



**The** \_\_\_\_\_  
**HARVARD DRUG GROUP, LLC**

*Rx Brands/Generics & MAJOR Consumer Products*

# **Comprehensive Compliance Program**

# ***COMPREHENSIVE COMPLIANCE PROGRAM***

*The Harvard Drug Group, LLC and its division that does business as Major Pharmaceuticals (here after “Harvard”)*

Harvard is committed to implementing and maintaining an effective Comprehensive Compliance Program in accordance with the Compliance Program Guidance for Pharmaceutical Manufacturers published by the Office of Inspector General (“OIG”), U.S. Department of Health and Human Services. The purpose of our Compliance Program is to prevent and detect violations of law or company policy. Our Compliance Program was established by the Senior Management and is a key component of our commitment to the highest standards of corporate ethics and conduct.

An effective Comprehensive Compliance Program must be dynamic and responsive to new developments. We expect to review our Compliance Program regularly and to enhance it over time to meet our evolving compliance needs. Effective programs also require the commitment and support of senior management, employees, and the contractors that work with a company. Each employee and affiliate of Harvard must recognize that he or she has assumed a number of ethical and professional responsibilities by affiliating with Harvard, including complying with the following two fundamental tenets of Harvard’s Compliance Program: (a) adherence to our Standards of Conduct and (b) reporting violations of our Standards of Conduct.

## ***Complying with Harvard’s Standards of Conduct***

As a Harvard employee, you are responsible for ensuring that your conduct conforms to Harvard’s Standards of Conduct and all applicable Federal and State laws and regulations. If at any time you have a question as to whether a procedure or action is inappropriate under the Standards of Conduct, then you should ask your immediate supervisor. If you do not feel comfortable discussing the situation with your supervisor, or if you have discussed the matter and remain unclear as to what is appropriate conduct, then you should speak with the Compliance Officer (“CO”).

Any employee who has a question about what constitutes proper conduct is able to consult the CO for guidance. This contact may be made confidentially. Our CO will take the appropriate steps to investigate a complaint and may institute corrective action if required. The CO also is responsible for answering questions about the Standards of Conduct and any Policies and Procedures that expand upon the Standards and for resolving disputed interpretations. You should have no hesitation whatsoever in consulting the CO if you believe it is necessary to do so.

## ***Reporting Violations of Standards of Conduct***

All Harvard employees must follow the Standards of Conduct. This obligation applies to every employee of Harvard, regardless of position. A violation of a Standard of Conduct is a serious matter. Under appropriate circumstances, and after proper procedures have been followed,

employees may be subject to discipline, up to and including termination, for violations of the Standards of Conduct.

It is the responsibility of each employee to report any known or suspected violation of the Standards of Conduct, any other company policy, or any Federal or State law or regulation. You can satisfy this reporting obligation in several ways. First, you may make a report, anonymously if you choose, by calling the company's compliance hotline. Your report will be evaluated by the CO to determine whether an investigation is warranted. Alternatively, you may send a letter to the CO discussing your concerns. Written reports will be treated with the same degree of confidentiality as oral reports, and they may be anonymous if you prefer. Employees should be assured that retaliation for filing a report of a suspected violation in good faith is absolutely prohibited, even if the report is not found to be accurate or it is determined that no violation of the Standards of Conduct or applicable laws occurred.

### ***Certification of Understanding of Harvard's Standards of Conduct***

As a condition of employment, every Harvard director, officer, or employer will be asked to certify that they (a) have received a copy of the company's Comprehensive Compliance Program, (b) have read the Program and the Policies and Procedures amplifying on the Standards of Conduct in the Program, and (c) will comply with the company's Standards of Conduct. These certifications will be retained in each individual's personnel file. Provisions requiring review of and adherence to Distributor's Comprehensive Compliance Plan will be included in contracts that Harvard executes with vendors.

### ***The Compliance Officer***

Our Compliance Officer (the "CO") is responsible for the implementation, operation, and monitoring of the Harvard's Comprehensive Compliance Program. Many of the principal elements of the Compliance Program are under the direction and supervision of the Compliance Officer. The Compliance Officer reports to C.E.O. and, when necessary has direct access to the Board of Directors.

