

Bayer HealthCare Code of Conduct



Compliance W.I.N.S.

Worldwide Integrity is Necessary for Success
Effective: February 1, 2009



Dear Colleague,

Bayer HealthCare LLC is committed to the highest level of ethical conduct, which includes complying with all applicable laws and regulations governing the sale and marketing of healthcare products in the United States, the laws and regulations governing U.S. government-reimbursed products and the Bayer HealthCare Corporate Integrity Agreement. It is the responsibility of every Bayer HealthCare employee to conduct the Company's business in conformity with the principles set forth in this Code of Conduct (the "Code"), which relate to issues associated with the Food and Drug Administration ("FDA"), the Centers for Medicare and Medicaid Services ("CMS"), the Office of Inspector General ("OIG") of the Department of Health and Human Services, and other healthcare regulatory agencies.

The principles set forth in this Code of Conduct represent a broad outline of the standards of business conduct that Bayer HealthCare expects its employees to follow. This Code cannot cover every circumstance that Bayer HealthCare employees may confront in the day-to-day conduct of business. Nevertheless, this Code will provide basic guidance and sensitize employees to the need to ask the right questions and act in compliance with federal, state, and other requirements in the conduct of Bayer HealthCare business. Compliance is a component of each employee's performance objectives, and adherence to this Code will be considered in connection with employee performance evaluations. Each of us in Bayer HealthCare will be asked to sign a statement indicating that we have read, understood, and will abide by this Code of Conduct. Additionally, many of you will receive additional training about compliance related issues.

Any Bayer HealthCare employee who violates, or encourages others to violate, this Code is subject to a broad range of discipline, up to and including termination of employment. Furthermore, individual employees, Bayer HealthCare LLC as a company, and Bayer HealthCare customers (including hospitals and physicians) may be subject to criminal, civil and administrative penalties for failure to comply with applicable laws and regulations. Violations may result in jail sentences, large fines, or exclusion from participation in federal and state programs, Medicare, Medicaid and Department of Defense programs. Thus, all employees, contractors, and agents have a responsibility to comply with all legal requirements and need to quickly report suspected violations of this Code to their supervisors, the Law and Patents Department, the Compliance Officer or via the confidential disclosure telephone line (the "IntegrityLine" – 1-888-765-3846). Reports may be made anonymously. Any employee 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 HealthCare will keep all such reports from employees confidential to the full extent of the law.

Thank you for your commitment to and compliance with this Code.



Gary Balkema
CEO Bayer HealthCare LLC

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1. Compliance with Federal Laws and Regulations

It is the policy of Bayer HealthCare that all employees comply fully with all applicable federal and state laws and regulations in every aspect of their business, including marketing, promoting, selling, advertising, contracting for, research, development, the provision of information about and, as required, reporting prices for, products that are reimbursed by the government and private insurers. All employees are expected to comply with all applicable Federal and state healthcare program and FDA requirements, as well as Bayer HealthCare's own policies and procedures including, but not limited to, those contained in each Division's Compliance Policies and Procedures.

Additional Guidance

Failure to comply with federal regulations and your Division's Compliance Policies and Procedures can have direct and severe consequences both to you and to Bayer HealthCare.

You may face disciplinary action from Bayer HealthCare, up to and including termination for violating the law or Bayer HealthCare's policies and procedures. In addition, you could be fined, precluded from working with federal healthcare programs, or sent to jail for failure to comply with Federal healthcare program and/or FDA requirements.

Bayer HealthCare could also be fined or could be excluded from participation in federal healthcare programs, such as Medicare, Medicaid and Department of Defense. Bayer HealthCare employees, contractors, subcontractors and agents are required to report actual or suspected violations of any Federal healthcare program requirements, FDA requirements, or of Bayer HealthCare's policies and procedures. All actual or suspected violations should be reported to your supervisor, the Law and Patents Department, the Compliance Officer, or via the IntegrityLine (toll free 1-888-765-3846). Reports may be made anonymously. Any employee 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 HealthCare will keep all such reports from employees confidential to the full extent of the law.

