

Approved By: Ken Lee

Policy Number: LEG/003 Rev: Date: 10/12/2014 Dept: Legal

# **California Compliance Policy and Declaration**

# **PURPOSE**

NOTICE: this information is provided pursuant to the requirements of California Health & Safety Code § 119402 (S.B. 1765), which requires certain pharmaceutical and medical device distributors 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.

### **POLICY GUIDELINES**

# 1. INTRODUCTION

Benco Dental 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, Benco Dental 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 Benco Dental's program for compliance with the standards regulating the marketing and promotion of its products.

### 2. OVERVIEW OF CALIFORNIA COMPLIANCE PROGRAM

### 1. Written Policies and Procedures

Benco Dental has written policies to assure substantial compliance with the applicable laws and regulations and standards governing the marketing and promotion of our products. These policies include:

# **Policy on Travel Expense Reimbursement**

Pursuant to the provisions of the ADVAMED industry Code, Benco Dental policy is to only pay for out-of-town travel which is necessary to efficiently deliver Training and Education on Medical Technologies to Health Care Professionals and their staffs. Benco's policy is not to pay for the meals, refreshments, travel, or other expenses for guests of Health Care Professionals who do not have a *bona fide* professional interest in the information being shared at the meeting or event.

### **Policy on Business Meals**

Benco Dental may occasionally offer a modest meal 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.

QAP0100-2 Rev: 1 Page 1 of 3

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

On occasion, Benco Dental representatives may provide items designed primarily for the education of patients or healthcare professionals (for example an anatomical model or medical text) if the items are not of substantial value (\$100 or less) and do not have value to healthcare professionals outside of his or her professional responsibilities and are infrequent.

# Total Annual Dollar Limit for Meals, and Educational or Practice-related Items

Benco Dental, has established an annual limit of \$2,500 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 and Personal Gift**

It is the policy of Benco Dental not to provide Entertainment (e.g. sporting events, golf outings, concerts, hunting, etc.) or personal gifts to customers in California.

### 2. Assigned Compliance Officer

Benco Dental has appointed a Compliance Officer who has been empowered with appropriate authority to exercise independent judgment and has free and unencumbered access to senior management.

Benco Dental has appointed a Compliance Committee. The committee is comprised of the company's Compliance Officer and members of the company's executive management team.

### 3. Training

Benco Dental has an annual training process that includes testing and annual certification of appropriate employees..

#### 4. Communication

Benco Dental encourages open and candid discussion between management and employees regarding any compliance concerns. Benco Dental employees are encouraged to report their concerns to their manager, to Company's Managing Directors, to the Company's Compliance officer and through the company's BencoAlert Compliance Hotline.

### 5. Auditing and Monitoring

Benco Dental self-assesses and periodically audits its compliance with its policies and procedures.

# 6. Enforcement and Disciplinary Guidelines

Benco Dental will take disciplinary actions in response to violation of the company's compliance policies or procedures. Benco Dental 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

Benco Dental 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.

# 3. DECLARATION FOR CALIFORNIA COMPLIANCE LAW

As part of Benco Dental'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, Benco Dental is in compliance with our Comprehensive Compliance Program, as described here, and with California Health & Safety Code sections 119400-119402. To request a copy of this declaration and a summary of Benco Dental's Comprehensive Compliance Program, please call 1-570-602-6819.

Dated: September 17, 2014