888-765-3846, which allows employees to report suspected violations of federal or state healthcare 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 who, in good faith, reports any such 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 on these factors.

6. Discipline

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

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, internal investigation and corrective action processes have been established to undertake corrective action and preventive measures, which are implemented as appropriate.

III. CONCLUSION

Bayer is committed to an ongoing assessment of ethical conduct and compliance with applicable 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 California Health and Safety Code §§119400-119402, "Compliance Program Guidance for Pharmaceutical Manufacturers" can be requested toll-free by calling 1-877-256-3562.