2. Compliance with Bayer AG Corporate Compliance Policy

Bayer HealthCare, as part of Bayer Corporation, complies fully with all applicable policies and procedures. All Bayer HealthCare employees must comply with the Corporate Compliance Policy issued by Bayer AG that covers the various Bayer sectors on a global basis. Bayer HealthCare employees must also comply with the relevant Division's compliance program.

Although the scopes of these programs differ, Bayer's commitment to ethical behavior is consistent throughout all the compliance programs, and Bayer employees are required to comply with all applicable Bayer Compliance Policies and Procedures. In cases where your Division's Policies and Procedures reflect more stringent or more restrictive requirements or activities than other corporate policies, the more stringent or more restrictive policies and procedures apply.

Additional Guidance

Bayer AG has established global standards of conduct to provide employees, suppliers, customers, and members of the general public with a clear indication of how it and each of its employees will conduct itself and themselves, both internally and in the marketplace. The compliance policies of the Bayer AG Corporate Compliance Policy are not intended to encompass all areas of business conduct but, as with other company policies, they establish general guidelines. These standards are more fully described in each Division's Policies and Procedures.

The provisions of each Division's Policies and Procedures are not intended to alter the employment-at-will relationship in any way. The employee or Bayer may terminate the employment relationship at any time, with or without notice, and for any or no particular cause or reason. Moreover, the Policies and Procedures of the Bayer HealthCare Compliance Program neither create an employment contract or term, nor limit the reasons or procedures for termination or modification of the employment relationship, nor do they create any substantive or procedural rights for Bayer personnel. In addition, the company reserves the right, in its sole discretion and without notice, to add, amend, delete or terminate any provision of this Code of Conduct or any of the Division Compliance Policies and Procedures at any time.

3. Compliance with Bayer HealthCare Policies and Procedures and Division Compliance Program

It is the policy of Bayer HealthCare to comply fully with all applicable Bayer HealthCare Policies and Procedures, including the Division's Compliance Policies and Procedures and this Code of Conduct.

Additional Guidance

If the Bayer HealthCare Compliance Policies and Procedures are more restrictive than other Bayer Corporation Policies and Procedures, the more restrictive policies and procedures apply.

If your Supervisor or other individual within your supervisory line of authority has established a directive or departmental procedure with more restrictive requirements or activities, then the more stringent or more restrictive policies and procedures apply.

Deviations from any Bayer policy or procedure without appropriate review and documented approval will subject employees to disciplinary action.



4. Advertising and Promotion of Bayer HealthCare Products

No Bayer HealthCare employee may advertise or promote any company product for uses that are not addressed in the approved product labeling or package insert or otherwise consistent with the product's regulatory status. Additionally, no Bayer HealthCare employee may use any materials for the advertising or promotion of any Bayer HealthCare product if those materials have not been reviewed and approved for such use under company policies and procedures.



5. Promotion and Government Reimbursement

Bayer HealthCare employees must comply with all applicable laws and federal healthcare program and FDA requirements in marketing, advertising and promoting Bayer HealthCare products. Bayer HealthCare promotes its products based upon their established efficacy and safety, as well as their health related value. Bayer HealthCare does not promote products by comparing Medicare or Medicaid payment amounts to purchase prices, determining the customer's potential profit margin, or encouraging purchases based on this "spread."



6. Incentives to Use, Recommend, or Prescribe Bayer HealthCare Products

No Bayer HealthCare employee may offer any remuneration, or item of value, to induce or encourage any individual or account to purchase, use, order, recommend, refer or prescribe Bayer HealthCare products in violation of the Anti-Kickback Statute. Remuneration can include anything of value (such as educational grants, charitable contributions, speaker payments, promotional funds, educational items, etc.) offered or provided to a customer, prospective customer, or referral source. The offer, payment, request or receipt, directly or indirectly, of any remuneration could constitute a kickback and thus be considered a violation of the Anti-Kickback Statute. The government may consider it a violation of the law if only one purpose of such remuneration is to induce or encourage the recipient to buy, order, prescribe, use, refer or recommend Bayer HealthCare products. Discounts and rebates are considered remuneration and must be properly disclosed so that they can be appropriately reflected by healthcare providers as reductions in claims submitted to government healthcare programs (e.g., Medicare or Medicaid).



