

NOTICE: this information is provided pursuant to the requirements of Cal. Health & Safety Code § 119402 (S.B. 1765), which requires certain pharmaceutical and medical device companies doing business in California to make available their program for compliance with applicable federal and state laws and industry standards regulating the marketing and promotion of their products

## **I. INTRODUCTION**

Ortho Clinical Diagnostics, Inc. has established a program designed to materially comply with applicable federal and state laws and industry standards relating to the marketing and promotion of its products. Additionally, Ortho Clinical Diagnostics recognizes that adherence to these standards can be furthered through a compliance program that is informed by the *Compliance Program Guidance for Pharmaceutical Manufacturers*, published by the Office of Inspector General of the U.S. Department of Health and Human Services (the “OIG Guide”). The OIG Guide advises that effective compliance programs are comprised of seven elements. As described below, these elements form the basis of Ortho Clinical Diagnostics’ program for compliance with the standards regulating the marketing and promotion of its products.

## **II. Overview of Compliance Program**

### **1. Written Policies and Procedures**

Ortho Clinical Diagnostics, Inc. has written policies to assure substantial compliance with the applicable laws and regulations and standards governing the marketing and promotion of our products. Among these standards are recognized industry codes of conduct including the *Code of Ethics on Interactions with Health Care Professionals* (AdvaMed Code), published by the Advanced Medical Technology Association (“AdvaMed”). Ortho Clinical Diagnostics has established written policies that govern activities involving communicating with customers about the appropriate use of our products including appropriate instruction, education, training, service and technical support required for the safe and effective use of our products. Ortho Clinical Diagnostics also has policies governing activities involving the advancement of scientific and educational activities supporting medical research and education. These policies include:

#### **Policy on Educational Grants and Research Grants**

Ortho Clinical Diagnostics may provide grants for specific educational purposes that benefit patients and customers. These may include, but are not limited to, continuing medical and paraprofessional education programs, fellowships provided to teaching institutions and similar organizations with a demonstrated commitment to scientific and technical education, and programs operated by organizations that provide high-quality, nationally recognized patient education. Funding of educational programs will generally be provided only to organizations and institutions and not to individual practitioners.

Research grants to support customer-initiated research may be provided for programs involving research in areas of legitimate interest to the company. All requests are subject to scientific review prior to funding approval.

### **Policy on Charitable Contributions and Patient Assistance**

Ortho Clinical Diagnostics will consider charitable contributions and requests for patient assistance in the areas of children's health, health care education, access to health care and community responsibility, consistent with Ortho Clinical Diagnostics policies.

### **Policy on Travel Expense Reimbursement for CME, Promotional or Product Training Meetings**

Ortho Clinical Diagnostics will, with very limited exceptions that are in accordance with nationally recognized standards, not reimburse for travel and lodging expenses of attendees at promotional and educational programs.

Ortho Clinical Diagnostics may reimburse attendees for their reasonable travel and lodging expenses associated with attendance at product training meetings. Product training meetings will be conducted in locations conducive to the exchange of information such as educational or conference settings. Where face-to-face or hands-on customer training is reasonably necessary for the safe and effective use of Ortho Clinical Diagnostics' medical device products is required, Ortho Clinical Diagnostics may provide training at company facilities, at independent teaching centers such as medical institutions, or in other appropriate clinical settings.

### **Policy on Business Meals**

Ortho Clinical Diagnostics may occasionally offer a modest meal, consistent with the standards of the AdvaMed Code as part of an educational presentation or a business discussion. Venues that feature entertainment or recreation, and attendance by spouses or guests, are not permitted. Modesty is to be judged by local standards, but in general cost of meals with customers should not exceed \$25 for breakfast, \$50 for lunch or \$125 for dinner.

### **Policy on the Provision of Educational and Practice-Related Items**

On occasion, Ortho Clinical Diagnostics representatives may provide items that benefit patients or serve a genuine educational function for Health Care Professionals, consistent with the standards of the AdvaMed Code

Ortho Clinical Diagnostics has established an annual limit of \$1500 for meals and educational items as the aggregate value of the items or activities that may be provided to California health care professionals pursuant to the requirements of Cal. Health & Safety Code § 119402 (S.B. 1765).

### **Policy Prohibiting Entertainment**

It is the policy of Ortho Clinical Diagnostics not to provide Entertainment (e.g. sporting events, golf outings, concerts, hunting, etc.) to customers.

## **2. Assigned Compliance Officer**

Ortho Clinical Diagnostics has appointed a Health Care Compliance Officer. Our Health Care Compliance Officer has been empowered with appropriate authority to exercise independent judgment and has free and unencumbered access to senior management.

Ortho Clinical Diagnostics has appointed a Health Care Compliance Committee. The committee is comprised of the company's Health Care Compliance Officer and members of the company's management team. The Health Care Compliance Committee is the Health Care Compliance leadership team.

## **3. Training.**

Ortho Clinical Diagnostics has an annual Health Care Compliance training process that includes testing and annual certification of appropriate employees. The training covers applicable guidelines governing our compliance program. Employees are also trained on the consequences of failure to comply with the requirements of the company's compliance program.

## **4. Communication.**

Ortho Clinical Diagnostics encourages open and candid discussion between management and employees regarding any compliance concerns. Ortho Clinical Diagnostics' employees are encouraged to report their concerns to their manager, to the Human Resources Department, to the Law Department or to the company's Health Care Compliance Officer.

## **5. Auditing and Monitoring.**

Ortho Clinical Diagnostics self-assesses and periodically audits its compliance with its policies and procedures.

## **6. Enforcement and Disciplinary Guidelines.**

Ortho Clinical Diagnostics will take disciplinary actions in response to violation of the company's compliance policies or procedures. Ortho Clinical Diagnostics will conduct a fair and diligent investigation of matters that are brought to the company's attention in order to ensure the consistent application of the company's standards.

**7. Responses To Detected Problems and Actions To Correct Issues.**

Ortho Clinical Diagnostics requires a prompt and diligent response to potential violations of the company's compliance program, including its standards regulating the marketing and promotion of our products. Actions in response to detected problems may include improving policies, procedures, training, communication and monitoring or may require disciplinary action to prevent future violations.

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**I. DECLARATION FOR CALIFORNIA COMPLIANCE LAW**

As part of Ortho Clinical Diagnostic's ongoing efforts in the area of compliance, we have developed a Comprehensive Compliance Program that is designed to comply with applicable federal and state laws and industry standards relating to the marketing and promotion of our products. To our knowledge as of the date of this declaration, Ortho Clinical Diagnostics is in compliance with our Comprehensive Compliance Program, as described here, and with California Health & Safety Code sections 119400-119402.

Dated: July 1, 2009