

April 2025

Recordati Rare Diseases, Inc.

Annual Declaration pursuant to the California Health and Safety Code §§ 119400 -119402

Section 119402 of the California Health & Safety Code requires a pharmaceutical company to adopt a Comprehensive Compliance Program that is in accordance with the U.S. Department of Health and Human Services, Office of Inspector General's ("OIG") "Compliance Program Guidance for Pharmaceutical Manufacturers" ("OIG Compliance Guidance"), and include policies for complying with the Pharmaceutical Research and Manufacturers of America Code ("PhRMA Code"). Further, the law requires that the Comprehensive Compliance Program include an annual limit for certain items and activities given to healthcare professionals covered by this California law. Finally, the law requires that each manufacturer make its Comprehensive Compliance Program and an annual declaration of compliance publicly available.

Recordati Rare Diseases, Inc. ("RRD") commits significant time and resources to the development of each of its policies, procedures and processes that make up its Comprehensive Compliance Program (the "Program"). Correspondingly, the Program is designed to ensure that it is able to identify potential non-compliance through audit and employee reporting, and provide a mechanism for investigation and resolution of such situations. Resolution, when appropriate, may involve disciplinary action up to and including termination of employment. The Program also includes an annual spend limit of \$2,000 for items and activities provided to healthcare professionals in California.

In ensuring compliance coverage through policies, procedures and processes, RRD reviewed the OIG Compliance Guidance and the PhRMA Code, and believes that its Program is consistent with a reasonable interpretation of those guidelines and is in compliance with other applicable laws and regulations as of the date of this declaration. Based upon RRD's good faith understanding of applicable laws and regulations, and to the best of its knowledge, RRD is in substantial compliance with its Compliance Program and the California law.

For additional information on RRD's Corporate Compliance Program Overview and the Code of Ethics, please visit:

<https://www.recordatirarediseases.com/us>
<https://rrd.ethicspoint.com/>
<https://recordati.com/compliance-programmes/>

Feel free to reach RRD's Director of Compliance for North America directly with any questions or concerns.

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