

FACT SHEET Issued June 12, 2009

ADA Addressing Members' Inquiries Regarding New Align Technology Inc. Proficiency Program

- Align Technology received FDA clearance to market Invisalign in 1998.
- According to the company's recent press release, effective June 1, 2009 every Invisalign dentist in North America is required to start 10 Invisalign cases and complete at least 10 Invisalign-specific continuing education (CE) credits each calendar year to maintain active provider status. The press release further states that the new program is being implemented "to help ensure that Invisalign-trained doctors have the experience and confidence necessary to achieve high quality treatment outcomes for Invisalign patients." Dentists who do not meet the annual case start and CE requirements by December 31, 2009 will not be eligible to submit new Invisalign cases or to use Invisalign marketing resources. <http://investor.aligntech.com/releasedetail.cfm?ReleaseID=387581>
- ADA has received a number of member inquiries about the recent announcement made by Align Technology on implementation of the new "product proficiency program" in North America.
- As a general matter, manufacturers in the United States are free to impose minimum purchase and training requirements for their products and related services.
- The right to freely contract generally permits a company to set participation terms. It's up to the dentist to decide whether or not the terms are acceptable based on his or her practice. Questions concerning contract matters and other specific potential legal issues between a dentist and Align Technology would need to be analyzed with the dentist's personal attorney.
- The ADA will contact the company to relay member concerns with representatives of Align Technology Inc. and will communicate to members any additional information provided.
- ADA members may wish to speak with their Invisalign representatives or Align Technology Inc. directly regarding the Company's new proficiency program. Align Technology Inc. ALGN (Nasdaq) can be reached at 1-408-470-1000.
- Of course, effective oral health outcomes must be based on sound, clinically relevant scientific principles. The contractual issue involved here is separate and distinct from considerations regarding the Invisalign product as a treatment option.
- Dentists are committed to advancing the welfare of their patients, as evidenced in the *ADA Principles of Ethics and Code of Professional Conduct*. The key issue regarding case quotas is an ethical one that is in the dentists' decision-making purview. For some dentists, this may not be an issue and for other dentists it may. The ADA Council on Ethics, Bylaws and Judicial Affairs issued a statement reminding dentists that business obligations do not excuse their ethical duty to put the welfare of their patients first.

Ethical Aspects of Dental Practice Arrangements Statement of the ADA Council on Ethics, Bylaws, and Judicial Affairs

The dental profession is continually challenged today to maintain its high ethical standards in the face of changes in the dental marketplace. The ethical statements subscribed to by the profession place the patient's welfare above any other consideration. Although the method of health care delivery may change, the overriding duty of the dentist will always be to provide quality care in a competent and timely manner.

Dentists who enter into practice arrangements with third parties may be called upon to reconcile the business demands of these arrangements with the needs of their patients. Dentists must not allow these demands to interfere with the patient's right to select a treatment option based on informed consent. Nor should dentists allow such demands to interfere with the free exercise of their professional judgment or their duty to make appropriate referrals if indicated. Dentists are reminded that business obligations do not excuse them from their professional duty to put the patient's welfare first.

Adopted 1/95; revised 6/97; revised 12/99
http://www.ada.org/prof/prac/law/code/ethical_practice.asp