



## **Graceway Pharmaceuticals, LLC Comprehensive Compliance Program and Marketing Code of Conduct\***

### **Introduction**

Graceway Pharmaceuticals, LLC is committed to the highest standards of corporate citizenship and ethical conduct, and Graceway continually strives to create a corporate culture that embodies these values in every aspect of its business. Accordingly, Graceway has established a Comprehensive Compliance Program and Marketing Code of Conduct (the “Compliance Program”) structured around the seven elements outlined in the April 2003 “Compliance Program Guidance for Pharmaceutical Manufacturers,” published by the United States Department of Health and Human Services, Office of Inspector General (“OIG Guidance”), as well as various applicable state and local laws.

Graceway’s Compliance Program is designed to prevent and detect violations of ethical norms, legal requirements, and company policy. While the implementation of any program of this type cannot guarantee that improper employee conduct will be eliminated in its entirety, Graceway expects that its employees will comply with its Compliance Program. In the event that Graceway becomes aware of violations of law or company policy, we will investigate the matter and, where appropriate, take disciplinary action and implement corrective measures to prevent future violations.

### **Overview of Compliance Program**

**1. Leadership and Structure.** Graceway’s compliance officer is John A. A. Bellamy, Executive Vice President & General Counsel, who is charged with the responsibility for developing, operating, and monitoring Graceway’s Compliance Program. Mr. Bellamy reports directly to Graceway’s Chief Executive Officer, Mr. Jefferson Gregory. Mr. Bellamy has the ability to effectuate change within the organization and to exercise independent judgment.

**2. Written Standards and Annual Spending Limit.** Graceway’s written compliance standards are set forth in three primary sets of documents: (1) Graceway’s Travel and Entertainment Expense Policy (“T&E Policy”); (2) Graceway’s Standard Operating Procedures and Policies (collectively “SOPs”); and (3) Graceway’s Corporate Code of Conduct and Ethics, a document located in Graceway’s Employee Manual.

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\* This Comprehensive Compliance Program, as well as the underlying programs and policies, are intended to satisfy certain legal and reporting requirements, including but not limited to Nev. Rev. Stat. § 639 (Nevada Marketing Code of Conduct); Cal. Code, Health & Safety § 119400 *et seq* (California Comprehensive Compliance Program); and 105 CMR 970.000 (Massachusetts Marketing Code of Conduct).

***T&E Policy*** – First, Graceway has in place an all-encompassing T&E Policy that governs nearly every aspect of allowable corporate and employee expenditures. The T&E policy covers a myriad of topics ranging from employee meals and cell phone use to corporate charitable donations and physician compensation. Most importantly for present purposes, Graceway’s T&E policy sets forth limitations on company interactions with healthcare providers, including by setting limitations (or, where appropriate, prohibitions) on sales and marketing expenditures such as customer meals, physician gifts, *etc.* The T&E Policy also sets forth procedures so that the company can monitor employee expenditures and prevent employee transgressions. Every employee is expected to become familiar with, and abide by, the T&E Policy.

***SOPs*** – Next, Graceway has in place a comprehensive set of SOPs that guide and shape our interactions with healthcare professionals. Graceway’s SOPs address various sales-and-marketing-compliance matters including, but not limited to, marketing standards and procedures, sales calls, prohibition on off-label promotion, gifts, meals, speaker agreements, and educational grants. Although Graceway is not a member of the Pharmaceutical Research and Manufacturers of America (“PhRMA”) and has not formally adopted their written Code on Interactions with Healthcare Professionals (the “PhRMA Code”), Graceway nonetheless fully and firmly endorses the core principles set forth therein. Accordingly, Graceway’s SOPs derive from the PhRMA Code and embody its ideals.

***Corporate Code of Conduct and Ethics*** – In addition to its T&E Policy and SOPs, Graceway also has a separate Corporate Code of Conduct and Ethics that extends beyond our direct relationships with healthcare providers, and embodies our fundamental business values. The Corporate Code of Conduct and Ethics sets a framework within which to conduct business, and addresses an array of business and ethical issues.

Together, these three sets of documents ingrain the notion that Graceway expects every employee to conduct business according to the highest standards of corporate citizenship and ethical conduct.

