BrainCOC2019

Braintree, A Part of Sebela Pharmaceuticals
Code of Conduct

A. INTRODUCTION

Braintree, A Part of Sebela Pharmaceuticals is committed to maintaining an effective compliance program in accordance with (a) the "Compliance Program Guidance for Pharmaceutical Manufacturers" dated April 23, 2003 and issued by the Office of Inspector General, U.S. Department of Health and Human Services on May 5, 2003 (the "OIG Guidance") and, (b) the Pharmaceutical Research and Manufacturers of America voluntary guideline entitled "Code of Interactions with Health Care Professionals," dated July 2008 and effective January 1, 2009 (the "PhRMA Code"). The purpose of our Compliance Program is (a) to prevent, detect, and respond to violations of law and/or Company policy and (b) to provide appropriate training to management, employees and agents. As acknowledged by the OIG Guidance, the implementation of such a program cannot guarantee that improper employee conduct will be eliminated. It is Braintree’s expectation that our employees will comply with our Code of Conduct/Ethics (the "Code") and other relevant policies. In the event that Braintree becomes aware of violations of law, the Code, or company policy, we will investigate the matter and, as appropriate, take disciplinary action and implement corrective measures to prevent future violations. The fundamental elements of our Compliance Program are described below. Consistent with the OIG's recommendation, Braintree’s Compliance Program has been established consistent with the environment that exists at Braintree.

B. SUMMARY OF COMPLIANCE PROGRAM

(1) Leadership and Structure.

(a) Compliance Officer. We have selected a member of management to serve as our Compliance Officer. The Compliance Officer has the ability to effectuate change within the Company as necessary and to exercise independent judgment. The Compliance Officer, among other responsibilities, is charged with developing, operating and monitoring the Compliance Program.

(b) Compliance Committee. Braintree established a Compliance Committee to advise the Compliance Officer and assist in the operation of the Compliance Program.

(2) Written Standards.

(a) Braintree’s Code of Conduct/Ethics is our statement of ethical and compliance principles that guide our daily operations. The Code establishes that we expect management, employees and agents of the Company to act in accordance with law and Company policy. The Code articulates our fundamental principles, values and framework for action within our organization.

(b) The OIG Guidance identified several key risk areas for pharmaceutical manufacturers and called on companies to develop compliance policies in these risk areas. These risk areas are (1) data integrity pertaining to government reimbursement practices; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating sampling activities. Braintree has established policies that address data integrity, kickbacks and sampling activity.

(c) In response to California’s Drug Marketing Practices Law (California Health and Safety Code 119400-119402) enacted in July 2005, we have also established an annual spending limit for certain promotional activities directed towards a health care professional. More specifically, the promotional
activities referenced in the preceding sentence shall not exceed the sum of Two Thousand Five Hundred Dollars ($2,500.00) annually, per health care professional, in all territories nationwide. This $2,500 amount is an upper limit and addresses spending on a health care professional for occasional meals and snacks; meals provided in connection with a Company speaker program; any patient related gift; and any medically related textbook or journal. This amount does not include the value of pharmaceutical drug samples; grants for medical education; medical scholarships; professional service fees; prescription pads and instruction sheets valued at less than $20; patient education materials; and approved scientific reprints. An exception to this $2,500 amount may be made only upon the prior, written approval by Braintree’s Vice President for Sales and Braintree’s Compliance Committee.

(3) Education and Training. Education of our employees and agents on their legal and ethical obligations is a key component of Braintree’s Compliance Program. Braintree is committed to taking steps to effectively communicate our standards and procedures to all affected personnel. In addition, Braintree will regularly review and update its training programs and identify additional areas of training on an as needed basis.

(4) Open Lines of Communication. Braintree has a longstanding policy of fostering dialog between management and employees. Our goal is that all employees, when seeking answers to questions or reporting potential instances of fraud and abuse, should know who to turn to for a meaningful response and should be able to do so without fear of retribution.

(5) Auditing and Monitoring. Braintree’s Compliance Program includes efforts to monitor, audit, and evaluate compliance with the Company's compliance policies and procedures through internal and external resources.

(6) Discipline. Although each situation is considered on a case-by-case basis, Braintree will impose appropriate disciplinary action to address inappropriate conduct and deter future violations.

(7) Corrective Actions. Braintree’s Compliance Program increases the likelihood of preventing, or at least identifying, unlawful and unethical behavior. However, consistent with the OIG's comment, Braintree recognizes that even an effective Compliance Program may not prevent all violations. Thus, Braintree’s Compliance Program requires that the Company respond promptly to all potential violations of law, the Code, and/or Company policy, take appropriate disciplinary action, perform an assessment of the violation to ascertain if the violation reveals a gap in our policies, practices, or internal controls and take appropriate action to prevent future violations.

Please call the Compliance Officer on 1-800-874-6756 ext. 799 if:
- You would like a copy of this summary and declaration document.
- You are aware of any activity that violates this policy, the Code, the law, and/or other company policies and would like to discuss that activity anonymously.
- You would like to anonymously report an incident that you believe should be brought to management’s attention.

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