

# **NOVEN COMPREHENSIVE COMPLIANCE PROGRAM**

## **I. INTRODUCTION**

Noven Pharmaceuticals, Inc., including its subsidiary Noven Therapeutics, LLC, (Noven) offers pharmaceutical products that enable physicians to better serve patients. As part of our commitment to deliver value to patients using our products and to conduct business honestly, lawfully, and ethically, Noven established and maintains a Comprehensive Compliance Program in accordance with federal, state, and industry regulations and guidelines, including the “Compliance Program Guidance for Pharmaceutical Manufacturers,” published by the Office of Inspector General (OIG), U.S. Department of Health and Human Services. Noven has dedicated significant time and resources to implement a commercial compliance program that represents our commitment to the highest standards of corporate conduct.

Key elements of our Comprehensive Compliance Program include, but are not limited to:

- Extensive policies and procedures that address specific areas of government concern;
- Dedicated compliance oversight functions;
- Multi-faceted training and education programs;
- Multiple compliance communication mechanisms, including an anonymous reporting system dedicated to Noven business;
- Targeted compliance monitoring and auditing;
- Published disciplinary guidelines; and
- A protocol for responding promptly to detected problems and implementing corrective action.

## **II. OVERVIEW OF NOVEN’S COMPREHENSIVE COMPLIANCE PROGRAM**

### **1. Leadership and Structure.**

**Compliance Officer.** Noven’s Compliance Officer is charged with the responsibility for developing, operating, and monitoring the compliance program. Our Compliance Officer has the ability to effectuate change within the organization and to exercise independent judgment.

**Compliance Committee.** Noven has established a Commercial Compliance Committee, which is a cross-functional group of individuals whose primary purpose is to assist the Compliance Officer in fulfilling his duty relating to Noven’s corporate compliance activities. The Commercial Compliance Committee includes representatives from the following departments: Legal, Regulatory, Sales and Marketing, and Compliance.

## **2. Written Standards.**

Noven has developed written compliance policies, procedures, and practices that guide Noven and the conduct of our staff in day-to-day commercial operations. These policies and procedures have been developed under the direction and supervision of our Compliance Officer, Compliance Committee, General Counsel, and management from various functional areas.

**Code of Conduct.** Noven has a Code of Conduct that is also posted on this corporate website. Every Noven director, officer, and employee is required to adhere to this Code of Conduct.

**Policies and Procedures.** Noven has established policies and procedures to address a variety of potential risk areas, including the potential risk of liability under several fraud and abuse statutes and regulations. These policies and procedures are part of a comprehensive framework of compliance controls that exist throughout various segments of our organization. In particular, Noven has developed and implemented significant policies and procedures to reduce and eliminate the potential risks identified by the OIG's Compliance Program Guidance for Pharmaceutical Manufacturers and addressed in the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals, including (1) data integrity pertaining to government reimbursement practices, (2) kickbacks and other illegal remuneration, and (3) compliance with laws regulating drug samples.

## **3. Education and Training.**

Noven educates and trains Noven staff on the facets of our Comprehensive Compliance Program both online through our interactive "Noven University" and in live classroom settings. Our education and training covers a variety of laws and regulations that affect the way we conduct business. Our live and computer-based programs include meaningful discussion of the application and consequences of the False Claims Act, Anti-kickback Statute, OIG Compliance Program Guidance, PhRMA Code on Interactions with Healthcare Professionals, as well as other applicable federal, state, and industry rules and guidelines. Noven periodically reviews and updates our training programs, and identifies additional areas of training on an "as needed" basis.

## **4. Internal Lines of Communication.**

Noven is committed to fostering dialogue between our management and staff. Our goal is that all employees, whether seeking answers to questions or reporting potential instances of fraud and abuse, will know who to turn to for a meaningful response and should be able to do so without fear of retribution. To that end, we have adopted open-door, confidentiality, and non-retaliation policies.

