



Kala Pharmaceuticals, Inc.

**Comprehensive Compliance Program
(As required by the California Health & Safety Code section 11904)**

Kala Declaration of Compliance:

Kala declares that, to the best of its knowledge and based on a good faith understanding of the statutory requirements, that as of January 1, 2019, it is in compliance with its Corporate Compliance Program, including its established annual aggregate spend limit of \$1,500 per California medical or healthcare professional and the requirements of California Health and Safety Code sections 119400-119402 (SB 1765). This declaration is based upon an analysis of information available as of the date of this declaration.

To obtain a printed copy of this document please call 781.996.5252.

1. Corporate Compliance

Kala maintains a comprehensive Corporate Compliance Program (the "Compliance Program") in accordance with all applicable federal, state, and industry guidelines, including 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 Pharmaceutical Research and Manufacturers of America (the "PhRMA Code"), and the California Health & Safety Code sections 119400-119402 (SB 1765).

2. Overview of the Comprehensive Compliance Program

The Comprehensive Compliance Program, described in further detail below, contains policies, procedures and processes to address risk areas identified in the HHS-OIG Guidance and the PhRMA Code. As recommended by the HHS-OIG Guidance, the Kala Compliance Program has been designed to fit the specific compliance needs of the company. Kala will regularly review and evaluate its Compliance Program to ensure it continues to meet the evolving needs of the company.

Key Elements of the Kala Compliance Program include:

- A Chief Compliance Officer
- A Code of Conduct Business Conduct and Ethics
- Availability of an anonymous reporting option for raising compliance concerns
- Monitoring activities and periodic audits to assess compliance with the Compliance Program
- Routine training of employees on the Compliance Program, including the Code of Business Conduct and Ethics

3. Compliance Officer

Kala has designated a Compliance Officer who is charged with the responsibility of developing, implementing, monitoring and updating the Kala Corporate Compliance Program. The Compliance Officer has the authority to effectuate change and exercise independent judgment within the company. Additionally, the Compliance Officer reports directly to the Chief Executive Officer and provides periodic updates the Board of Directors.

4. Written standards

Consistent with the HHS-OIG Guidance, Kala has tailored its Compliance Program to its business as a pharmaceutical company. Kala has established written policies and procedures to ensure compliance with the PhRMA Code, including the Code of Business Conduct and Ethics, and other complementary policies that outline the company's commitment to compliance and corporate accountability. The standards set forth in the policies apply to all Kala employees, contractors and agents, and failure to comply with such policies and procedures may result in disciplinary action, up to and including termination.

5. Education and Training

All employees are required to receive compliance training applicable to their job function and responsibilities, which includes training on the Compliance Program and relevant Kala policies. In addition, further specialized training may be provided where a need for additional training has been identified. Annual compliance training is required of all employees, contractors and agents who engage in, or support, commercial activities. Kala regularly reviews and updates its training programs to help ensure it continues to meet the educational needs of its employees.

6. Effective Lines of Communication

Kala is committed to open dialogue between management and employees. Kala's goal is to foster an open door policy to encourage employees to ask questions or report potential instances of inappropriate activity without fear of retaliation. The company has established a confidential and anonymous Compliance Hotline number that is available 24 hours a day, seven days a week for making good faith reports of known or suspected violations. Any such report relating to this Compliance Program may be directed to the Compliance Officer or designated Compliance staff through any of the following means:

Compliance Hotline: 877-441-1767
Compliance Email: KALA@openboard.info

7. Auditing and Monitoring

Kala recognizes that a comprehensive auditing and monitoring plan is critical to maintaining the effectiveness of a Compliance Program. The subject of Kala's auditing and monitoring assessments, as well as the extent and frequency of its 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 senior management in order to help guide the Kala risk-assessment process.

8. Responding to Potential Violations

A key purpose of the Kala Compliance Program is to prevent and detect violations of law or company policy. As the HHS-OIG Guidance recognizes, however, the implementation of such a program cannot guarantee that improper employee conduct will be entirely eliminated. Nonetheless, it is Kala's expectation that all employees will comply with the Compliance Program, and the policies established in support of such program. All Kala employees have a duty to promptly report any violation of the Compliance Program or any company policies using any of the available company resources. In the event that Kala becomes aware of violations of law or company policy, it will promptly investigate the matter and take appropriate corrective action to ensure the integrity of the Compliance Program and prevent future violations. Personnel who violate Kala's policies and procedures and applicable state and federal laws may be subject to disciplinary action, up to and including termination.

9. Annual Aggregate Dollar Limit in California

Kala does not permit gifts, promotional materials, items, or activities that are prohibited by the PhRMA Code, HHS-OIG Guidance, or related federal or state laws or regulations. For items and activities that are not prohibited, Kala has set an annual aggregate spending limit of \$1,500 per medical or healthcare professional in California, as required by California SB 1765. This amount represents an upper limit rather than a spending goal or a usual, customary or typical amount for medical or healthcare professionals. This limit excludes amounts attributable to drug samples, financial support for continuing medical education, and payment at fair market value for legitimate professional services. In setting this limit, Kala has taken into account the size of the company and its portfolio and may revise this limit as the company and/or product portfolio changes.

Effective: January 1, 2019

This is a summary document and does not include all the policies and procedures that comprise the Kala Corporate Compliance Program. Kala is committed to conduct the ongoing assessment that is necessary to ensure an effective Corporate Compliance Program. This Corporate Compliance Program thus may be amended, altered or revised from time to time as needed and without prior notice.

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