

NuVasive®. Inc. California Comprehensive Compliance Program

Introduction

Committed to establishing and maintaining the highest standards of ethical practice, NuVasive, in conjunction with its Board of Directors and Senior Management, has created a Comprehensive Compliance Program (“Program”). For purposes of California Health and Safety Code § 119402, this Program constitutes the NuVasive Comprehensive 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 NuVasive 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 our Program. Accordingly, NuVasive has adopted the MDMA Revised Code of Conduct for Interactions with Healthcare Providers as assembled by the Medical Device Manufacturers’ Association (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 company policy, which accords with California Health and Safety Code § 119402. Consistent with HHS-OIG Guidance, NuVasive 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 program cannot guarantee that improper conduct will be entirely eliminated. Nonetheless, NuVasive expects its employees, officers, and directors, as well as its distributors, agents, and independent contractors¹ (collectively referred to as “Shareowners” for purposes of this document) to comply with its Code of Ethical Business Conduct (the “Code”) and the policies established in support of the Code.

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

2. Description

NuVasive has provided below a *description* of its Program. NuVasive 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 the NuVasive Comprehensive Compliance Program

1. Written Standards

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

¹ “Independent contractors” refers to personnel who perform the type of core job function or services on behalf of NuVasive that would otherwise be provided by an employee.

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 Code, NuVasive® 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, or items or activities provided by NuVasive to individual medical or health professionals licensed in California.

2. Leadership and Structure

The NuVasive Compliance Officer (the “Compliance Officer”) shall be the individual to oversee the Program. He or she shall serve as the focal point for compliance activities; however, NuVasive expects every Shareowner to operate with the professional and ethical responsibilities designated within the Code. NuVasive is committed to ensuring that the Compliance Officer has the ability to effectuate change within the organization as necessary and to exercise independent judgment. To assist the Compliance Officer provide effective leadership and oversight to the Program, NuVasive has created a Corporate Integrity Steering Committee and a Compliance & Ethics Committee, each of which is constituted of appropriate executive and management officials.

The Audit Committee is the Board-designated committee that oversees the development and refinement of the Program and advises the Compliance Officer.

3. Education and Training

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

4. Internal Communication

NuVasive is committed to fostering dialogue between management and Shareowners. The company’s goal is that all Shareowners, 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, we have established a toll-free phone line for anonymous reporting, which is listed at the bottom of this document.

5. Auditing and Monitoring

The NuVasive 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 new regulatory requirements, changes in business practices, and other considerations.

6. Responding to Past and Potential Violations

NuVasive® requires a prompt and diligent response to potential violations of the company's Program and the Code. 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 increases 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, the NuVasive 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.