Our Compliance Officer is key to the effective implementation of our Comprehensive Compliance Program. The Compliance Officers duties include:

## **A. Development and Implementation of an Investigative Protocol**

The Compliance Officer is responsible for reviewing, assessing and, as appropriate, investigating reports of possible misconduct from Company employees, independent contractors or any one else who contacts the Harvard's compliance hotline. A report log will be kept in which the Compliance Officer records pertinent data. All reports will be retained in a secure location pursuant to the Company's record retention policy. If the Compliance Officer concludes, based upon the initial review of a report, that the report contains allegations that should be investigated further, the Compliance Officer will initiate an investigation. The Compliance Officer is responsible for developing a protocol for the expeditious investigation of any credible report that alleges a violation of the Company's Standards of Conduct or applicable law. If necessary, the Compliance Officer may request assistance from Legal Counsel in completing any of these responsibilities.

Promptly at the conclusion of any investigation, the Compliance Officer will draft a report of findings and recommendations. The report will contain a summary of the initial report, the steps taken to investigate the report, the investigative findings, and the recommendations, if any, for corrective action. This report will be forwarded for review by the Company's Senior Management or, if Senior Management is implicated in any wrongdoing, to the Board of Directors.

## **B. Development of Audit Protocols**

The Compliance Officer will institute a plan for periodic audits and reviews of certain facets of the Company's operations, including its sales and marketing practices. The nature of these reviews as well as the extent and frequency of our monitoring and auditing activities will vary depending upon perceived regulatory risk, new regulatory requirements, changes in business practices, and other considerations. Some audits and reviews will be conducted using internal resources. Other may involve the retention of outside consultants or attorneys. We expect our routine evaluation of enforcement developments coupled with our periodic assessments of our operations to result in the identification of new and emerging risk areas that will be address through enhancements to our Compliance Program.

## **C. Design and Coordination of Compliance Training**

The Compliance Officer is responsible for the development and coordination of new hire compliance training, annual training and periodic refresher training for Harvard's managers, employees and independent contractors. Participation in annual compliance training will be mandatory. The Compliance Officer will create or identify appropriate programs for new and existing personnel. The focus of the initial compliance training will be the Comprehensive Compliance Program in general as well as the applicable Federal and State laws and regulations that apply to Harvard's operations. When an area of perceived compliance risk involves specialized issues not of general concern to the entire employee population, the Compliance Officer may direct certain employees or contractors to attend appropriate continuing education courses offered by commercial conference organizers or government agencies. All participants will be required to sign an attendance sheet at each internal training session that is conducted or certify attendance at external training sessions.

Training may be presented in a variety of ways. In-person meetings, video presentations, web-based training programs, and outside seminars are all acceptable training approaches. For certain situations, the Compliance Officer may also elect to require self-training through the review of documents and the completion of a certification that the materials have been read. Regardless of the medium used for training, the Compliance Officer maintains an open-door policy and routinely will be available to answer questions and clarify instructions.

Harvard will regularly review and update its training programs and materials to ensure that they reflect changes to Harvard's operations, its Comprehensive Compliance Program, the OIG Compliance Program Guidance for Pharmaceutical Manufacturers, the PhRMA Code, and applicable law. Harvard may also identify additional areas of training on an as-needed basis.

#### **D. Establishment of Internal Lines of Communication**

It is the responsibility of the Compliance Officer to maintain contact with Legal Counsel and other sources in order to keep the Company aware of new regulatory and legal developments affecting its operations, particularly those relating to sales and marketing. It is also the duty of the Compliance Officer to disseminate to the appropriate Company personnel information concerning regulatory and legal developments. Normally this will be accomplished through memoranda or circulated copies of the pertinent regulations, laws, or other documents. The Compliance Officer, however, should be prepared to conduct or arrange for compliance workshops if extensive and complicated changes must be implemented and new procedures developed as a consequence of any statutory or regulatory development.

Just as importantly, the Compliance Office also must foster dialogue between management and employees. The Compliance Officer must ensure that all employees and contractors know who to turn to for a meaningful response to a compliance question and how to report suspected violations of the company's Standards of Conduct. The Compliance Office also must ensure that our employees and our contractors feel free to ask questions or report concerns, knowing that they may do so without fear of retribution. Harvard operates under an open-door policy and follows confidentiality and non-retaliation policies as well. We also have set up a 1-800-telephone system to handle questions or complaints that individuals want to raise anonymously.

