

## **Annual Declaration Under California Health and Safety Code, §§ 119400-119402**

*July 1, 2022*

The California Health and Safety Code, §§ 119400-119402, requires pharmaceutical companies to adopt a comprehensive compliance program that meets the expectations set forth in the U.S. Department of Health and Human Services, Office of Inspector General's ("OIG") "Compliance Program Guidance for Pharmaceutical Manufacturers" ("OIG Guidance"). The law also requires that each manufacturer has policies for complying with the Pharmaceutical Research and Manufacturers of America "Code on Interactions with Health Care Professionals" ("PhRMA Code"). Finally, the law requires that each manufacturer impose annual limits for certain items or activities given to healthcare professionals and make its comprehensive compliance program, along with an annual declaration of compliance, publicly available.

Kaléo has implemented a comprehensive Compliance Program consistent with the California Health and Safety Code's requirements, based on its good faith understanding of the statutory requirements and its interpretation of the OIG Guidance and PhRMA Code. The company's Compliance Program is based on the objectives, principles, and best practices underlying these guidelines, and is tailored to its unique circumstances and business. While the OIG Guidance recognizes that even an effective compliance program may not eliminate all misconduct by individuals, Kaléo's Compliance Program is designed to prevent and detect violations. Kaléo's expectation is that all employees will adhere to company policies and procedures. The company will implement disciplinary and corrective actions when misconduct is identified.

Kaléo encourages individuals to report actual or suspected wrongdoing, and violations of laws, rules, regulations, company standards, or any other irregularities. Our Compliance Helpline is always available by calling 877-338-3039 to report any known or potential concerns. The Compliance Helpline is operated by an independent, external service provider offering confidentiality and anonymity.

Kaléo has established an annual spend limit of two thousand dollars (\$2,000.00) per healthcare professional who is licensed in California. Kaléo monitors employee activities to ensure compliance with this limit. Additionally, Kaléo's comprehensive Compliance Program and this annual declaration are publicly available on our website at <http://www.kaleo.com> or by contacting our Compliance Helpline at (877) 338-3039 or emailing us at [compliance@kaleo.com](mailto:compliance@kaleo.com).

Kaléo conducts an annual audit and assessment for purposes of this declaration. As of the date above, Kaléo declares, based on a good faith understanding of the statutory requirements of the California Health and Safety Code, §§ 119400-119402, that it is in substantial compliance with its comprehensive Compliance Program and the requirements of the California Health and Safety Code, §§ 119400-119402.