



## **Comprehensive Compliance Plan**

### **1.0 Introduction**

At Ironwood, compliance starts with, and is the responsibility and continuing obligation of, each employee, officer, director, contractor or other third parties acting on behalf of Ironwood, as well as Ironwood subsidiaries ("Ironwood Representative"). We rely upon and expect that Ironwood Representatives will conduct themselves in compliance with Ironwood policies, and applicable laws, rules and regulations. In an effort to ensure that Ironwood Representatives remain abreast of and informed about these policies, and the laws, rules and regulations that impact and govern our business, Ironwood has developed this Comprehensive Compliance Plan (the Compliance Plan). In addition to providing training and education, the Compliance Plan is designed to monitor, detect, correct, and as necessary take disciplinary action, in respect of activities or practices that do not comply with the law or Ironwood policies and expectations. The ultimate goal of the Compliance Plan is to ensure that Ironwood Representatives have the knowledge and resources necessary to comply with these policies, laws, rules, and regulations.

In developing the Compliance Plan, reference was made to and reliance placed upon the Compliance Program Guidance for Pharmaceutical Manufacturers issued in April 2003, as amended to date, by the Office of Inspector General of the Department of Health and Human Services (Compliance Program Guidance), the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals, effective as of July 1, 2002, as amended to date (the PhRMA Code), the Prescription Drug Marketing Act, relevant guidelines of the American Medical Association, the guidelines of the Accreditation Council for Continuing Medical Education (ACCME), and other guidance issued by the US Food and Drug Administration and other government agencies.

### **2.0 Ironwood Code of Conduct and other Policies and Procedures**

Ironwood has adopted a written Code of Business Conduct and Ethics that provides a general statement of the expectations of Ironwood regarding the ethical standards by which Ironwood Representatives are to adhere when acting on behalf of Ironwood. Although not a member of PhRMA, Ironwood supports and has implemented written policies and procedures that are consistent with the requirements of the PhRMA Code. In addition, Ironwood has implemented various written policies and procedures designed to ensure compliance with applicable legal and regulatory requirements governing the advertising and promotion of pharmaceutical products as set forth in, without limitation, the Federal Food, Drug and Cosmetic Act, the False Claims Act, the Federal Anti-Kickback Statute, Compliance Program Guidance, the American Medical Association's Code of Professional Ethics Opinion 8.061 on Gifts to Physicians from Industry, Section 6002 of the Patient Protection and Affordable Care Act, commonly known as the Physician Payment Sunshine Act, and federal and state privacy laws, as well as other and applicable state laws. Ironwood Representatives are expected to comply with the Ironwood Code of Business Conduct and Ethics, the PhRMA Code, and any and all compliance policies and procedures applicable to their function at, and activities performed on behalf of, Ironwood.

### **3.0 Compliance Officer and Compliance Committee**

Ironwood has appointed a Head of Compliance to serve as a focal point for compliance activities and has established a Compliance Committee that is chaired by the Head of Compliance. In addition to the Head of Compliance, other Standing Members of the Compliance Committee are

the Ironwood CEO, Chief Business Officer, Chief Legal Officer, Chief Financial Officer, and Chief Medical Officer. The membership of the Compliance Committee, and the title of Compliance Committee members, may be modified from time to time. The Compliance Committee shall have general oversight of the Company's Compliance Plan.

#### **4.0 Compliance Training and Education**

Ironwood is committed to developing and providing Ironwood Representatives with effective compliance training. This training includes both new hire training as well as mandatory annual training on the Ironwood Code of Business Conduct and Ethics, as well as other company policies and procedures governing the conduct of Ironwood Representatives, and applicable state and federal laws, rules and regulations as is relevant for the particular job function.

#### **5.0 Monitoring and Auditing**

To assess the efficacy of Ironwood's training and education program, as well as to confirm that Ironwood Representatives are acting in the expected compliant manner, Ironwood will periodically perform monitoring and auditing activities designed to evaluate compliance with company policies and applicable laws. The nature, frequency and extent of these reviews may vary according to factors such as internal risk assessments, regulatory requirements and developments, and changes in Ironwood's business practices. The Compliance Committee annually reviews and approves the monitoring and auditing plan.

#### **6.0 Employee Communications**

Ironwood has developed and implemented a written Policy on Reporting Suspected Law and Company Policy Violations in an effort to promote the prevention, detection, reporting and correction of unlawful or improper conduct. Under this Policy, Ironwood Representatives are obligated to report any actual or suspected violation of law, regulation or company policy involving any Ironwood Representative to their managers, or to the Compliance, Legal or Talent, Team and Culture Departments. In addition, Ironwood Representatives are free to report concerns anonymously 24 hours a day, 7 days per week through the Ironwood Compliance Hotline by calling 1-800-781-6257, or by submitting a report online via <https://ironwood.alertline.com>. The Compliance Department and other departments as appropriate will evaluate all reports and as appropriate investigate the reports promptly and thoroughly.

#### **7.0 Enforcement**

Ironwood is committed to maintaining the highest level of ethical conduct. Employees who violate the law, or Ironwood's Code of Conduct or other company policies, or who attempt to circumvent a law or policy, may be subject to discipline up to and including termination of employment or, as applicable, termination of a contractual or other relationship. Corrective disciplinary action will be imposed without regard to the Ironwood Representative's level within, or relationship to, the organization. No retaliation will be taken against any Ironwood Representative for a good faith report of what they honestly believe to be an actual or suspected violation.

#### **8.0 California Health & Safety Code Sections 119400-119402**

##### **Declaration**

Ironwood declares that to the best of its knowledge, and based upon a good faith understanding of California Health & Safety Code Sections 119400-119402 (the California Statute), that Ironwood (1) has established a comprehensive compliance program that is reasonably designed to prevent or detect and address misconduct and that encompasses the compliance program requirement set forth in the California Statute, and (2) is in compliance with its comprehensive

compliance program and the California Statute. This Compliance Plan and annual written declaration of compliance with the program are available to the public on Ironwood's website or by calling 1-617-621-7722.

Compliance is a dynamic concept and the Ironwood Compliance Plan is similarly intended to be a dynamic program designed to meet the company's evolving compliance needs. Accordingly, Ironwood will at least annually review and, as needed, modify its Compliance Plan to enhance its effectiveness.

### **Annual Spending Limit**

The California Statute requires that companies such as Ironwood establish an annual dollar limit on educational items and other appropriate items covered by the California Statute that are provided by Ironwood to individual healthcare professionals as part of Ironwood's interactions with these professionals. Ironwood has adopted an annual dollar limit of \$2,000 per individual healthcare professional. This limit is a maximum amount and is neither an average nor a targeted spending limit. Ironwood believes that its actual annual spending will fall short of this limit. The annual limit may be revised from time to time as deemed appropriate by Ironwood.

The annual spending limit set forth in this declaration does not include the value of:

1. Drug samples given to physicians and healthcare professionals intended for free distribution to patients;
2. Financial support of continuing medical education programs;
3. Financial support for health education scholarships;
4. Payments made for legitimate professional services provided by a healthcare professional, and any meals or reasonable expenses associated with the provision of such services, so long as the amount paid is based upon the fair market value of the services provided;
5. Items of nominal value with a retail value of less than \$10 (e.g., visual aids, reprints of medical journal articles, etc.), and
6. Patient educational materials provided to patients by their physician with the purpose of educating the patient or enhancing the patient's understanding or management of the condition

### **Attachments**

None

### **Sponsorship and Policy Management**

Head of Compliance