### **E. Due Diligence Oversight of Employee and Contractor Selection**

Harvard will not employ or contract with any individual or entity that (a) has been convicted of a criminal offense related to health care, or (b) is debarred, excluded, or otherwise ineligible for participation in federal health care programs. Working with representatives of Harvard's Human Resources Department, the Compliance Officer will assure that every new director, officer, manager, employee and contractor is screened through the OIG and GSA listings of excluded individuals and that no one appearing on the list is hired. Harvard also will conduct appropriate additional background checks on all such individuals.

Periodically and as necessary, Harvard will rerun the names of managers and current staff involved in sales and marketing through the OIG and GSA exclusion listings. Furthermore, all individuals or entities employed by, under contract with or otherwise affiliated with Harvard must notify Human Resources or the Compliance Office immediately if they are charged with a criminal offense related to health care or become subject to a debarment or exclusion proceeding. Failure to provide such notice could result in termination.

### **F. Oversight of Disciplinary Actions**

The Compliance Officer will be responsible for ensuring that any officer, employee, or contractor of Harvard who is found to have violated the Standards of Conduct is disciplined in an appropriate, measured, and consistent fashion. The Board of Director shall review all significant decisions on an annual basis to ensure that this standard has been met.

All managers and supervisors should take appropriate action to identify any misconduct committed by employees or others whom they supervise. Managers may be subject to discipline for failure to detect compliance violations that occur to the extent that the manager is negligent in this duty. If a manager or supervisor, through negligence, carelessness, or inattention, facilitates or prolongs misconduct, then an appropriate penalty based on the seriousness of the offense will be imposed.

Harvard acknowledges that different categories of conduct may exist (i.e., simple negligence, gross negligence, or willful misconduct) and this will be taken into consideration when determining the appropriate discipline. Certain offenses may justify immediate termination of employment:

- (1) Violation of any Federal or State criminal statute;
- (2) Failure to report conduct by an employee, contractor, officer, or director that a reasonable person under the circumstances should have known was a violation of law;

- (3) Failure to report a violation of the Standards of Conduct by any employee, contractor, officer, or director that a reasonable person under the circumstances should have known violated the Standards;
- (4) Knowingly or willfully obstructing any government investigation or audit.

It shall be the Compliance Officer's responsibility working in cooperation with Human Resources to establish an appropriate schedule of penalties, including possible termination, which shall be applicable to violations of this Comprehensive Compliance Program. The Compliance Officer also will take steps to ensure that the applicable disciplinary guidelines are well publicized throughout the organization.

An employee or independent contractor whose conduct would otherwise justify termination may have a lesser discipline imposed depending upon (a) whether the employee or independent contractor reported his or her own violation; (b) whether the report constitutes Harvard's first notice of the violation and the employee's or contractor's involvement; and (c) whether the employee or independent contractor has provided full and complete cooperation during the Compliance Officer's investigation of the violation.

#### **G. Conducting Exit Interviews**

It shall be the responsibility of a designee of the Compliance Officer to conduct an exit interview with each employee and independent contractor terminating his or her relationship with Harvard. The purpose of this interview shall be to solicit information about the level of the Company's compliance with the Compliance Program and the Standards of Conduct.

#### **H. Establishment of an Ongoing Program of Compliance Monitoring**

This Comprehensive Compliance Program is intended to adapt to changes in the law and to Distributor's operation and experiences. The Program itself will be reviewed regularly to assess how it is working. As part of this process, the Compliance Officer will prepare an annual report for the Board of Directors that describes the general compliance efforts that Harvard has undertaken. This report also will describe any changes that are needed in the implementation or operation of the Program to ensure Program efficiency or effectiveness. The annual report will incorporate substantive learning about risk areas and risk management learned from periodic audits and reviews, complaint-driven investigations, employee and contractor questions, exit interviews and the like.

If anything in the report identifies areas of possible non-compliance, the Compliance Officer will report that fact to Senior Management and the Distributor Board of Directors. Operation of the Harvard's Comprehensive Compliance Program increases the likelihood of preventing unlawful and unethical behavior. However, even an effective Compliance Program may not prevent all violations of applicable laws. As such, our Compliance Program requires Harvard to respond promptly to potential violations of our Standards of Conduct or of applicable law, take appropriate disciplinary action, assess whether the violation is in part due to gaps in our policies, practices, or internal controls, and take action to prevent future violations. In addition to assessing the Compliance Program annually and making recommendations to the Board for needed responses to concerns, the Compliance Office

coordinates these tasks in an ongoing manner throughout the year and ensures the Compliance Program is promptly revised to reflect changes in the law or industry standards.

