

Declaration of Compliance with Marketing Code of Conduct

As part of Align Technology, Inc.'s ongoing efforts in the area of compliance, we have developed and implemented a Marketing Code of Conduct (formerly referred to as the “Comprehensive Compliance Program”) that is designed to comply with applicable federal and state laws as well as industry standards relating to the marketing and promotion of our products to healthcare professionals. To our knowledge, as of the date of this declaration, Align Technology, Inc. is in material compliance with its Marketing Code of Conduct, as described here, and, should they apply, with California Health & Safety Code, Sections 119400-119402, and Commonwealth of Massachusetts Regulations, 105 C.M.R. 970.00, et seq.

Align Technology Marketing Code of Conduct

NOTICE: This information is provided pursuant to the requirements of Cal. Health & Safety Code § 119402, which requires certain pharmaceutical and medical device companies doing business in California to make available their policy for compliance with applicable federal and state laws and industry standards regulating the marketing and promotion of their products to California health care professionals.

I. INTRODUCTION

Align Technology, Inc. ("Align") has established a program designed to help ensure: (1) ethical interactions with health care providers; and (2) promotion and marketing practices that are in compliance in material respects with applicable federal and state laws and industry standards. An overview of Align's Marketing Code of Conduct follows.

II. OVERVIEW OF MARKETING CODE OF CONDUCT

Written Policies and Procedures

Align has developed and implemented a written Marketing Code of Conduct governing the ethical marketing and promotion of our products and interactions with health care providers. Our Marketing Code of Conduct is intended to ensure material compliance with applicable federal, state and industry standards, such as the *Code of Ethics on Interactions with Health Care Professionals*, published by the Advanced Medical Technology Association ("AdvaMed"). This code includes:

III. EDUCATIONAL GRANTS AND RESEARCH GRANTS

Align 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 grant requests are subject to scientific or clinical review prior to funding approval.

IV. MEETINGS AND SALES AND PROMOTIONAL MEETINGS

Align will not, with limited exceptions that are in accordance with nationally recognized standards, reimburse for travel and lodging expenses of attendees at third party educational conferences.

Align may reimburse attendees for their reasonable travel and lodging expenses, and provide modest hospitality, associated with attendance at meetings focused on the education and training in the safe and effective use of Align products and/or in the sale and promotion of Align products involving matters such as product features and sales terms. These meetings are conducted in locations intended to be conducive to the exchange of information such as customer facilities, conference settings or company facilities. Align will not pay for lodging or travel for guests or spouses of attendees.

V. BUSINESS MEALS AND HOSPITALITY

Align may occasionally offer a modest meal and/or reception, typically as part of an educational or product training meeting. These educational or product training meetings do not include entertainment or recreation, and a representative of Align is present for the duration of the meeting. Where possible, these meetings will be held on the health care professional's premises or other location reasonable and conducive for the educational or product training purpose.

VI. PROVISION OF EDUCATIONAL AND PROMOTIONAL ITEMS

On occasion, Align representatives may provide patient or practice-related items. These items will be of reasonable value (generally less than \$100 retail value per item) and not capable of non-educational use.

Gifts of promotional or "reminder" items of nominal value, such as pens, coffee mugs and gift cards, are no longer permitted under Align's policy.

VII. ACTING COMPLIANCE OFFICER

Align's General Counsel acts as Compliance Officer for purposes of this compliance program. Our General Counsel has been empowered with appropriate authority to exercise independent judgment and has free and unencumbered access to senior management.

VIII. EMPLOYEE TRAINING

A critical element of Align's Marketing Code of Conduct is the education and training of our employees on their legal and ethical obligations under applicable healthcare programs as well principles of general science related to the Align device(s). Align is committed to taking necessary steps to effectively communicate our standards and procedures to all affected personnel. The education and training includes new territory sales manager orientation sessions, employee review and certification of acceptance annually of company policies and procedures via an electronic Learning Management System, presentations at bi-annual sales meetings, and frequent regional sales manager conference calls.

Additionally, Align regularly reviews and updates its training programs, as well as identifies additional areas of training on an "as needed" basis. Align also provides targeted training in key risk areas to those employees whose job functions are affected by those risk areas, such as training on the Marketing Code of Conduct for employees in marketing and sales functions.

IX. COMMUNICATION

Align encourages dialogue between management and employees. Our goal is that all employees, when seeking answers to questions or reporting potential instances of legal violations, should know to whom to turn for a meaningful response and should be able to do so without fear of retaliation. Employees are expected to report suspected violations of company policy by contacting the Compliance Officer. Employees may also report potential violations to their manager or to Human Resources.

X. AUDITING AND MONITORING

Align's Marketing Code of Conduct includes ongoing efforts to monitor, audit, and evaluate adherence to its compliance activities, including annual employee certification of acceptance of company policies and procedures via Align's electronic Learning Management System. The nature of our reviews as well as the extent and frequency of our compliance monitoring, auditing, and evaluation varies according to a variety of factors, including new regulatory requirements, changes in business practices, and other considerations.

XI. ENFORCEMENT AND INVESTIGATION

Align's Marketing Code of Conduct strives to ensure that the consequences of violating the law or company policy are clearly understood by its employees and that appropriate, consistent disciplinary action is enforced. Our Marketing Code of Conduct requires the company to evaluate each case and 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 our policies, practices, or internal controls, and take action to prevent future violations.