



**PROMETHEUS**<sup>®</sup>  
Therapeutics & Diagnostics

# **Corporate Compliance and Ethics Program**

**Effective as adopted on February 21, 2012**

## **SECTION 1. STATEMENT OF INTENT**

As a specialty pharmaceutical company and diagnostic laboratory, Prometheus operates in a highly complex and regulated business environment. Prometheus' reputation for integrity and doing the right thing for the right reason is an intangible asset that is highly valued by Prometheus and its employees. Our reputation gives us credibility, and creates value for our patients, physicians, employees, contractors, Board of Directors, and Nestlé Health Sciences, S.A.

The Compliance and Ethics Program provides a comprehensive approach to identifying and managing organizational risk. The elements of the Compliance and Ethics Program have been customized to fit Prometheus' business operations, the size of our company, and the unique environment in which we operate. Our Compliance and Ethics Program is dynamic, involving not only company policies and procedures, but also the commitment of our patients, physicians, employees, contractors, and Board of Directors to make the program effective. It involves regular assessment and adjustment to ensure that the program is responsive to the company's evolving business needs.

The Compliance Officer collaborates with department managers early in the development and implementation of business strategies to ensure that specific plans meet the Compliance and Ethics Program objectives. Department managers are accountable for managing the compliance program requirements within their department.

### **Purpose**

The Corporate Compliance and Ethics Program is the framework by which Prometheus establishes a consistent and collective process to manage the legal, regulatory, compliance and ethical challenges of our ever-changing and highly regulated industry. By design, Prometheus has adopted a comprehensive Compliance and Ethics program to reinforce our commitment to integrity in all aspects of our business. The Corporate Compliance and Ethics Program is also consistent with the recommendations set forth in both the "Compliance Program Guidance for Pharmaceutical Manufacturers," and "Compliance Program Guidance for Clinical Laboratories," published by the Office of Inspector General, U.S. Department of Health and Human Services (the HHS-OIG Guidance), the US Federal Sentencing Guidelines, and the provisions of the Code on Interactions with Healthcare Professionals created by the Pharmaceutical Research and Manufacturers of America (PhRMA Code).

## **Strategic Objectives**

- To promote an organizational culture that encourages ethical conduct, a commitment to integrity, and compliance with applicable laws and regulations.
- To exercise due diligence to prevent, detect and correct potential violations of the Compliance and Ethics Program, applicable federal and state law, and company policy.
- To provide a comprehensive approach to identifying, managing and mitigating organizational risk.

## **SECTION 3. COMPLIANCE PROGRAM FRAMEWORK**

### **Governance and Leadership**

To provide high-level oversight, ultimate accountability and oversight of the Compliance and Ethics Program is vested in the Board of Directors. The Board delegates to the Compliance Officer the responsibility and authority for establishing and maintaining the Compliance and Ethics Program. The Compliance Officer is given unrestricted access to information, executives and meetings related to business operations. The Compliance Officer reports directly to the Vice President, Legal Affairs, with a dotted line to the Board. The Compliance Officer provides periodic status reports to the Prometheus Executive Team and the Board to keep the members informed of compliance activities. The Compliance Officer provides strategic guidance and oversight for the processes leading to a culture of compliance and ethics.

The Compliance Officer will chair a Corporate Compliance and Ethics Committee. The Committee is responsible for supporting the Compliance Officer in managing the day-to-day operation of the Program. The participants will include key leaders who are responsible for collaborating with the Compliance Officer to develop specific plans for identifying, managing and mitigating risk at Prometheus.

### **People**

The Compliance and Ethics Program is an expression of our commitment to conducting business with the highest standards of integrity. The success of this commitment depends on each of us, and the responsibility we have to make sure that appropriate business decisions are made with integrity. Each individual brings to the workplace a unique set of experience and values, which influence how we make decisions. Our actions and behaviors are a reflection of our culture and our company values, and we have a responsibility to align our actions and behaviors with our company values.