### ***Standards of Conduct***

#### **A. Employment at or Affiliation with Harvard**

Harvard will take reasonable steps to avoid employing or contracting with any individual or entity who (a) has been convicted of a criminal offense related to health care, or (b) is debarred, excluded or is otherwise ineligible for participation in Federal or State health care programs. Harvard will make every reasonable and lawful effort to obtain this information when it screens employment or independent contractor applications. For each new director, officer, employee or independent contractor Distributor will require:

- (1) A reference check;
- (2) A review of (a) the Cumulative Sanctions Report maintained by the Office of the Inspector General of the Department of Health and Human Services (“OIG”) ([www.dhhs.gov/progorg/oig](http://www.dhhs.gov/progorg/oig)) and (b) the List of Persons Excluded from Federal Procurement and Non-Procurement Programs maintained by the General Services Administration (“GSA”) ([www.arnet.gov/epl](http://www.arnet.gov/epl)).

The performance of these background investigations shall be documented and maintained in the appropriate personnel or contract files. Exclusion list reviews will be repeated periodically and as needed for individuals and entities with responsibilities for sales and marketing, and records of these periodic reviews also will be maintained in the appropriate personnel or contract files.

#### **B. Conduct of Harvard’s Business in a Legal and Ethical Manner**

Harvard expects that all officers, employees, agents, and independent contractors will:

- (1) Understand applicable laws, rules, and Harvard’s Standards of Conduct and policies to the degree needed for them to carry out their responsibilities in accordance with those laws, Standards, and policies.
- (2) Understand applicable laws, rules, and Harvard’s Standards and policies to the degree needed to identify situations where other individuals may put Harvard at risk of violating those laws, rules, Standards, or policies.
- (3) Promptly contact Harvard’s Compliance Officer whenever there is a question as to whether or not particular conduct violates the law or a Harvard’s Standard or policy.
- (4) Attend any Harvard-sponsored compliance training, as it relates to job functions.

- (5) Report to the Compliance Officer any pending criminal investigations involving health care fraud of which they are a target or any pending proceedings against them that could result in them being excluded or debarred.
- (6) Not commit or tolerate any conduct that may put Harvard at risk of violating the law or the company's ethical principles and Standards of Conduct.

### **C. Compliance with the Law**

Harvard will operate all aspects of its business in compliance with all applicable Federal, State and Local laws and regulations.

#### **(1) Healthcare Fraud and Abuse Laws**

Harvard will comply with all applicable Federal and State healthcare fraud and abuse or "anti-kickback" laws and regulations, including the federal Anti-Kickback Statute (42 U.S.C. §1320a-7b(b)) and the Public Contract Anti-Kickback Act ((41 U.S.C. §§ 51-58), as well as with all applicable provisions of the Federal False Claims Act. (31U.S.C. §3729 *et seq.*). The fraud and abuse laws prohibit, among other things, payment or receipt of kickbacks and other forms of improper "remuneration" in return for purchasing, leasing, ordering or recommending the purchase, lease or ordering of any goods, facilities, services or items covered under the benefits of Federal or State health care programs.

Common business practices such as providing discounts, rebates, or services to customers may have potential fraud and abuse law implications if Harvard does not document and structure these practices properly. Inappropriate consulting arrangements or educational or research grants also may have potential fraud and abuse law implications.

The Federal False Claims Act prohibits submission or causing the submission of fraudulent claims to Medicare and other Federal and State programs. Only true and accurate reimbursement information may be provided to customers. The Federal False Claims Act also prohibits the filing of incorrect reports if the result of the filing may be a reduction in Harvard's financial obligations to the government.

(2) Food and Drug Laws

Harvard will comply with all applicable laws and regulations and all Harvard's policies, procedures, rules and practices that govern the research, development, manufacture, and distribution of prescription drugs approved by under the Food, Drug and Cosmetic Act.

(3) Anti-Trust Law

Harvard will comply with all applicable antitrust and competition laws.

