Statement Regarding Compliance with California Health and Safety Codes §§ 119400-119402


The Bracco Group and Bracco Imaging S.p.A., including, but not limited to its U.S.-based subsidiary, Bracco Diagnostics. Inc. (collectively referred to herein as “Bracco”) operates with highest standards of ethical behavior legal conduct. Bracco has established a global Anti-Corruption Program and Code of Conduct and Business Ethics. As stated in its Anti-Corruption Program and Code of Conduct and Business Ethics, Bracco is committed to ethical and legal conduct that is compliant with all relevant laws and regulations and to correcting wrongdoing wherever it may occur in the organization. As part of its continued efforts in the area of compliance, Bracco has also developed a Comprehensive Compliance Program that is reasonably designed to prevent and detect violations.

Consistent with the HHS-OIG Guidance, Bracco has tailored its Compliance Program to the nature of its business as a pharmaceutical and medical device manufacturer. While California Health and Safety Code §§ 119400-119402 only makes reference to compliance with the PhRMA Code, as a manufacturer of both pharmaceutical products and medical devices, Bracco has also adopted policies and procedures consistent with both the PhRMA Code as well as the AdvaMed Code of Ethics on Interactions with Healthcare Professionals (“AdvaMed Code”).

For purposes of compliance with the requirements of the California Health and Safety Code §§ 119400-119402 and as part of its Compliance Program, Bracco has established a specific annual aggregate dollar limit of $2,000 for certain promotional activities directed towards healthcare professional practicing in California. This annual aggregate dollar limit includes: the value medical textbooks and other items that principally entail a patient benefit or are related to the healthcare professional’s practice; modest meals associated with a substantive discussion of a Bracco product or a disease state; and other items or activities permitted under the PhRMA Code, the AdvaMed and/or HHS-OIG Guidance.

These items and activities are primarily directed to the dissemination or communication of medical and scientific information as a resource for healthcare professionals to assist in making clinical or other medical judgments. This limit may be revised from time to time, in which case the revised limit will be published in this section of the Bracco website. The Company has established an internal monitoring system designed to help ensure compliance with the annual spending limits in California and is working to establish additional monitoring processes.
The annual aggregate dollar limit set forth above does not include the following:

- The value of drug/product samples given to physicians and healthcare professionals
- Financial support for continuing medical education
- Financial support for health educational scholarships
- Fair market value payments for legitimate professionals services, and any meals or expenses associated with the provision of such services
- Training programs necessary for the safe and effective use of Bracco products
- Items of nominal value with a retail value of less than $10 (e.g., visual aids, reprints of medical journal articles)