Prometheus seeks to employ individuals with a strong sense of integrity and commitment to ethical behavior. Prior to commencing employment, Prometheus conducts background investigations, criminal background checks, and if appropriate to

the position, verifies licensure, motor vehicle records, and credit history. In addition, the overall hiring process includes a screening of all candidates to determine if they are excluded from participating in federally-funded health care programs, or have been convicted of a criminal offense related to the provision of health care items or services. Prometheus does not hire individuals excluded from participation in federally-funded health care programs. Additionally, Prometheus annually screens all current employees, contracted physicians and contractors to verify that they have not been excluded from participation in federally-funded health care programs.

Prometheus will not knowingly do business with persons or organizations that have been excluded, debarred, suspended, or are otherwise ineligible to participate in Federal healthcare programs.

If Prometheus has notice that an employee or contractor has become an ineligible person or is a party to a civil or criminal case related to any federal health care program, that individual will be removed from responsibility for, or involvement with Prometheus' business operations related to the federal health care programs and any position for which the individual's salary or the items or services rendered or ordered by the individual are paid for in whole or in part, directly or indirectly, by federal health care programs at least until such time as the individual is reinstated or until the resolution of such civil or criminal action.

## **Written Standards**

The *Prometheus Code of Ethical Business Conduct* (our Code) is a commitment we make to ourselves, to those with whom we conduct business, and to the patients we serve. The *Prometheus Code of Ethical Business Conduct* is our statement of essential ethical and compliance principles that guide our daily operations. Our Code applies to anyone conducting business on behalf of Prometheus (i.e. consultants, contracted physicians, temporary or contracted employees, vendors, etc.)

Our Code reinforces our fundamental principles, values and framework for action within our organization, and is a reflection of our commitment to conducting business with integrity. In addition to our *Code of Ethical Business Conduct*, Prometheus has formally adopted the PhRMA Code on Interactions with Healthcare Professionals (the "PhRMA Code").

All employees, as a condition of their employment, are expected to comply with our Code. Each year, all employees will certify that they have read, understood, and agree to abide by the principles outlined in our Code. The Code shall be reviewed annually and as necessary, updated, with any revisions and distributed to all employees.

Compliance with our Code and the principles of the Compliance Program is used to evaluate the performance of all Prometheus employees and contractors.

The Code of Ethical Business Conduct is available to all employees on the company's intranet, on Prometheus' website, or by requesting a copy from Human Resources.

In addition, Prometheus has adopted written policies and procedures. Specifically, Prometheus has adopted policies in compliance with California Health and Safety Code §119402 regarding the adoption of a comprehensive compliance program, state laws regarding specific disclosures, establishing specific annual dollar limits on gifts, promotional materials, or items or activities that Prometheus may provide to an individual medical or health care professional.

## **Education and Training**

A critical element of our Compliance and Ethics Program is the education and training of our employees on their legal and ethical obligations under company policy, and applicable federal health care program requirements. Education is an important part of every employee's career development and individual growth.

Prometheus is committed to taking all necessary and appropriate steps to develop comprehensive education, effectively communicating to all affected employees our Code of Ethical Business Conduct, company policies, as well as the relevant areas of risk associated with our business. This includes education regarding compliance with federal and state laws/regulations or guidance publications that relate to pharmaceutical sales and marketing and diagnostic lab services, and receiving reimbursement for lab services. Minimum education and training requirements are established consistent with employees' roles and responsibilities, and all mandatory education and training will be documented. Prometheus will regularly review and update its educational content, as well as identify and provide additional areas of education as needed.

## **Communication and Reporting**

Each employee shares in the responsibility to hold themselves, as well as those they work with, accountable for aligning their conduct with our corporate values and our Code of Ethical Business Conduct. The strength of our integrity will grow when individuals speak up to ask questions or raise concerns when they should.

In addition, Prometheus is committed to providing a work environment that encourages employees to communicate openly with management, or the Compliance Officer about all types of workplace issues.

Whenever an employee witnesses another violating our Code of Ethical Business Conduct, company policy, or the law, it is their responsibility to report it immediately. Reporting suspected violations is not an act of disloyalty. Rather, it shows responsibility and fairness to fellow employees, patients, and physicians, and protects Prometheus' reputation for integrity. Knowingly failing to report a suspected violation may be grounds for disciplinary action.

