

# **COMPREHENSIVE COMPLIANCE PROGRAM & DECLARATION OF COMPLIANCE**

## **INTRODUCTION**

Stemline Therapeutics, Inc. ("Stemline") is committed to establishing and maintaining a comprehensive and effective healthcare compliance program that promotes ethical conduct in accordance with California Health and Safety Code §§ 119400-119402, Connecticut Compliance Program Law Conn. Stat. Chapt. 417 § 21a-70e, Nevada Revised Statute 639.570, Massachusetts General Laws ch. 111N, § 4, the Office of Inspector General, U.S. Department of Health and Human Services, "Compliance Program Guidance for Pharmaceutical Manufacturers" (OIG Guidance), and Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals (the "PhRMA Code").

The purpose of Stemline's Healthcare Compliance Program is to prevent and detect violations of law or Stemline policy. But, as acknowledged by the OIG Guidance, implementing a Healthcare Compliance Program may not eliminate improper employee conduct in its entirety. Nevertheless, Stemline expects all employees, executive officers and directors to comply with applicable laws and regulations, Stemline's Code of Conduct, and the policies and procedures established in support of the Code of Conduct. If Stemline becomes aware of violations of law or Stemline policy, we will investigate the matter and, if appropriate, take disciplinary action and implement corrective measures to prevent future violations.

## **HEALTHCARE COMPLIANCE PROGRAM OVERVIEW**

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

- **Compliance Officer.** Stemline has appointed a Compliance Officer, who is charged with establishing, operating and monitoring the Healthcare Compliance Program. The Compliance Officer has direct access to the Stemline Board of Directors and senior management. The Compliance Officer provides periodic reports on the status of the Healthcare Compliance Program to the Stemline Compliance Committee and the Stemline Board of Directors.
- **Compliance Committee.** Stemline has appointed a Compliance Committee to advise and assist in the implementation of the Healthcare Compliance Program. The Compliance Committee is comprised of senior management from functional units across the company. It meets on a regular basis to assess the compliance program and identify areas for enhancement.

### **2. Written Standards**

Stemline has established written policies and procedures to ensure compliance with the OIG Guidance and PhRMA Code, including the Code of Business Conduct, Policy on Interactions with Healthcare Professionals and other complimentary policies and procedures that outline our commitment to compliance and corporate accountability. The standards set forth in these

policies apply to all Stemline employees, and adherence to company policies is a condition of employment.

### 3. Education and Training

All employees are required to receive compliance training applicable to their job function and responsibilities, which includes both initial and refresher training on the Healthcare Compliance Program and Stemline policies. In addition, further specialized training may be provided where a need for additional training has been identified. Annual healthcare compliance training is required of all employees, who engage in, or support, commercial activities.

### 4. Internal Lines of Communication

Stemline is committed to open dialogue between management and employees. Our goal is to foster a “speak up” culture where employees may ask questions or report potential instances of inappropriate activity without fear of retribution. We have established a toll-free Compliance Hotline, +1-844-635-4641, to report known or suspected violations of Stemline policies. Anonymous reports can be left on the hotline.

### 5. Auditing and Monitoring

Stemline recognizes that an auditing and monitoring plan is critical to maintaining the effectiveness of a Healthcare Compliance Program. The subject of our auditing and monitoring assessments, as well as the extent and frequency of our reviews, may vary according to a variety of factors, including new regulatory requirements, changes in business practices and other considerations. As appropriate, auditing and monitoring results will be reported to the Legal department, the Compliance Committee and senior management in order to help guide the Stemline risk-assessment process.

### 6. Responding to Potential Violations

The purpose of our Healthcare Compliance Program is to prevent and detect violations of law or company policy. As the OIG Guidance recognizes, however, the implementation of such a program cannot guarantee that improper employee conduct will be entirely eliminated. Nonetheless, it is Stemline’s expectation that employees will comply with the Stemline Healthcare Compliance Program, and the policies established in support of such program. In the event that Stemline becomes aware of violations of law or company policy, the Legal department will promptly manage the investigation of the matter and, where appropriate, take disciplinary action and implement corrective measures to address potential policy gaps and prevent future violations. When appropriate, a compliance report may be provided to the relevant authorities.

Employees who violate company policies and procedures and/or applicable state and federal laws may be subject to disciplinary action, up to and including termination, as determined on a case-by-case basis.

## 7. Corrective Action Procedures

A key element of the Stemline Healthcare Compliance Program is to provide clear disciplinary policies that set out the consequences of violating the law or company policy. After investigation of a reported or detected issue, the company will assess whether disciplinary action is appropriate, and whether a violation is in part due to gaps in our policies, practices, training or internal controls, and take action to prevent future violations.

### **STATEMENT OF ANNUAL AGGREGATE LIMIT**

California Health and Safety Code §§ 119400, 119402 requires pharmaceutical companies to adopt a Comprehensive Compliance Program that imposes an annual aggregate dollar limit on gifts and expenditures provided to medical and healthcare professionals ("HCPs"). In accordance with the requirements of California's law, Stemline has determined an annual aggregate limit on gifts, promotional materials, and items or activities that may be provided to HCPs within California. In setting the aggregate annual limit, Stemline has taken into account the development stage of the company and the size and scope of its product portfolio. As the size of the company and product portfolio changes, Stemline may revise its annual aggregate limit.

It is important to note that Stemline's annual aggregate limit represents a maximum limit and is not a spending goal. In tracking expenditures, Stemline excludes from its annual aggregate limit the following items that are exempt under California law: (1) drug samples given to HCPs for the free distribution to patients; (2) financial support for continuing medical education forums; (3) financial support for health educational scholarships; and (4) payments made at fair market value for legitimate professional services provided by HCPs.

For purposes of making its declarations under California law, Stemline applies its annual aggregate limit to expenses incurred during the calendar year (January 1st through December 31st of each year).

### **DECLARATION OF COMPLIANCE**

Stemline declares, in good faith, that as of July 1, 2023, it is in substantial compliance with its Comprehensive Healthcare Compliance Program, which incorporates the principles articulated in the OIG Guidance and the PhRMA Code, and the requirements of California Health and Safety Code §§ 119400-119402. Our declaration is based upon an analysis of information available as of the date of this declaration. While we cannot completely eliminate the possibility that an individual employee will violate these standards, our Healthcare Compliance Program is designed to prevent, detect, and address violations of state and federal laws as well as our own

internal policies and procedures. As appropriate and in accordance with the law, Stemline will amend and update its policies and procedures and this Declaration as necessary to assure compliance. This Declaration is effective as of July 1, 2023.

#### **CONTACT INFORMATION**

For a copy of this Comprehensive Healthcare Compliance Program Policy, please call the Stemline toll-free Compliance Hotline at +1-844-635-4641.