7. Educational Items

Educational items (referred to as “business gifts and courtesies” in prior versions of this Code) may not be given to encourage any individual or account to purchase, order, refer, use, prescribe or recommend Bayer HealthCare products or to reward a healthcare professional or account for doing so. Healthcare professionals should select and use Bayer HealthCare products based solely upon medical considerations and patient needs.

Additional Guidance

Only items that are designed primarily for the education of patients or healthcare professionals that have no value outside of their professional responsibility and are permitted by law can be offered or provided to healthcare professionals. Examples of permissible items include medical textbooks, patient educational materials, and anatomical models.

Federal law governing items of value – including educational items – provided to Federal government employees (including part-time federal government employees) are much stricter than the laws and regulations for private customers. In order to ensure that Bayer HealthCare complies with Federal law, it is Bayer HealthCare’s policy not to provide any items of value to Federal government employees. You should consult your Division’s Compliance Policies and Procedures for details.

Some states have separate and very strict laws regarding the provision of educational items and other promotional activities that are more restrictive than Bayer HealthCare’s general policy. You should consult your Division’s Compliance Policies and Procedures for details on which states are affected and whether the law applies to your Division and/or business unit. If you interact with healthcare professionals from any of these states, you must consult the relevant Bayer HealthCare procedures prior to providing any item of value to those healthcare professionals.



8. Educational Grants

All educational grants must be made for the purpose of fostering the increased understanding of scientific, clinical or healthcare issues that contribute to the improvement of patient care. A grant cannot be made in order to induce or encourage a healthcare professional to prescribe, purchase, order, refer, use or recommend Bayer HealthCare products or to encourage off-label use. Grants may not be provided if one of the purposes is to encourage or reward referrals for Bayer HealthCare products. The website for submissions of educational grants is: <http://bayerus.com/bhc/supportrequest.aspx>.



9. Support of Medical Education Programs

Bayer HealthCare provides financial support for educational programs in compliance with FDA regulations, OIG guidance, ACCME guidelines, other professional accreditation agency guidelines, and industry guidelines. Educational programs may either be controlled by Bayer HealthCare or controlled by an independent third-party, such as a Continuing Medical Education (CME) or Continuing Education (CE) vendor.

Bayer HealthCare-controlled promotional programs are educational programs where Bayer HealthCare employees are permitted to control and influence elements of the program, such as content and audience selection. This type of promotional program generally takes the form of a Bayer HealthCare sponsored speaker event where Bayer HealthCare contracts directly with the speaker and selects the invitees. These programs must only discuss uses of Bayer HealthCare products that are consistent with the FDA-approved labeling. Sales personnel may attend and conduct promotional activities at such programs. Materials used in the program must be reviewed and approved through Bayer HealthCare procedures governing the review and approval of promotional materials.

Bayer HealthCare may also support CME, CE 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. Support for medical education programs that relate to unapproved product uses should be handled through a third party, in accordance with your Division's Compliance Policies and Procedures, in order to ensure that the programs are independent of Bayer HealthCare and non-promotional in nature.

Bayer HealthCare employees may not, directly or indirectly, control or influence the content, faculty, attendees, educational methods or materials of a CME or other third-party educational program. Under certain limited circumstances, sales personnel may attend third-party educational programs, including CME, but may not conduct promotional activities during these programs. Appropriate promotional activities may be conducted outside program meeting rooms, such as at an adjacent exhibit, to the extent these activities are permitted by the educational provider or conference sponsor. The website for submissions of CME programs is: <http://bayerus.com/bhc/supportrequest.aspx>.

10. Clinical Research, Development and Clinical Study Support

All clinical research and development as well as clinical studies supported by Bayer HealthCare should promote legitimate research goals. Support for any research, development or clinical study cannot be provided to induce, influence, encourage or reward the purchase, order, referral, use, prescription or recommendation of Bayer HealthCare products. Any research, development or clinical study supported by Bayer HealthCare must be conducted pursuant to a written agreement approved by the Law and Patents Department.