**D. Compliance with Industry Standards**

Harvard will comply with recommendations included in the OIG's Compliance Guidance for Pharmaceutical Manufacturers and the PhRMA Code on Interactions with Health Professionals. Employees must follow the Code's requirements whenever they interact with customers, potential customers or their representatives who are licensed health professionals (including, but not limited to, physicians, nurses, and pharmacists), medical students, or members of drug formulary committees. A copy of the Code may be viewed and downloaded at <http://www.phrma.org/files/PhRMA%20Code.pdf>. Copies of the Code and OIG Guidance are also appended to Harvard's Compliance Policies and Procedures.

**E. Conflicts of Interest**

Employees must avoid any investment, interest, activity or association that interferes, or might interfere with, their obligation to perform responsibilities in the best interests of the Harvard.

**F. Protection of Confidential Information**

The disclosure of confidential information regarding Harvard's business or scientific operations, whether intentional or accidental, may adversely affect the financial stability and competitive position of Harvard as well as the job security of employees.

Employees shall not, without the written consent of Senior Management, during the term of employment or thereafter, use, directly or indirectly, for the personal benefit of themselves or others, or disclose to others, any confidential information of Harvard or of other entities obtained during the course of employment at Harvard.

Employees shall not seek or accept confidential information of a competitor in an illegal or unethical manner, and if information is offered or given that is reasonably viewed as having been obtained through illegal or unethical means, or even accidentally, the employee shall immediately report the matter to the Compliance Officer.

**G. Gifts and Entertainment**

Employees shall not seek, accept, offer, promise or give any payment, fees, loans, services or gifts from or to any person or firm as a condition or result of doing business with the Harvard. Businesses courtesies, gifts and entertainment must comply with the requirements of the PhRMA Code.

Harvard has established and will enforce an annual limit on the value of gifts, promotional materials, and items or activities – each of which must individually comply with the requirements of the PhRMA Code – that may be given to a California-licensed medical or health care professional. This limit is \$100.00

**H. Maintenance of the Accuracy and Integrity of Books and Records**

Harvard's books, records and accounts must accurately reflect the nature of the transactions recorded. This includes, but is not limited to, financial transactions, expense reports, activity reports and other documents used in the normal course of business.

**I. Dealings with Government Agencies**

Any communication with a government agency must be responsive, accurate, and complete. Any data or other information provided to a government agency must be accurate, complete, and include an explanation of any omission or inability to respond. All government agents will be treated with respect. Any inquiry from a government agent outside the normal course of ministerial interactions for purposes of compliance with mandatory reporting requirements will be referred to the Compliance Officer and Chief Operating Officer. In no event will any employee be prohibited from speaking voluntarily with a government agent engaged in an investigation or an enforcement action, although they may be advised that they are not obligated to speak with an agent.

**J. Compliance with Employment Laws**

It is the policy of Harvard to provide employment opportunities without regard to race, religion, color, national origin, sex, age, ancestry, citizenship, veteran status, marital status, sexual orientation or disability, or any other reason prohibited by law. Decisions as to hiring, promotion and other aspects of the employment relationship are based solely upon job-related qualifications.

Harvard also prohibits sexual harassment, as well as harassment based on any of the other characteristics listed above, and will take appropriate action to eliminate prohibited harassment and remedy the effects of such harassment.

**K. Appropriate Use of Electronic Media**

Harvard provides access to and use of electronic mail, voicemail, the Internet and other electronic media for business purposes. Distributor's electronic media shall not be used for any purposes that violate federal, state or local laws.

**L. Policies Relating to Document Retention and Destruction**

Harvard will retain those documents that it is required to retain in order to comply with pertinent laws and regulations and that are needed for its daily operations. Documents will be retained long enough to satisfy specific legal requirements. Where documents are no longer required to be maintained by law or by legitimate business needs, they may be destroyed. Harvard routinely destroys documents in accordance with an established document retention policy.

The basic rule allowing destruction of certain documents shall not apply in the following circumstances:

- (1) Service of legal process;
- (2) Inquiries indicating the commencement of litigation; or
- (3) Notice from the Compliance Officer.

Under these circumstances, no documents should be destroyed until written approval has been received from Harvard's Compliance Officer. Contact the Compliance Officer if you are uncomfortable with or have questions about the appropriateness of destroying certain documents.

Documents developed in connection with Harvard's Compliance Program, such as employee complaints, annual reports, and investigative files, will be maintained for four years from the date of creation.