

SUCAMPO PHARMACEUTICALS, INC.
COMPREHENSIVE COMPLIANCE PROGRAM

1. Introduction

It is the policy of Sucampo Pharmaceuticals, Inc., (“Company”) to promote our products in full compliance with law, to foster scientific research and education in medical fields relating to our products, and to ensure that our relationships with healthcare professionals involve no communication or remuneration that is inconsistent with law or regulations regarding the promotion of pharmaceutical products. This Comprehensive Compliance Program (“CCP”) is adopted to help ensure that all Company employees who interact with healthcare professionals or engage in promotional activities carry out both the letter and the spirit of this policy.

This CCP is intended to be consistent with the Federal Food, Drug, and Cosmetic Act and Food and Drug Administration (“FDA”) regulations governing labeling and advertising of prescription drug products; relevant FDA guidance (including *Guidance for Industry on Industry-Supported Scientific and Educational Activities* [Nov. 1997]); the Pharmaceutical Research and Manufacturers of America (“PhRMA”) Code on Interactions with Healthcare Professionals (July 1, 2002); the Department of Health and Human Services Office of the Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers (68 Fed. Reg. 23731, May 5, 2003) (and related anti-kickback statutes and regulations); California Health and Safety Code §119402; and other statutes and regulations as applicable.

2. Compliance Officer

The Compliance Officer shall be charged with responsibility and authority for overseeing the development and operation of the CCP, with advice from outside counsel and assistance from other sources, as necessary.

The Compliance Officer’s role will include, but not limited to, the following activities:

- Strategic guidance and oversight for the processes, training, and implementation needed to ensure full compliance with the laws, regulations and policies that direct interactions with healthcare professionals, and to reduce the Company’s vulnerability to fraud and abuse;
- Periodic direction of the revision of the CCP, as appropriate, to respond to changes in the Company’s needs and applicable laws and regulations, identified weakness in the CCP, or identified systemic patterns of noncompliance;
- Supervision of development of an educational and training program that focuses on the elements of the CCP, to ensure that all relevant employees and management understand and comply with pertinent federal and state standards;

- Receiving reports of possible noncompliance from employees or other sources (*e.g.*, through internal audits or reports from managers), evaluating such reports, directing the conduct of any necessary investigations, recommending to management any necessary corrective actions, monitoring the implementation of such corrective actions, and ensuring that all steps in this process are documented; and
- Reporting directly to the Board of Directors and/or the President or Chief Executive Officer regarding compliance activities.

Sucampo Pharmaceuticals is committed to ensuring that its Compliance Officer has the ability to effectuate change within the organization as necessary and to exercise independent judgment. As a result, the compliance function has unrestricted access to information, executives, and meetings related to business operations.

3. Education and Training

Sucampo Pharmaceuticals shall ensure that its employees are trained on their legal and ethical obligations under Company policy and the laws, regulations, and guidelines that govern pharmaceutical marketing activities in the United States.

All Company employees are required to participate in training as a condition of their employment. Employees will undergo periodic re-training and remedial training programs as necessary. Training shall cover this CCP and, in general, compliance with federal laws and regulations that relate to pharmaceutical sales and marketing such as the Anti-Kickback Statute, the Prescription Drug Marketing Act, and Food and Drug Administration drug promotion regulations.

All Company employees are required to certify as a condition of employment that they have received training on this CCP and will abide by it.

4. Employee Communications

Sucampo Pharmaceuticals encourages employees to communicate openly with management about all types of workplace issues. Employees are encouraged to bring workplace issues to the attention of management without fear of retaliation or recrimination. Thus, employees are encouraged to ask questions about the CCP, discuss compliance issues, and report instances of possible noncompliance. Sucampo Pharmaceuticals encourages employees to communicate first with their supervisor. In addition, or in the alternative, the Company encourages employees to communicate with the Compliance Officer.

Direct communication with the Compliance Officer is available to all employees. In addition, the Compliance Officer will receive communications from employees who wish to remain anonymous, via voice mail message, e-mail, written communications, or other means. If desired by the employee, the matter will be kept as confidential as possible, consistent with the Company's legal obligations. All communications from employees about compliance issues, whether or not the communications are anonymous, will be carefully evaluated and investigated.

5. Internal Monitoring and Auditing, Discipline, and Corrective Action

Internal monitoring and auditing are vital components of this CCP. In addition, under this program all employees, including management, are subject to disciplinary action, up to and including termination of employment, for failure to adhere to compliance standards. This CCP supports prompt response and corrective action for detected problems as appropriate. All compliance concerns reported through any communication channel will be carefully reviewed, thoroughly investigated, and appropriately resolved in a timely manner.

6. Hiring and Enforcement Actions

The Compliance Officer in coordination with Human Resources shall ensure that potential employees and contractors are appropriately checked to ensure that Sucampo Pharmaceuticals does not employ or contract with persons or entities that have been identified as “Excluded Individuals/Entities” by the Department of Health and Human Services or as “Debarred” by the FDA.

The Company’s policies for discipline in response to employee violations of the CCP are designed to be appropriate, consistent, documented, and clearly communicated to all affected employees.

The Compliance Officer shall receive reports of possible noncompliance from employees or other sources, arrange for the evaluation of such reports and the conduct of any necessary investigations, recommend to management any necessary corrective actions, monitor the implementation of such corrective actions, and document all steps in this process.

7. Interactions with Healthcare Professionals

Sucampo Pharmaceuticals policy and the PhRMA Code permit the occasional offering of (a) items primarily for the benefit of patients and (b) items of minimal value that are primarily associated with a healthcare professional’s practice. Gifts and meals cannot: (a) be used to solicit business or (b) be offered or provided in a manner or under conditions that would interfere with the independence of a healthcare professional’s prescribing practices.

In connection with informational presentations and discussions by Company representatives, Sucampo Pharmaceuticals may offer occasional meals (but no entertainment or recreational events) so long as they: (a) are modest as judged by local standards; (b) occur in a venue and manner conducive to informational communication; and (c) the presentations or discussions provide scientific or educational value. Inclusion of a healthcare professional’s spouse or other guests is not permissible. Offering “take-out” meals or meals to be eaten without a company representative being present (such as “dine & dash” programs) is not appropriate.

Items primarily for the benefit of patients may be offered to healthcare professionals if they are not of substantial value (\$100 or less). For example, an anatomical model for use in an examination room primarily involves a patient benefit, whereas a DVD player does not. Items should not be offered on more than an occasional basis, even if each individual item is

appropriate. Providing product samples for patient use in accordance with the Prescription Drug Marketing Act is acceptable.

Items of minimal value may be offered if they are primarily associated with a healthcare professional's practice (e.g., pens, notepads, and similar "reminder" items with company or product logos). Items intended for the personal benefit of healthcare professionals (e.g., floral arrangements, artwork, candy or cookies, music CDs, golf balls, umbrellas, or tickets to a sporting event) may not be offered.

Payments in cash or cash equivalents (such as gift certificates) may not be offered to healthcare professionals either directly or indirectly, except as compensation for *bona fide* services in accordance with a consultant agreement. Cash or equivalent payments of any kind create a potential appearance of impropriety or conflict of interest.

Gifts to physicians in Minnesota must not exceed an aggregate annual retail value of \$50.

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