REFLEXION MEDICAL, INC.

Annual Declaration Pursuant to California Health & Safety Code §§ 119400-119402

RefleXion Medical, Inc. (“RefleXion”, “we” and “our”) is a medical device company committed towards the highest standards of business conduct including the [Compliance Program Guidance](https://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf) for Pharmaceutical Manufacturers, published by the Office of Inspector General of the Department of Health and Human Services (“OIG Guidance”), pursuant to [California Health & Safety Code §§ 119400 -119402](https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=HSC&division=104.&title=&part=15.&chapter=8.&article=#:~:text=119400.,includes%20either%20of%20the%20following%3A&text=(1)%20A%20person%20licensed%20by,prescribe%20drugs%20for%20human%20patients.), and in conjunction with the [AdvaMed Code of Ethics on Interactions with U.S. Health Care Professionals](https://www.advamed.org/sites/default/files/resource/advamed-code-of-ethics-2021.pdf) (Jan. 1, 2021) (“AdvaMed Code”).

As an emerging medical device company, RefleXion has implemented a Comprehensive Compliance Program as a key component of our ethical and business standards. The California Health and Safety Code §§ 119400-119402 references compliance with the [Pharmaceutical Research and Manufacturers of America Code on Interactions with Healthcare Professionals](https://www.phrma.org/en/Codes-and-guidelines/Code-on-Interactions-with-Health-Care-Professionals) (June 30, 2020) (the “PhRMA Code”). Instead, since RefleXion is a medical device company and not a pharmaceutical company, our compliance program will be developed accordance with the AdvaMed Code which is substantially similar to the PhRMA Code, with respect to the interactions between medical device manufacturers and healthcare professionals.

The purpose of our compliance program is reasonably designed, based on a good faith effort, to (i) prevent and detect violations of law or company policy and (ii) comply with applicable statues and regulations as well as federal health care program requirements. However, we cannot guarantee the elimination of improper conduct as the OIG Guidance acknowledges. It is RefleXion’s expectation that all employees and associates will comply with our compliance program as well as with all applicable laws, regulations, and policies. Any actual or reasonably suspected instance of misconduct or violation of the compliance policy by an employee or associate will be subject to review and may include disciplinary action.

We recognize that compliance programs must adapt to changing external requirements as

well as a company’s evolving business and risk management needs. We plan to continuously review, assess and improve our compliance program to meet changing needs and circumstances.

RefleXion has demonstrated a good faith effort to comply with the OIG Guidance through its Comprehensive Compliance Program.

Below are additional details regarding RefleXion’s Comprehensive Compliance Program.

*Implementation of Written Policies and Procedures*

(1) The development and distribution of written standards of conduct, as well as written policies, procedures and protocols that verbalize the company’s commitment to compliance (e.g., by including adherence to the compliance program as an element in the expected performance of management and employees) and address specific areas of potential fraud and abuse, such as the reporting of pricing and rebate information to the federal health care programs, and sales and marketing practices;

*Compliance Leadership*

(2) The designation of a Chief Compliance Officer and other appropriate bodies (e.g., a corporate compliance committee) charged with the responsibility for developing, operating, and monitoring the compliance program, and with authority to report directly to the Audit Committee of the board of directors and/or the CEO;

*Education and Training Programs*

(3) The development and implementation of regular, effective education and training programs for all affected employees;

*Compliance Communication*

(4) The creation and maintenance of an effective line of communication between the compliance officer and all employees, including a process (such as a hotline or other reporting system) to receive complaints or questions, and the adoption of procedures to protect the anonymity of complainants and to protect whistleblowers from retaliation;

*Internal Monitoring Auditing Policies*

(5) The use of audits and/or other risk evaluation techniques to monitor compliance, identify problem areas, and assist in the reduction of identified problems;

*Disciplinary Action*

(6) The development of policies and procedures addressing the non-employment or retention of individuals or entities excluded from participation in federal health care programs, and the enforcement of appropriate disciplinary action against employees or contractors who have violated company policies and procedures and/or applicable federal health care program requirements; and

*Investigation and Corrective Actions*

(7) The development of policies and procedures for the investigation of identified instances of noncompliance or misconduct. These should include directions regarding the prompt and proper response to detected offenses, such as the initiation of appropriate corrective action and preventive measures and processes to report the offense to relevant authorities in appropriate circumstances.

In response to California Health & Safety Code §§119400 et seq., RefleXion has established an annual spending limit of $4,000 for gifts, promotional materials, items or activities directed toward "individual medical and healthcare professionals" in California.