

# California Compliance Policy and Declaration

NOTICE: this information is provided pursuant to the requirements of California Health & Safety Code § 119402 (S.B. 1765), 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

Rare Disease Therapeutics, Inc. (RDT) has established a compliance program designed to materially comply with applicable federal and state laws and industry standards relating to the marketing and promotion of its products. Additionally, RDT recognizes that adherence to these standards can be furthered through a compliance program that is informed by the Compliance Program Guidance for Pharmaceutical Manufacturers, published by the Office of Inspector General of the U.S. Department of Health and Human Services (the “OIG Guide”) and the Pharmaceutical Research and Manufacturers of America (PhRMA).

## OVERVIEW OF COMPLIANCE PROGRAM

### **1. Written Policies and Procedures**

RDT has written policies to assure substantial compliance with the applicable laws and regulations and standards governing the marketing and promotion of our products. Among these standards are recognized industry codes of conduct including the PhRMA Code on Interactions with Healthcare Professionals (PhRMA Code) published by the Pharmaceutical Research and Manufacturers of America (PhRMA). RDT has established written policies that govern activities involving communicating with customers about the appropriate use of our products; advancing scientific and educational activities; and supporting medical research and education. These policies include:

#### **Policy on Product Promotion and Interactions with Healthcare Providers and Other Customers**

RDT abides by the PhRMA code as it relates to gifts, meals and entertainment and product promotion.

On occasion, RDT representatives may provide items designed primarily for the education of patients or healthcare professionals (for example an anatomical model or medical text) if the items are not of substantial value (\$100 or less) and do not have value to healthcare professionals outside of his or her professional responsibilities and are infrequent.

### **Compliance Officer and Committee Policy**

RDT has designated a Compliance officer and a Compliance Committee. The Compliance Committee is comprised of the company's Compliance Officer and members of RDT's management team. The Compliance Committee is the Compliance leadership team.

### **Policy on Effective Education and Training**

RDT trains employees in Compliance. The training covers applicable guidelines governing our compliance program. Employees are also trained on the consequences of failure to comply with the requirements of the company's compliance program.

### **Policy on Code of Conduct**

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

RDT 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 improving policies, procedures, training, communication and monitoring or may require disciplinary action to prevent future violations.

### **Policy on Open Door Policy**

RDT encourages open and candid discussion between management and employees regarding any compliance concerns. RDT employees are encouraged to report their concerns to their manager, to the company's Compliance Officer or the company's contracted hotline.

## **2. DECLARATION FOR CALIFORNIA COMPLIANCE LAW**

As part of RDT's ongoing efforts in the area of compliance, we comply with applicable federal and state laws and industry standards relating to the marketing and promotion of our products. To our knowledge as of the date of this declaration, RDT is in compliance with our Compliance Program, as described here, and with California Health & Safety Code sections 119400-119402.

To report potential fraud or misconduct, please contact the compliance hotline:

Phone: 888-850-4754

Web: <https://report.syntrio.com/raretx>