

# **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. As of May 2016, however, Noven ceased its active field sales activities. To the extent applicable to Noven’s remaining Sales and Marketing operations, the following Comprehensive Compliance Program will apply.

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 Comprehensive 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 Compliance Committee, which is a cross-functional group of individuals whose primary purpose is to assist the Compliance Officer in fulfilling their duty relating to Noven’s corporate compliance activities. The Compliance Committee includes representatives from the following departments: Legal, Regulatory, Product Development, and Human Resources.

### **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 non-manufacturing 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 Business Conduct and Ethics 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 through both our online, interactive "Noven iLearn" program 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 or Legal Department, 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 actions, up to and including potential 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 such 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.