11. Reports of Adverse Events involving Bayer HealthCare Products

If you become aware of adverse information or an adverse event involving a Bayer HealthCare product, you must immediately report it. Please refer to your Division's standard operating procedures to report adverse events. Bayer HealthCare is required to report such adverse events to the FDA. You must report this information regardless of whether you believe that the facility will report it and regardless of whether the adverse event appears to have been caused by, or related to, the use of a Bayer HealthCare product.



12. Confidential Disclosure Program

Bayer HealthCare maintains a confidential disclosure program, referred to as the “IntegrityLine,” that allows employees to report to the Bayer HealthCare Compliance Officer suspected violations of federal or state healthcare program or FDA requirements or of Bayer HealthCare’s policies and procedures. Bayer HealthCare has established a toll free number (1-888-765-3846) which can be used for confidential, anonymous reporting. Bayer HealthCare will keep such reports confidential to the full extent of the law. The Bayer HealthCare Compliance Officer (or designee) will make a good faith inquiry into any reported violation. It is Bayer HealthCare’s policy not to retaliate against any employee for reporting suspected violations in good faith.



13. Compliance Training

All Bayer HealthCare “Covered Persons” will be trained on this Code of Conduct as part of their regular employee training. Additional training may be mandated by each Division.

Employees must certify their completion of all training.

Additional Guidance

Bayer HealthCare directors, officers and employees (other than officers and employees of Animal Health and Consumer Care that do not engage in manufacturing, marketing, distribution, sales, promotion or pricing of government reimbursed products and certain employees engaged solely in manufacturing operations) are considered “Covered Persons” under the Corporate Integrity Agreement signed on November 25, 2008 (“the CIA”). Covered Persons also include contractors, subcontractors, agents and other persons who perform Promotional and Product Services Related Functions, which include: (a) the promotion, advertising, distribution, marketing and sale of Government Reimbursed Products; and (b) the development or dissemination of materials or information about, or the provision of services relating to, Government Reimbursed Products. Covered Persons must complete two hours of General Training in their first year as a Covered Person under the CIA, and at least one hour of General Training in each subsequent year. General Training covers Bayer HealthCare’s obligations under the CIA and Bayer HealthCare’s Compliance Program, to include this Code of Conduct and Policies and Procedures as they relate to general compliance issues.

Covered Persons involved with the initiation, negotiation, proposal, development, approval, implementation, management, oversight (including accounting functions), or review of Bayer HealthCare’s Arrangements (e.g., grants, speaker agreements, product purchase contracts) are considered “Arrangements Covered Persons” under the CIA. Arrangements Covered Persons must complete three hours of Arrangements Training each year covering Bayer HealthCare’s policies, procedures and other requirements relating to Arrangements including, but not limited to, the Focus Arrangements Database, the internal Arrangements review and approval process, and the tracking of remuneration to and from sources of referrals or sales to ensure the Arrangement does not violate the Anti-Kickback Statute. In addition, Arrangements Training also includes examples of violations of the Anti-Kickback Statute, legal sanctions for such violations, as well as the personal obligation of each individual involved in the Arrangement process to understand the applicable laws and Bayer HealthCare policies concerning Arrangements.

14. Ineligible Persons

It is the policy of Bayer HealthCare not to hire Ineligible Persons - individuals who are excluded, suspended, debarred or otherwise ineligible to participate in Federal healthcare programs or in Federal procurement or nonprocurement programs; or who have been convicted of a criminal offense related to federal healthcare programs. If an individual becomes an Ineligible Person while employed with Bayer HealthCare, Bayer HealthCare will, at a minimum, remove the employee from work involving government reimbursement programs and from any position for which the Ineligible Person's compensation, or the items or services furnished, ordered, or prescribed by that person are paid in whole or in part, directly or indirectly, by Federal healthcare programs, or Federal funds, until such time as the person is reinstated into participation in Federal healthcare programs.