As part of our commitment to ethical and legal behavior, Noven requires our employees to report any actual or suspected violations of law or ethical standards so that they can be appropriately investigated and addressed. Noven employees can raise legal or ethical

concerns in a number of ways including with an appropriate member of management, through our Human Resources, Legal, or Compliance Departments, or by calling the toll-free, 24-hour, anonymous hotline maintained specifically for Noven employees, contractors, and business partners.

#### **5. Auditing and Monitoring.**

Noven's comprehensive compliance program includes activities to monitor, audit, and evaluate compliance with Noven's policies and procedures. Noven's approach includes targeted monitoring and auditing based on identified and prioritized risk areas. In accordance with the OIG Compliance Program Guidance, the nature of Noven's reviews as well as the extent and frequency of our compliance monitoring and auditing vary according to a number of factors, including new regulatory requirements, changes in business practices, and other considerations.

#### **6. Enforcing Standards Through Discipline.**

Any violation of a manager's or employee's obligations under the Comprehensive Compliance Program can subject the manager or employee to serious disciplinary measures, including possible termination of employment. A manager's or employee's obligations include strict observance of all laws and regulations applicable to Noven business (e.g., laws and regulations governing the Federal healthcare programs). Although each situation is considered on a case-by-case basis, Noven attempts to ensure consistent and appropriate disciplinary action is taken in response to violations.

#### **7. Responding to Detected Problems.**

As part of our Comprehensive Compliance Program, Noven has established a comprehensive internal investigation and corrective action protocol to ensure that timely, complete, and objective investigations are conducted in response to allegations. In accordance with the OIG's Compliance Program Guidance, the exact nature and level of thoroughness of the internal investigation will vary according to the circumstances. Upon conclusion of an internal investigation, corrective action and preventative measures are determined and implemented as appropriate.

### **III. CLOSING**

Noven is dedicated to the maintenance and ongoing assessment required of an effective Comprehensive Compliance Program.

## **California Health and Safety Code §119402**

Noven's relationships with healthcare professionals (HCPs) are intended to benefit patients and enhance the practice of medicine. Informational presentations and discussions by Noven representatives and others speaking on behalf of Noven are intended to provide valuable scientific and educational benefits. In conjunction with such presentations and discussions, Noven employees may offer occasional meals and healthcare practice-related items in accordance with the PhRMA Code on Interactions with Healthcare Professionals.

The California Health and Safety Code requires pharmaceutical companies to maintain a Comprehensive Compliance Program (CCP) relating to their interactions with health care professionals as provided above, and to:

- Establish "a specific annual dollar limit on gifts, promotional materials, or items or activities that the pharmaceutical company may give or otherwise provide to a health care professional";
- Make an annual written declaration that it is in compliance with its CCP and the law;
- Make its compliance program and its annual declaration of compliance available to the public on its website as is done here; and
- Provide a toll-free number to obtain a copy of the CCP and the annual written declaration. That number is 888-253-5099.

For medical or healthcare professionals in California, Noven has declared a specific annual dollar limit of \$1,500 on promotional materials, healthcare practice items, and activities in accordance with the PhRMA Code. Noven expects that few, if any, California HCPs will approach this limit. Consistent with pharmaceutical marketing laws in other states, certain items (e.g. plastic pens, small notepads) or activities (e.g. in-office food or beverage provided on an occasional basis) of limited value (less than \$25) are not included in determining the annual dollar limit. This spending limit is set by Noven and revisited at least annually.

## **California Declaration of Compliance – June 2010**

Noven Pharmaceuticals has established a Comprehensive Compliance Program in accordance with relevant laws and with consideration to our size, organization, and operations. A compliance program cannot guarantee that no violations will take place. The goal is to deter violations and to identify them as promptly as possible and then facilitate corrective actions. Since compliance is a dynamic process, Noven evaluates and assesses our Comprehensive Compliance Program on an ongoing basis to adjust to new circumstances and to maintain and improve the strength of the Program.

To the best of our knowledge, as of June 30, 2010, Noven is in material compliance with our Comprehensive Compliance Program and the requirements of the California Health & Safety Code.