

# STEREOTAXIS, INC.

## HEALTHCARE COMPREHENSIVE COMPLIANCE PROGRAM

### Introduction

Stereotaxis, Inc. (“Stereotaxis” or the “Company”) is committed to establishing and maintaining the highest standards of ethical practice. With this goal in mind, Stereotaxis, in conjunction with its board of directors and senior management, has created a healthcare compliance program that 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 “OIG Guidance”), and the AdvaMed Code on Interactions with Healthcare Professionals (the “AdvaMed Code”) (collectively, the OIG Guidance and the AdvaMed Code are referred to as the “Guidance”).

#### 1. Purpose

The purpose of the healthcare compliance program (“Program”) is to prevent and detect any violations of law or company policy. Our Company’s commitment to the highest standard of ethics in the conduct of our business is expressed in our Code of Ethics and Business Conduct (the “Code”). It is Stereotaxis’ expectation that all employees will comply with the Code and the policies established in support of the Code. Consistent with the Guidance, the Company has tailored the program to fit the size and unique environment of Stereotaxis.

In the event that Stereotaxis becomes aware of potential violations of law or company policy, Stereotaxis will, where appropriate, investigate the matter and take disciplinary action and implement corrective measures to prevent future violations.

#### 2. Description

Stereotaxis has provided below a description of the fundamental elements of the Program. We regularly review and enhance the Program to meet our evolving compliance needs as well as the changing nature or environment of our business.

### Overview of Comprehensive Compliance Program

#### 1. Written Standards

The Code is Stereotaxis’ statement of ethical and compliance principles that guide its daily operations. The Code establishes that Stereotaxis expects all Stereotaxis directors, officers, employees, consultants and other representatives (“Representatives”), to act in accordance with the law and applicable company policy. The Company’s fundamental principles, values, and framework are articulated throughout the Code.

The 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: (1) data integrity pertaining to government reimbursement practices, and (2) kickbacks and other illegal remuneration. Our Code and our compliance program address these issues. A specific annual dollar limit of \$1,000 per healthcare practitioner has been imposed for educational items, healthcare practice-related items, and meals provided by Stereotaxis employees.

## 2. Leadership and Structure

Stereotaxis' General Counsel acts as its ethics officer with respect to the Code. He or she will serve as the Company's compliance officer and the focal point for compliance activities under the Program. Nevertheless, Stereotaxis expects every Stereotaxis Representative to operate with the professional and ethical responsibilities designated within the Code. Stereotaxis is committed to ensuring that its compliance officer has the ability to effectuate change 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 federal healthcare program requirements. Stereotaxis is committed to effectively communicating our standards and procedures to all affected personnel.

## 4. Internal Lines of Communication

Stereotaxis is committed to fostering dialogue between management and Stereotaxis 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 and should be able to do so without fear of retribution. In order to further encourage open lines of communication regarding potential violations, we have established both a toll-free compliance line and a web-based reporting system, both of which allow for anonymous reporting and are listed at the bottom of this document.

## 5. Auditing and Monitoring

The Program includes efforts to monitor and evaluate compliance with the Company's compliance policies and procedures. In accordance with the 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

Stereotaxis requires a prompt and diligent response to potential violations of the Code. Actions in response to detected problems may include improving policies, procedures, training, communications and monitoring and may require disciplinary action. Each situation is evaluated on a case-by-case basis and management will undertake appropriate disciplinary action to address inappropriate conduct and deter future violations.

## 7. Corrective Action Procedures

A compliance program increases the likelihood of preventing, or at least identifying unlawful and unethical behavior. However, government agencies recognize that even an effective compliance program may not prevent all violations. As such, the 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.

## **Stereotaxis' Declaration of Compliance**

Stereotaxis has developed a Comprehensive Compliance Program that is reasonably designed to prevent and detect violations. Consistent with the OIG Guidance, we have tailored our Comprehensive Compliance Program to the nature of our business as a medical device manufacturer. The medical device industry has established a voluntary ethical code called the AdvaMed Code of Ethics on Interactions with Healthcare Professions ("AdvaMed Code"). The AdvaMed Code is substantially equivalent to the Pharmaceutical Research and Manufacturers of America Code on Interaction with Healthcare Professionals, but reflects the unique interactions between medical device companies and healthcare professionals.

As described herein, Stereotaxis has established, adopted and is actively implementing its Program in accordance with the OIG Guidance and the AdvaMed Code. The Program incorporates the material elements from the OIG Guidance and AdvaMed Code that are fundamental to an effective compliance program. To the best of the Company's knowledge, Stereotaxis is effectively operating under the Program, which is in compliance with California Health and Safety Code § 119402.

By making this declaration, Stereotaxis is not asserting that in all circumstances it can prevent individual Stereotaxis Representatives from conduct that deviates from its policies, but it will make a good faith effort to develop and enforce its Program, prevent violations, and address any inappropriate conduct that may occur.

### **Compliance Hotline**

In order to anonymously contact Stereotaxis to report any violations of the Code or our healthcare compliance policies, you may do so by calling the Compliance Telephone Hotline at 877-874-8416, or by electronic message [www.stereotaxis.silentwhistle.com](http://www.stereotaxis.silentwhistle.com).

A copy of this document may be obtained by calling 314.678.6100.

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