All prospective employees for positions that are deemed Covered Persons must certify whether they are Ineligible Persons. Current employees must inform Human Resources immediately in the event that they become ineligible during their employment.



15. Discipline

Violations of this Code of Conduct or of the employee's Division's policies and procedures including those contained in the respective Division's Compliance Policies and Procedures will 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 sanctions, including, but not limited to, the following:

Written letter of reprimand;
Compliance training;
Monetary penalty;
Suspension; or
Termination.

All discipline will be subject to Bayer HealthCare's discretion.

Nothing in this Code of Conduct is intended to change the employment-at-will relationship in any way nor is it intended to create legal rights.



16. Employee Education about False Claims Acts

The Federal Government has enacted laws to prevent, detect, and punish healthcare fraud and abuse, such as the Federal Anti-Kickback Statute, Federal False Claims Act, and other civil and criminal laws. Many states have enacted similar laws. The Federal False Claims Act, and some state False Claims Acts, also include provisions under which individual citizens with evidence of fraud against the government may sue on behalf of the government to recover the lost funds. These laws also prohibit retaliation against persons who file such whistleblower suits. More information about these laws, and the company's compliance policies and procedures, can be obtained from the respective Division's Compliance Policies and Procedures booklet, the Compliance Department, and the Law and Patents Department.

Bayer HealthCare has established a comprehensive compliance program, including policies and procedures to prevent, detect, and correct violations of law and company policy. Bayer HealthCare employees, contractors, and agents are required to report actual or potential violations of the law or company policy. You can report compliance concerns to your supervisor, the Law and Patents Department, the Compliance Department, or via Bayer HealthCare's confidential disclosure process, the IntegrityLine at 1-888-765-3846. Company policy prohibits retaliation against employees for good faith reports of compliance issues.



A Brief Summary of the Law

17. Regulation of Product Promotion

The Off-Label Promotion Rule

It generally is a violation of the law for manufacturers or marketers to promote a product in the United States or to U.S. healthcare professionals for any use that has not been approved by the Food and Drug Administration (FDA). It is legal, however, for a healthcare professional to use or prescribe a product for a use that has not been approved by the FDA.

There are some very narrow exceptions to the off-label promotion rule which can be employed only after review by Division counsel.

Practical Definition of the Rule

Prohibited "off label" promotion includes such practices as:

- Using sales and promotional materials, such as reprints of journal articles or any "unofficial" promotional materials including materials prepared by individual sales representatives that are not approved, to promote products for uses that are not approved by the FDA or consistent with the regulatory status of the product.
- Providing financial support for speaker programs, grand rounds, symposia or other educational presentations on off-label uses, in circumstances in which a Bayer HealthCare employee participates in or influences the content of the presentation. Attempts to influence content may be seen as an effort to induce, influence or encourage the purchase, order, referral, use, prescription or recommendation of a Bayer HealthCare product in a manner that is not approved by the FDA or consistent with its regulatory status.
- Targeting healthcare professionals who do not have an opportunity to use a product in a manner approved by the FDA.

Bayer HealthCare may keep its employees informed of research developments, but such information cannot, except in rare circumstances, be used to promote the company's products for any use not approved by the FDA.

18. The Anti-Kickback Statute

The Anti-Kickback Rules

It is a violation of the law to offer or pay, directly or indirectly, “remuneration” - that is, anything of value (such as discounts, rebates, educational grants, charitable contributions, cash, educational items, promotional funds, fee-for-service arrangements, etc.) to a customer, or prospective customer, with an improper intent to induce, influence, encourage or reward that customer’s or prospective customer’s purchase, order, referral, use, prescription or recommendation of a Bayer HealthCare product(s). Intent may be considered by the government to be improper if even one purpose of the remuneration is to induce the recipient to prescribe or order Bayer HealthCare products.

There are some exceptions (“Safe Harbors”) to this general rule, which can be used only after review by and consultation with Bayer’s Law and Patents Department or other appropriate personnel.

