



# **Comprehensive Compliance Plan**

## **1.0 Introduction**

At Ironwood, compliance starts with, and is the responsibility and continuing obligation of, each Ironwood employee. We rely upon and expect that Ironwood employees will conduct themselves in compliance with Ironwood policies, and applicable laws, rules and regulations. In an effort to ensure that our employees 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 Plan). In addition to providing training and education, the 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 Plan is to ensure that Ironwood employees have the knowledge and resources necessary to comply with these policies, laws, rules, regulations.

In developing the Plan, reference was made to and reliance placed upon the Compliance Program Guidance for Pharmaceutical Manufacturers issued in April 2003 by the Office of Inspector General of the Department of Health and Human Services, the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals as updated and made effective as of January 2009 (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, Policies, and Procedures**

Ironwood has adopted a Code of Business Conduct and Ethics that provides a general statement of the expectations of Ironwood regarding the ethical standards by which its directors, officers, employees and contractors are to adhere when acting on behalf of Ironwood. In addition, although not a member of PhRMA, Ironwood supports and has implemented policies and procedures that are consistent with the requirements of the PhRMA Code. Ironwood employees 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 Chief Compliance Officer and has established a Compliance Committee that is chaired by the Chief Compliance Officer. In addition to the Chief Compliance Officer, other Standing Members of the Compliance Committee are the Ironwood CEO, Senior Vice President and Chief Legal Officer, Chief Commercial Officer, Chief Financial Officer, Chief Development Officer, Vice President of Regulatory Affairs, Vice President of Global Quality, and the Senior Vice President of Talent Team and Culture. Rotating Members of the Compliance Committee may include representatives of other departments. The membership of the Compliance Committee, and the title of Compliance Committee members, may be modified from time to time.

## **4.0 Compliance Training and Education**

Ironwood is committed to developing and providing its employees with effective compliance training. This training will include mandatory annual training on the Ironwood Code of Business Conduct and Ethics and also will cover relevant company policies and procedures governing the conduct of Ironwood employees, and applicable state and federal laws, rules and regulations.

## **5.0 Monitoring and Auditing**

To assess the efficacy of Ironwood's training and education program, as well as to confirm that Ironwood employees 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.

## 6.0 Employee Communications

Ironwood has developed and implemented a Policy on Reporting Suspected Law and Company Policy Violations. Under this Policy, Ironwood encourages and promotes the prevention, detection, reporting and correction of unlawful or improper conduct. Employees are encouraged to report any concerns to their managers, or to the Compliance, Legal or Human Resources Departments. In addition, employees 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. When appropriate, corrective disciplinary action will be imposed without regard to the employee's level within the organization. No retaliation will be taken against any employee for a good faith report of what they honestly believe to be an actual or suspected violation.

## 7.0 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.

Compliance is a dynamic concept and the Ironwood Comprehensive Compliance Program 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 Comprehensive Compliance Program 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 independent education including continuing medical education forums;
3. Financial support for health education scholarships, and
4. Payments made for legitimate professional services provided by a healthcare professional so long as the amount paid is based upon the fair market value of the services provided.

## 8.0 Revision History

Revision No.	Effective Date	Supersedes	Reason for Revision
00	May 24, 2012	New document	New Document
01	May 15, 2014	May 24, 2012	Administrative Revisions
02	November 15, 2017	May 15, 2014	Administrative Revisions and Modification to Section 4.0 confirming Ironwood's long-standing practice that training on Ironwood Code of Conduct is done annually

## 9.0 Attachments

None

## **10.0 Sponsorship and Policy Management**

Chief Compliance Officer