



**Guide to  
United States  
Healthcare  
Compliance**

**2018/2019**

Promius Pharma, LLC

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NOTICE: this information is provided pursuant to the requirements of California Health & Safety Code §§ 119400, 119402, which requires certain pharmaceutical and medical device companies doing business in California to make available their program for compliance with applicable federal and state laws and industry standards regulating the marketing and promotion of their products.

## **Introduction:**

Promius Pharma, LLC, (the “Company” or “Promius”) is committed to complying with the relevant laws, regulations, and recognized industry standards that govern these activities. In furtherance of that commitment, the Company has established a healthcare compliance program that, among other things, guides our company’s interactions with healthcare professionals.

While we have designed our compliance program to address the specific areas of risk we face as a company, we also recognize that no compliance program can reasonably be expected to address every situation that an employee may encounter. In these situations we expect that employees will discuss the appropriate course of action with their manager or seek guidance from the HR Department, Compliance Department, Legal Department, or any member of the North America Leadership Team. Employees should always make decisions and/or follow a course of action that is consistent with the Company’s Code of Business Conduct and Ethics (“CoBE”) and the Company’s Core Values.

While this guide uses the term “employees,” it broadly applies to all employees, including part-time and contract employees, as well as agents who act on behalf of the Company.

The Company’s compliance program is designed to prevent and detect misconduct based upon the specific risks faced by the Company and in accordance with numerous laws, regulations, industry standards, and government guidance documents, including those discussed on the pages that follow.

**The Office of Inspector General (“OIG”) Compliance Program  
Guidance for Pharmaceutical Manufacturers (The “OIG  
Guidance”):**

The OIG Guidance provides guidance to companies that develop, manufacture, market and sell pharmaceutical drugs and biological products in developing and implementing internal controls and procedures that promote adherence to applicable statutes, regulations, and requirements of the US federal healthcare programs. The OIG Guidance provides the OIG’s views on the fundamental elements of pharmaceutical manufacturer compliance programs and principles that each pharmaceutical manufacturer should consider when creating and implementing an effective compliance program.

According to the OIG Guidance, the elements of an effective compliance program include:

- Designation of a Compliance Officer (CO) and compliance committee
- Implementation of written policies and procedures
- Education and training of affected employees
- Development of lines of communication between the CO and all employees through hotlines or other means
- Internal monitoring and auditing
- Enforcement of standards through disciplinary guidelines
- Prompt responses to detected problems and implementation of corrective action

**Pharmaceutical Research and Manufacturers of America  
“Code on Interactions with Healthcare Professionals”  
 (“PhRMA Code”):**

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The PhRMA Code addresses interactions between industry representatives and healthcare professionals and provides guidance on how to ensure that these interactions are conducted in an ethical manner. The purpose of the PhRMA Code is to reinforce the intention that interactions with healthcare professionals are to benefit patients and to enhance the practice of medicine. The Company's pharmaceutical business is committed to abiding by the PhRMA Code.

The PhRMA Code can be found at: <http://www.phrma.org>

**Promius Pharma, LLC**  
**Comprehensive Compliance Program:**

Consistent with the OIG Guidance and with California Health and Safety Code §§ 119400, 119402, the Company has adopted a comprehensive compliance program. The following sections outline the key elements of the Company's compliance program.

**North America Compliance**  
**Leadership and Structure:**

**COMPLIANCE OFFICER AND COMMITTEE**

The Head of North America Compliance is ultimately accountable for developing, managing, and ensuring implementation of the North America Compliance Program. The North American business heads, in their roles as heads of these businesses and as members of the North American Compliance Committee, are accountable for implementing processes designed to ensure adherence to the North

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American Compliance Program developed by the Head of North America Compliance.

The Head of North America Compliance chairs the Company's North America Compliance Committee. The Compliance Committee provides oversight and strategic direction to the Company's compliance program and accountability for their functional areas' adherence to the North America Compliance Program. The Committee also reviews internal audit results, as well as corrective actions recommended by the Chair.

The Committee meets at least quarterly, or more frequently as deemed necessary by the Chair. More details regarding the roles and responsibilities of Committee Members can be found in the North America Compliance Committee Charter.

**Written Standards of Conduct  
&  
Policies and Procedures:**

The Company places a high priority on compliance with applicable laws and regulations. Central to our growth and success is our record of conducting our business with integrity and transparency. The Company has adopted a Code of Business Conduct and Ethics ("CoBE") that sets out the legal and ethical principles that guide the actions of all employees acting on behalf of the Company.