The purpose of these rules is to keep manufacturers such as Bayer from improperly influencing the clinical judgment of its customers, which could result in increased costs to government payers from over-utilization of a product or the inappropriate selection of one product over another.

Applying these rules can be complicated. If you are uncertain about a particular arrangement or practice, promptly bring it to the attention of the Division counsel.

Practical Definition of the Rule

Remuneration may be an illegal “kickback” if it:

- is provided to a person in a position to generate, influence or encourage prescriptions, sales or otherwise promote business (such as a physician, pharmacist or group buying agent);
- is related to the volume or value of business generated; or
- exceeds the fair market value of any good or service provided by the recipient.

Any remuneration to a healthcare professional that violates the Anti-Kickback Statute will also create a financial arrangement that may violate the law.

The most important issue to keep in mind in determining whether remuneration is an illegal “kickback” is intent -- whether something of value is being given with the purpose of inducing, influencing, encouraging or rewarding the purchase, order, referral, use, prescription or recommendation of a product. Law enforcement officials seldom find direct evidence of a reciprocal “deal,” so they determine the intent of the parties from the circumstances surrounding the transaction and the provision of remuneration. Bayer HealthCare’s policies are designed to avoid all circumstances where an improper intent might be inferred.

19. The False Claims Act

The False Claims Act Rules

It is a violation of the law for anyone knowingly to make or cause others to make false statements or claims to the government. A manufacturer, or employees acting on its behalf, may “knowingly” cause or contribute to the filing of a false statement or claim if it actually knows that the statement or claim is false or if it acts in “deliberate ignorance” of, or with “reckless disregard” for, whether the statement or claim is actually true or not.

Practical Definition of the Rule

It is rare, but sometimes people tell the Government information they know to be incorrect or file a claim knowing that they are not entitled to get what they request. Bayer HealthCare needs to make sure that information it provides to the government, especially reimbursement and pricing information, is accurate and consistent with the requirements of Federal and state healthcare programs, such as Medicare and Medicaid.

The Government may charge companies or employees with violating the False Claims Act when they do the following:

- Make little or no effort to verify the truth or accuracy of their statements or claims so that it appears that they were acting recklessly even if they did not know for sure that the information was false;
- Act to avoid finding out whether their statements or claims are true or false, like the proverbial ostrich sticking its head in the sand;
- Make incorrect or inaccurate statements or claims over and over again, so that it appears they just do not care about getting it right; and/or
- Help someone else (such as a customer or physician) make a false claim or statement to the Government.

Innocent or inadvertent mistakes occasionally do happen in the course of work. Those types of errors should not violate the False Claims Act. However, care must be taken so that those mistakes are identified, corrected and prevented.

The federal False Claims Act, and some state False Claims Acts, also include provisions under which individual citizens with evidence of fraud against the government may sue on behalf of the government to recover the lost funds. These laws also prohibit retaliation against persons who file such whistleblower suits.

20. Antitrust Laws and Regulations

It is the long-standing policy of Bayer Corporation that its operations, in all respects, are conducted in full compliance with all applicable laws, including Federal and State Antitrust Laws, and that its affairs be conducted in keeping with the highest legal and ethical standards. Antitrust laws are fundamental to our free enterprise system. They provide the environment in which we can achieve our profit and growth objectives unrestricted by anti-competitive practices.

The principal Federal Antitrust Laws are the Sherman Act, the Clayton Act, the Robinson-Patman Act, the Federal Trade Commission Act and the Hart-Scott-Rodino Act. Their purpose is to maintain the fundamental business conditions necessary for the proper functioning of a free enterprise system by prohibiting unreasonable restraints on competition and discriminatory business practices having anti-competitive effects. Basically, these laws require that each company act independently and sell its products fairly and honestly on the basis of price, quality and service.

The Bayer Corporation Antitrust Compliance Program includes training for all Bayer Corporation employees and is available for your review with the following URL: <http://www.bayernet.com/ombudsman/antitrust.cfm>

All employees are responsible for complying with this policy, and must not inadvertently give the appearance of having violated the law or engaging in questionable conduct.





Bayer HealthCare

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