There are several ways to report suspected misconduct, or to inquire about the appropriateness of a course of action. The following options are available to report concerns:

- Manager or supervisor
- Human Resources
- Prometheus' Compliance Officer or the Legal Department
- Prometheus' 24 hour Ethics HelpLine (888) 776-7939 (PRO-RXDX)

Prometheus encourages employees to discuss workplace issues with an immediate supervisor or manager. If the matter is not successfully resolved, employees may pursue the issue with his/her next level of management, the Compliance Officer, or a member of the Legal or Human Resources departments. At any time, if an employee prefers to remain anonymous, reports can be made to the Prometheus Ethics HelpLine.

In those situations where employees do not feel free to discuss or report suspected misconduct to their supervisor, manager, or Compliance Officer, Prometheus has established an anonymous reporting hotline, the Ethics HelpLine. The Ethics HelpLine 1-888-776-7939 is an external, toll-free, anonymous and confidential reporting line available 24 hours a day, 7 days a week to facilitate the reporting of suspected violations of our Code, company policy, or the law. All callers to the Ethics HelpLine will have the option of remaining anonymous if they so choose. All information provided will be recorded, and a written report will be forwarded to the Compliance Officer and/or his/her designee for follow up. The Compliance Officer will direct an investigation of all suspected violations, and take appropriate action to ensure that all compliance and ethics issues are promptly addressed and resolved.

Regardless of how an issue is reported, Prometheus has a strict policy against retaliation so that employees can feel free to ask questions or raise concerns. Anyone who reports, in good faith, an issue of misconduct will not be subject to retaliation or retribution. However, the reporting of misconduct will not absolve the individual reporting who was involved in the activities reported, although it may be considered in the level of disciplinary action, taken if appropriate. Any employee engaging in retaliatory activity is subject to disciplinary action, up to and including termination of employment.

Managers must set the tone by maintaining a work environment that encourages ethical and responsible behavior, open reporting of inappropriate conduct, and compliance with the Code of Ethical Business Conduct and principles set forth in this Compliance Program. Managers are expected to enforce a strict policy of non-retaliation. Anyone who retaliates against another, whether a peer or direct report, will be subject to discipline up to and including termination of employment.

## **Auditing and Monitoring**

Prometheus' Compliance and Ethics Program includes efforts to monitor, audit and evaluate compliance with the law, company policies and procedures, and the Code of Ethical Business Conduct. The nature of reviews as well as the extent and frequency of compliance monitoring and auditing varies according to a variety of factors, including new regulatory requirements, changes in business practices and other considerations.

The Compliance Officer will determine the personnel necessary for the audit team, based upon the expertise required. The Compliance Officer will collaborate with leadership to develop monitoring and auditing plans. Ongoing assessment efforts will help to identify new and emerging risk areas so that they can be addressed via audit plans. Results shall be reported to the Compliance and Ethics Committee, the Executive Team, and if appropriate, the Board. Results are followed up on specifically, and if necessary, incorporated in future education and training.

Another part of the compliance auditing program will include periodic reviews of whether the Compliance Program elements have been satisfied, i.e., whether there has been appropriate dissemination of the Code of Ethical Business Conduct, and whether necessary education and training sessions have been given and appropriately attended. This process will verify actual compliance by all departments with the Compliance Program and may identify necessary improvements in both the Compliance Program and operational processes to promote compliance.

## **Enforcement**

Employees are expected to comply with the Code of Ethical Business Conduct, company policies and procedures, and applicable law as a condition of continued employment. Our goal is that we continue to build on an already strong compliance program and will increase the likelihood of compliance and prevent misconduct or unethical behavior. However, even an effective compliance program will not prevent such misconduct or behavior. As such, our Compliance and Ethics Program requires a prompt response by investigating potential violations of the Code of Ethical Business Conduct, company policies and procedures, and applicable law, taking appropriate disciplinary or other corrective action when necessary, and taking action to prevent future violations.