



California Compliance Declaration

NOTICE: This information is provided pursuant to the requirements of California Health & Safety Code, Section 119402, which requires pharmaceutical companies doing business in California to make the details regarding their compliance program available, to set an annual aggregate dollar limit for California HCPs, and to make an annual written declaration of compliance with their compliance program.

1. California Health & Safety Code, Sections 119400 – 119402, (“California Compliance Law”) requires pharmaceutical companies to adopt a compliance program in accordance with the OIG Guidance and policies for compliance with the PhRMA Code. ONY, Inc. has implemented a comprehensive compliance program and will make appropriate updates as needed.

2. The California Compliance Law also requires pharmaceutical companies to set an annual aggregate limit on certain promotional expenditures provided to a medical or healthcare professional as defined under the statute. For purposes of compliance with the requirements of the California Compliance Law and as part of its Compliance Program, ONY, Inc. has established a specific annual aggregate dollar limit of \$1,500 on gifts, promotional materials, or items or activities that ONY, Inc. may give or otherwise provide to an individual medical or healthcare professional in California. This limit represents a spending cap; it is not a goal, an average, customary or a typical amount. The Company has established internal monitoring mechanisms designed to help ensure compliance with our established annual spending limit in California.

The annual limit does not include the following:

- Drug samples given to physicians and healthcare professionals
- Financial support for continuing medical education forums
- Financial support for health educational scholarships
- Payments for legitimate professional services that are provide at the fair market value, and any meals or expenses associated with the provision of such services
- Patient educational materials provided to patients by their physician with the purpose of educating the patient or enhancing the patient’s understanding or management of the condition

3. Lastly, the California Compliance Law requires pharmaceutical companies interacting with medical or healthcare professionals in California to make an annual written declaration of their compliance with their compliance program.

ONY, Inc. has developed a compliance program reasonably tailored to the size, organizational structure, and resources of the company and reasonably intended to meet the specific needs of the company. Internal monitoring mechanisms have been implemented which are designed to measure compliance with the spending limits as set by the company for California medical and healthcare professionals. Thus, subject to the limitations described above, ONY, Inc. hereby declares that to the best of its knowledge, information, and belief, it is in material compliance with its Compliance Program, its good faith understanding of the requirements of the California Compliance Law, and its established annual spending limits for the current time period. ONY, Inc. will assess its Compliance Program at least annually each calendar year. ONY, Inc. last assessed its Compliance Program in March 2016.

A copy of the Comprehensive Compliance Program may be obtained by calling ONY, Inc. at 716-636-9096 or emailing [Compliance](#).