SecuraBio



Marketing Code of Conduct

1. PURPOSE

SECURA BIO ("SECURA") is committed to the highest ethical standards in our marketing practices. This Marketing Code of Conduct (the "Code") establishes guidelines to ensure our interactions with Healthcare Professionals (HCPs) are respectful, transparent, and focused on improving patient care while complying with the PhRMA Code on Interactions with Healthcare Professionals and all applicable laws and regulations including the Anti-Kickback Statute (AKS), False Claims Act and 42 U.S.C. § 1320a-7h (Physician Payments Sunshine Act).

2. SCOPE

All employees, contractors, and representatives of SECURA must adhere to this Code to maintain the highest ethical standards in promoting our pharmaceutical products.

3. Marketing Code of Conduct

1. Commitment to Ethical Marketing

- 1.1 All marketing activities must prioritize the health and well-being of patients.
- 1.2 Interactions with HCPs should be professional, transparent, and focused on the exchange of scientific and medical information.

2. Promotion and Advertising Standards

- 2.1 All promotional materials must be accurate, balanced, and not misleading.
- 2.2 Materials should be reviewed and approved through Materials Review Committee (MRC) to ensure compliance with FDA regulations.
- 2.3 Comparative claims must be supported by substantial evidence.

3. Interactions with Health Care Professionals (HCPs)

3.1 Informational Presentations

- Presentations to HCPs must provide scientific and educational information that is truthful and relevant to their practice.
- Meals provided during presentations must be modest and occur in a venue conducive to learning.

3.2 Prohibition of Gifts

- No gifts, other than educational items valued at \$100 or less and approved by MRC, may be provided to HCPs.

3.3 Consulting Arrangements

- HCP consulting relationships must be based on a legitimate need and formalized through a written contract.
- Payments must reflect fair market value (FMV) for the services provided.

4. Educational Support

- 4.1 The company may provide grants for continuing medical education (CME) programs if:
- The program is independent of the company's influence.
- The funding is provided through a transparent grant process.
- 4.2 Scholarships or educational funding for students and trainees must be administered through the academic or training institution.

5. Speaker Programs

- 5.1 Speakers must be selected based on their qualifications and expertise in the therapeutic area.
- 5.2 Compensation for speakers must be reasonable and documented.
- 5.3 Attendees should have a legitimate professional interest in the program's content.

6. Compliance with Federal Laws and Regulations

6.1 Anti-Kickback Statute (AKS):

- No marketing activity may involve inducements or arrangements that could be interpreted as an exchange for prescribing, recommending, or purchasing the company's products.

6.2 False Claims Act:

- The company must ensure that all claims submitted to government programs are accurate and truthful, and marketing activities must not promote off-label use of products.

6.3 Physician Payments Sunshine Act (42 U.S.C. § 1320a-7h):

- Accurately track and report all transfers of value, including payments and gifts, to HCPs and teaching hospitals.

7. Transparency in Reporting

- 7.1 The company will comply with the Physician Payments Sunshine Act by reporting payments and transfers of value (TOV) to HCPs and teaching hospitals.
- 7.2 Accurate records of all interactions and expenditures must be maintained.
- 7.3 The company will make reasonable efforts to ensure data reported to the Centers for Medicare & Medicaid Services (CMS) and applicable U.S. States is accurate and complete.

8. Social Media and Digital Marketing

- 8.1 Digital content must adhere to the same standards of accuracy and balance as traditional promotional materials.
- 8.2 Interactions on social media platforms must remain professional and avoid sharing confidential or proprietary information.

9. Internal Training and Monitoring

- 9.1 All employees involved in marketing and sales activities must receive regular training on this Code, the Physician Payments Sunshine Act, and applicable federal laws.
- 9.2 The company will conduct periodic audits to ensure compliance with the Code and federal regulations.

10. Reporting Non-Compliance

- 10.1 Employees are encouraged to report suspected violations of this Code to their manager, the Compliance Officer, or through the company's confidential reporting hotline.
- 10.2 Retaliation against employees who report concerns in good faith is strictly prohibited.

4. ENFORCEMENT

Failure to comply with the requirements outlined in this CODE may result in disciplinary actions up to and including termination of employment or contracts.