

# **Flexion Therapeutics, Inc.**

## **Comprehensive Compliance Program Description**

### **I. Introduction**

Flexion Therapeutics, Inc. (“Flexion”) is committed to establishing and maintaining an effective compliance program that we believe to be in accordance with the “Compliance Program Guidance for Pharmaceutical Manufacturers,” published by the Office of Inspector General, U.S. Department of Health and Human Services (the “HHS-OIG Guidance”).

The purpose of Flexion’s Compliance Program is to prevent and detect violations of law, regulation or Company policy, and to promote an ethical culture within the organization. It is Flexion’s expectation that employees will comply with its Compliance Program and the policies established in support of such Program. As the HHS-OIG Guidance recognizes, however, the implementation of such a program cannot guarantee that improper employee conduct will be entirely eliminated. In the event that it becomes aware of violations of law or Company policy, Flexion will investigate the matter and, where appropriate, take disciplinary action and implement corrective measures to prevent future violations.

Flexion has described below the fundamental elements of its Compliance Program. As called for in the HHS-OIG, Flexion has tailored its Compliance Program to fit the unique environment of the Company. Moreover, the Compliance Program is dynamic; Flexion regularly reviews and enhances the Compliance Program to meet evolving compliance needs as well as changes in state and federal laws and regulations.

### **II. Overview of Compliance Program**

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

**Chief Compliance Officer.** Flexion has appointed a Chief Compliance Officer to oversee compliance activities. The Chief Compliance Officer is the Vice President of Legal and is charged with the responsibility for developing, operating, and monitoring the Compliance Program. Flexion is committed to ensuring that the Chief Compliance Officer has the ability to effectuate change within the organization as necessary and to exercise independent judgment. The Chief Compliance Officer reports to the General Counsel and has a direct line of communication and provides routine updates to the Chief Executive Officer and the Audit Committee of the Board of Directors on all compliance matters.

**Audit Committee & Board of Directors.** On a quarterly basis the Chief Compliance Officer meets with the representatives of the Audit Committee (in conjunction with regularly scheduled Audit Committee meetings) to identify and manage areas of risk and areas of critical focus for the Company. Annual compliance updates are provided to the entire Flexion Board of Directors.

#### **2. Written Standards.**

- Flexion’s Healthcare Compliance Program Manual (the “Manual”) and the Code of Business Conduct and Ethics (the “Code”) are Flexion’s statements of ethical

and compliance principles that guide daily operations. The Manual and the Code establish the expectation that management, employees, and agents of the Company act in accordance with all laws, regulations and Company policies.

- The HHS-OIG Guidance has identified several potential risk areas for pharmaceutical manufacturers, and calls on companies to develop compliance policies in these risk areas. These risk areas are: (1) data integrity pertaining to government reimbursement policies; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples. Flexion has published and trained its employees on various compliance policies to help address these risks and Flexion employees are expected to act in accordance with these policies.
- As required by section 119402 of the California Health and Safety Code, Flexion has established annual spending limits on gifts, promotional materials or items or activities that the Company may provide to individual medical or healthcare professionals in California, in accordance with the HHS-OIG Guidance and the PhRMA Code. As of January 1, 2014 through the period ending on December 31, 2014, the annual dollar limit is \$1,500.00. As provided by the statute, the following are exempt from such limit: (i) drug samples given to health care professionals intended for free distribution to patients; (ii) financial support for continuing medical education forums; (iii) financial support for health education scholarships; and (iv) fair market value payments made for legitimate professional services rendered, all of which are provided in accordance with the HHS-OIG Guidance and the PhRMA Code. Flexion does not and will not provide any item of value to any healthcare provider with the intent of influencing that healthcare provider's prescribing habits. Flexion may change this annual limit from time to time.

**3. Education and Training.** A critical element of Flexion's Compliance Program is the education and training of its employees regarding their legal and ethical obligations under applicable federal health care program requirements among other things. Flexion is committed to taking all necessary steps to effectively communicate standards and procedures to all affected personnel. Moreover, Flexion will continue to regularly review and update its training programs, as well as identify additional areas of training on an "as needed" basis.

**4. Internal Lines of Communication.** Flexion is committed to fostering dialogue between management and employees. Our goal is that all employees, when seeking answers to questions or reporting potential instances of fraud and abuse or other violations, should know who to contact for a meaningful response, and should be able to do so without fear of retribution. To that end, Flexion has adopted open-door policies as well as confidentiality and non-retaliation policies. Flexion has a confidential Compliance Hotline (844-222-6101) or email [compliance@flexiontherapeutics.com](mailto:compliance@flexiontherapeutics.com) through which employees and any person outside of the Company may report any concerns or suspected violation of law, regulation or Company policy.

**5. Auditing and Monitoring.** Flexion's Compliance Program includes efforts to monitor, audit, and evaluate compliance with the Company's compliance policies and procedures. Note that in accordance with the HHS-OIG Guidance, the nature of reviews as well as the extent and frequency of compliance monitoring and auditing varies according to a

number of factors, including new regulatory requirements, changes in business practices, and other considerations.

- 6. Responding to Potential Violations.** Flexion's Compliance Program includes clear disciplinary policies that set out the consequences of violating laws or Company policies. Although each situation is considered on a case-by-case basis, Flexion will consistently undertake appropriate disciplinary action to address inappropriate conduct and deter future violations.
- 7. Corrective Action Procedures.** A compliance program increases the likelihood of preventing, or at least identifying, unlawful and unethical behavior. However, HHS-OIG recognizes that even an effective compliance program may not prevent all violations. As such, Flexion's Compliance Program requires the Company to respond promptly to potential violations of law, regulation or Company policy, take appropriate disciplinary action, assess whether the violation is in part due to gaps in policies, practices, or internal controls, and take action to prevent future violations.

### **Annual Declaration of Compliance**

Based on its good faith understanding of the statutory requirements, Flexion believes that as of October 6, 2017 its Compliance Program meets the requirements of Chapter 8, Part 15, Division 104 of the California Health and Safety Code (§§119400-119402). Flexion also believes that it complies with its Compliance Program in all material respects.

Copies of this Declaration may be obtained from Flexion's Compliance Department by calling 781-305-7777 or emailing [compliance@flexiontherapeutics.com](mailto:compliance@flexiontherapeutics.com).