The CoBE can be accessed through the following URL: <http://www.drreddys.com/investors/governance/code-of-business-conduct-and-ethics-cobe/>. A copy of the CoBE as well as the Company's written declaration of compliance with California Health & Safety Code §§ 119400, 119402 may also be obtained by calling (866) 733-3966.

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Corporate Policies:**

Numerous corporate policies and procedures govern the Company's activities in North America, and the legal and ethical standards found in the COBE provide an overarching framework under which these policies and procedures must operate.

**Training Programs:**

The Company has established an annual compliance certification program for all employees, which includes assessment and certification of compliance with the Company's CoBE. In addition, the Company also conducts periodic compliance training for employees involved in certain activities, such as pharmaceutical sales and marketing.

The Company training program provides information on compliant pharmaceutical sales and marketing practices. Employees are also informed of applicable disciplinary actions for failing to comply with the Company's compliance program, including warnings, probation periods, and grounds for termination.

**Auditing and Monitoring:**

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Promius conducts ongoing monitoring of its compliance with its policies and procedures. Ongoing reviews evaluate whether: (i) the Company has policies that address identified risk areas; (ii) these policies were implemented and communicated; and (iii) these policies were followed. The Head of North America Compliance documents all monitoring efforts, including reports of suspected noncompliance and, in coordination with the Compliance Committee, initiates internal audits when patterns of noncompliance signal significant risk areas for the Company.

### **Lines of Communication and Employee Reporting:**

Promius is committed to the highest moral, legal and ethical standards in conducting its business. Each employee is obligated to report any conduct that is unprofessional, inappropriate, or inconsistent with the Company's commitment to ethical standards, including suspected violations of the CoBE, Company policies and procedures, or any law or regulation.

An employee should report any violation or potential violation to his or her direct supervisor. If an employee is not comfortable approaching the supervisor, the employee may contact Human Resources, the Head of North America Compliance, the Legal Affairs Department, or any member of senior management.

In addition, employees may directly contact the Global Chief Compliance Officer at U.S. toll-free (877-328-0707), or write to [complianceofficer@drreddys.com](mailto:complianceofficer@drreddys.com).

Promius will make all reasonable efforts to keep the identity of the complainant confidential. The Company will not retaliate, and will not allow any retaliation or discrimination by its employees, against any employee who submitted a complaint in good faith.

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Details regarding the reporting of violations and the Company Ombudsman Procedure can be found in the COBE posted at [www.drreddys.com](http://www.drreddys.com).

### **Enforcement and Disciplinary Guidelines:**

The Company will take disciplinary actions in response to violation of the Company's compliance policies or procedures. The Company will conduct a fair and diligent investigation of matters that are brought to the Company's attention to ensure the consistent application of the Company's standards.

### **Responses to Detected Problems and Corrective Action:**

Promius requires a prompt and diligent response to potential violations of the company's compliance program, including its standards regulating the marketing and promotion of our products. Actions in response to detected problems may include disciplinary action to prevent future violations, changes in policies and procedures, additional training, or increased auditing and monitoring.

### **Overview of Policies Related to Interactions with Healthcare Professionals:**

**Annual Dollar Limit for Meals and Educational Items (California Healthcare Professionals).**

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The Company has established an annual limit of \$2,000 for meals and educational items, which it has implemented consistent with applicable provisions of the PhRMA Code. This limit represents the aggregate annual value of the expenses incurred for items or meals provided to a California healthcare professional pursuant to the requirements of California Health & Safety Code §§ 119400, 119402.

Consistent with the California Health & Safety Code §§ 119400, 119402, the following items are not counted toward the annual limit:

- Drug samples given to physicians and healthcare professionals intended for free distribution to patients;
- Financial support for continuing medical education programs;
- Finance support for health educational scholarships;
- Fair market value payments to healthcare professionals for legitimate professional services, such as consulting; and,
- Meals provided to consultants while working on behalf of the Company.

### **Policy Prohibiting Entertainment and Recreation**

Entertainment and recreational items (e.g., tickets to sporting events, golf outings, concerts, hunting, etc.) may not be offered to healthcare professionals, other than salaried employees of the Company.

**Declaration of Compliance with  
California Health & Safety Code §§ 119402, 119402**

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As described above, Promius has developed a compliance program that is designed to comply with applicable federal and state laws and industry standards relating to the marketing and promotion of our products. Promius Pharma, LLC hereby declares that, to the best of its knowledge, and based on its good faith understanding of all applicable statutory requirements, that Promius is not aware of any violations between June 1, 2017 and May 31, 2018 of the Company's Compliance Program or of California Health and Safety Code §§ 119400, 119402 relating to California medical or health professionals that have not been addressed and for which corrective action has not been taken.

Dated: May 25, 2018