***Annual Spending Limit*** – For purposes of complying with California Health and Safety Code §§ 119400-02, Graceway has established a “specific annual dollar limit on gifts, promotional materials, or items or activities that [Graceway] may give or otherwise provide to an individual medical or healthcare professional.” This annual dollar limit is fifteen hundred dollars (\$1500.00) and primarily reflects dollars that may be expended in association with programs designed to inform healthcare professionals about Graceway products and associated disease states.<sup>1</sup> This annual dollar limit is an *upper* limit, and Graceway anticipates that the *average* value of such spending would be significantly lower than the limit set forth above. Graceway will evaluate this limit on an annual basis, and reserves the right to modify the limit as necessary.

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<sup>1</sup> This annual dollar limit does not include certain amounts associated with drug samples, financial support for continuing medical education and certain educational scholarships, or legitimate professional services or consulting agreements. *See* Cal. Code, Health & Safety § 119402(d). It is Graceway’s policy to comply with other laws that may set different or lower spending thresholds in certain circumstances or jurisdictions (*See, e.g.,* Minn. Stat. §§ 151.461, 151.47).

**3. Education and Training.** Graceway educates and trains employees on the facets of our compliance program through programs developed and conducted primarily by the Legal Department, the Learning and Development Department, and the Human Resources Department. Our education and training cover a variety of laws and regulations that impact the way we conduct business. Through its first year of operations in 2007, Graceway focused primarily on live training modules with an opportunity for question-and-answer sessions. In 2008, the company rolled out computer-based training programs, as well as other interactive training modules to ensure ongoing education and training as it pertains to compliance and other important areas. Most recently, Graceway has conducted several state-specific training sessions for employees who conduct business in states that closely regulate interactions between pharmaceutical companies and healthcare providers (e.g., Washington, D.C. and Massachusetts). To date, our training sessions have focused on a broad array of topics such as the Anti-Kickback Statute, the OIG Compliance Program Guidance, the PhRMA Code, and the False Claims Act, as well as other applicable federal, state, and industry rules and guidelines, including as embodied in Graceway's own SOPs and Corporate Code of Conduct and Ethics. Beginning in late 2009, Graceway will roll out an annual assessment and certification for sales and marketing personnel to ensure continued proficiency in areas such as product knowledge, general scientific knowledge, and compliance. As a young and growing company, Graceway remains committed to updating and expanding its training programs.

**4. Internal Lines of Communication.** Graceway is committed to creating and maintaining internal lines of communication between management and employees. Our goal is that all employees, whether seeking answers to questions or reporting potential instances of fraud and abuse, will know to whom to turn and will be able to do so without fear of retribution. To that end, we have adopted open-door and non-retaliation policies as set forth in our Corporate Code of Conduct and Ethics.

As part of its ongoing commitment to ethical and legal behavior, Graceway requires its employees to report any actual or suspected violations of law or ethical standards, so that the company can investigate them. Employees can raise their concerns in a number of ways including through our Human Resources or Legal departments, through individual employees' management chains, or through our Ethics and Compliance Hotline.

**5. Auditing and Monitoring.** Graceway's compliance efforts include activities to monitor, audit, and evaluate compliance with the company's policies and procedures. Graceway's approach includes targeted monitoring and auditing based on identified and prioritized risk areas. Additionally, management is responsible for reviewing employee expense reports to ensure compliance. In accordance with the OIG Compliance Program Guidance, the nature of Graceway's reviews (as well as the extent and frequency of our compliance monitoring and auditing) varies according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations.

**6. Responding to Potential Violations.** Adherence to Graceway's T&E Policy, Corporate Code of Conduct and Ethics, and SOPs is a condition of employment at Graceway. Violations of an employee's obligations under these mandatory documents can subject an employee to serious disciplinary measures, including possible termination of employment. An employee's obligations under the Corporate Code of Conduct and Ethics include strict observance of all laws and regulations applicable to our company (*e.g.*, laws and regulations governing the health care programs), ethical standards, and applicable Graceway SOPs. Although each suspected violation of a company policy is considered on a case-by-case basis, Graceway undertakes significant efforts to ensure consistent and appropriate disciplinary action is taken in response to violations.

**7. Corrective Action Procedures.** As part of our compliance program, Graceway has put in place an internal investigation and corrective action procedure to ensure that timely, complete, and objective investigations are conducted in response to allegations regarding the Graceway Corporate Code of Conduct and Ethics and other applicable policies. In accordance with the OIG Compliance Program Guidance, the exact nature and level of thoroughness of the internal investigation will vary according to the circumstances. Upon conclusion of an internal investigation, corrective action and preventative measures are determined and implemented as appropriate.