

SeaSpine Orthopedics Corporation California Comprehensive Compliance Program

Introduction

Committed to establishing and maintaining the highest standards of ethical practice, SeaSpine, in conjunction with its Senior Management, has established a comprehensive compliance program consistent with the SeaSpine Good Compliance Program Practices (collectively, the “Program” or “Comprehensive Compliance Program”). For purposes of California Health and Safety Code § 119402, the Program constitutes the SeaSpine compliance program, which is designed in accordance with the Compliance Program Guidance published by the Office of Inspector General, U.S. Department of Health and Human Services (the “HHS-OIG Guidance”). Since SeaSpine is a medical device company—not a pharmaceutical company—certain guidance set forth in the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals is not applicable to SeaSpine’s Program. Accordingly, SeaSpine has adopted the Medical Device Manufacturers Association Revised Code of Conduct for Interactions with Healthcare Providers (the “MDMA Code”) to address specific risk areas for medical devices companies.

1. Purpose

The purpose of the Program is to prevent and detect any violations of law or SeaSpine policy, which accords with California Health and Safety Code § 119402. Consistent with HHS-OIG Guidance, SeaSpine has tailored its business as a medical device manufacturer and implemented the Program to deal with any such violations. As the HHS-OIG Guidance recognizes, however, the implementation of such a compliance program cannot guarantee that improper conduct will be entirely eliminated. Nonetheless, SeaSpine expects its employees to comply with its Program and the policies established in support of the Program.

The Program promotes ethical and professional behavior by SeaSpine employees. In the event that SeaSpine becomes aware of potential violations of law or company policy, SeaSpine will, where appropriate, investigate the matter and take disciplinary action and implement corrective measures to prevent future violations.

2. Description

SeaSpine has provided below a description of its Program. SeaSpine regularly reviews and enhances its Program to meet its evolving compliance needs, the voluntary standards established by the HHS-OIG Guidance, and its unique environment and size of the company.

Overview of Comprehensive Compliance Program

1. Written Standards

The Program is a statement of ethical and compliance principles that guide daily operations at SeaSpine. The Program establishes that SeaSpine expects its employees to act in accordance with law and applicable company policy. The company’s fundamental principles, values, and framework are articulated throughout the Program for within its organization.

The HHS-OIG Guidance has identified several potential risk areas for medical device manufacturers, and called on companies to develop compliance policies in these risk areas. As relevant to medical device manufacturers, these risk areas include: (i) data integrity pertaining to government reimbursement practices, and (ii) kickbacks and other illegal remuneration.

Along with the Program, SeaSpine has adopted the MDMA Code to address these specific risk areas. Furthermore, a specific annual dollar limit of \$3,000 has been imposed on gifts, promotional materials, items, or activities provided by a SeaSpine employees to covered recipients in California.

2. Leadership and Structure

The SeaSpine Compliance Committee constituted of appropriate executive and management officials (the “Compliance Committee”) will oversee the Program. The Compliance Committee will serve as the focal point for compliance activities; however, SeaSpine expects every employee to operate with the professional and ethical responsibilities designated within the CCP. The SeaSpine General Counsel assists the Compliance Committee with leadership and oversight of the Program, along with ensuring the exercise of the day to day needs of the Program. The Compliance Committee has authorized the General Counsel with the ability to effectuate change within the organization as necessary and to exercise independent judgment.

3. Education and Training

A critical element of the Program is the education and training of relevant personnel on their legal and ethical obligations under applicable federal healthcare program requirements. SeaSpine is committed to effectively communicating its standards and procedures to all affected personnel.

4. Internal Communication

SeaSpine is committed to fostering dialogue between management and employees. The company’s goal is that all employees, when seeking answers to questions or reporting potential instances of compliance violations, should know whom to turn to for a meaningful response. In order to further encourage open lines of communication regarding potential violations, SeaSpine has established a toll-free phone line for anonymous reporting, which is listed at the bottom of this document.

5. Auditing and Monitoring

The SeaSpine Program includes efforts to monitor and evaluate compliance with the company’s compliance policies and procedures. In accordance with the HHS-OIG Guidance, the nature of the company’s reviews, as well as the extent and frequency of its compliance monitoring and auditing, varies according to a variety of factors, including, company resources, new regulatory requirements, changes in business practices, and other considerations.

6. Responding to Past and Potential Violations

SeaSpine requires a prompt and diligent response to potential violations of the Program. Actions in response to detected problems may include improving policies, procedures, training, communications and monitoring and may require disciplinary action to prevent future violations.

7. Corrective Action Procedures

A compliance program is designed to increase the likelihood of preventing, or at least identifying unlawful and unethical behavior. However, HHS-OIG recognizes that even an effective compliance program may not prevent all violations. As such, SeaSpine's Program requires the company to respond promptly to potential violations of law or company policy, take appropriate disciplinary action, assess whether the violation is in part due to gaps in the company's policies, practices, or internal controls, and take action to prevent future violations.

SeaSpine Annual California Declaration of Compliance

To the best its knowledge and based upon a good faith understanding of the applicable statutory requirements, SeaSpine hereby declares that it is not aware of any violations as of July 1, 2019, of its Comprehensive Compliance Program, or of the requirements of Cal. Health and Safety Code §§ 119400-119402 relating to California medical or health professionals, that have not been addressed and for which corrective action has not taken place.

Copies of this certification and the Comprehensive Compliance Program may be obtained at www.seaspine.com or by calling toll free, the SeaSpine Ethics Hotline at 1-855-792-6402.

Dated Effective: June 25, 2019