



# Biogen™

*Biogen*  
*Comprehensive Compliance Program*  
(As required by the California Health & Safety Code section 11904)

Biogen's goal is to create advances in human healthcare through our pioneering research, development, manufacturing and commercial capabilities. Biogen is committed to meeting this goal while maintaining the highest level of integrity and ethical behavior in the conduct of our business. To this end, Biogen's Code of Business Conduct is available to the public through its posting on this website.

To conduct our business with integrity and ethically, Biogen has established and maintains a compliance program. This program has been developed in accordance with the laws applicable to our industry and the "Program Guidance for Pharmaceutical Manufacturers" published by the Office of the Inspector General of the U.S. Department of Health and Human Services ("OIG Guidance"). Moreover, the Pharmaceutical Research and Manufacturers of America, the pharmaceutical industry's trade group, voluntarily adopted its own "Code on Interactions with Healthcare Professionals" known as the "PhRMA Code." Biogen's compliance program requires compliance with the PhRMA Code, which addresses topics such as informational presentations by the Company, third party continuing education and professional meetings, use of consultants and speakers, as well as restrictions on the provision of gifts and financial incentives to healthcare professionals.

Consistent with the OIG Guidance, Biogen's compliance program includes:

- Written standards of conduct, policies, and practices that verbalize the company's commitment to compliance and set forth the ethical and compliance principles applicable to all employees.
- A compliance officer and compliance committees charged with the responsibility for operating and monitoring of the compliance program and with authority to report directly to the board of directors and the company's president and chief executive officer.
- Regular education and training programs for all applicable employees.

- Line of communication between the compliance officer and all employees, including a process to receive complaints and ask questions (a hotline).
- Policies and practices to protect the anonymity of employees who make complaints and prohibit retaliation against complainants.
- Use of audits and other techniques to monitor compliance and identify and address of risk.
- Enforcement of compliance obligations through guidelines that include penalties for non-compliance.
- Mechanisms to promptly and properly investigate and respond to reports of non-compliance, including processes to initiate corrective measures and to report offenses to the relevant government authorities where appropriate.
- Written compliance materials that address specific areas of potential fraud and abuse, including risk areas relating to:
  - The integrity of company-generated data that is used for government reimbursement purposes.
  - Prohibition of kickbacks and illegal remuneration to persons or entities in a position to generate federal health care business for the company, either directly or indirectly.
  - Compliance with laws regulating drug samples.

In addition, Biogen has adopted policies and practices that govern the full arena of interactions with healthcare professionals. These policies prohibit illegal remuneration in violation of federal and state anti-kickback statutes and incorporate compliance with the PhRMA Code as a key element, including appropriate:

- Support for medical education, as well as the use of healthcare professionals to provide services to the Company as researchers, consultants and speakers.
- Provision of business courtesies.
- Making of grants and charitable contributions so that such funds are not conditioned, express or implied, on any agreement to prescribe, purchase, recommend, influence or provide favorable formulary status for any Biogen product.
- Promotion of Biogen products in compliance with the U.S. Food and Drug Administration’s regulatory framework regarding promotion of pharmaceutical products.

As required by California Health & Safety Code section 119402, with specific reference to the provision of “gifts, promotional material, or items or activities” that a pharmaceutical company may provide to an individual medical or healthcare professional, the Company has established an aggregate dollar limit of \$1,500.00 on applicable gifts, promotional material, or items or activities for each medical or healthcare professional in the State of California for the 12-month period beginning July 1, 2018. Drug samples intended for free distribution to patients, financial support for continuing medical education forums, financial support for health education

scholarships, and payments for professional services are exempt from this limit pursuant to section 119402. The dollar limit is a maximum only.

To the best of our knowledge, as of July 1, 2019, Biogen is in material compliance with its Comprehensive Compliance Program and the requirements of the California Health & Safety Code section 119402.

To obtain a copy of the certification please call the Compliance Helpline at 866-418-2859