

BILL ANALYSIS

Senate Research Center
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C.S.S.B. 384
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Health & Human Services
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Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Clear aligners are transparent orthodontic braces that align an individual's teeth. These devices can be purchased through dentists or orthodontists after the completion of a dental examination. Additionally, companies sell clear aligners directly to consumers, avoiding the process of consulting a dentist for their opinion. In Texas, these purchases are allowed without prior confirmation of an in-person dental examination.

If a patient that is not a suitable candidate for clear aligners pursues the treatment, they may incur significant damage to their teeth. An in-person exam would demonstrate if clear aligners were an appropriate treatment option. Clear braces may not be an adequate treatment option if an individual has gum disease, short roots, or other dental conditions.

S.B. 384 classifies clear aligners as a medical device, regulated by Chapter 431 of the Health and Safety Code. Further, the bill will ensure that patients are protected from unsafe medical practices by guaranteeing they receive adequate medical supervision. An individual cannot sell clear aligners to a person without having received confirmation that: an in-person examination, a review of dental x-rays, and a prescription from a supervising dentist for the clear aligners was provided. Finally, a dentist must outline the varying treatment options and the risks associated with each treatment, acquiring the patients written consent of this action.

Key Provisions:

- S.B. 384 prohibits the sale of clear aligners unless a dentist confirms a dental examination was conducted, the individual's x-rays were reviewed, and a dentist prescribes clear aligners.
- The bill will require dentists to outline the possible treatment options and risks associated with each treatment, documenting this interaction with the patient's signature.

Committee Substitute Changes:

C.S.S.B. 384 amends the provision prohibiting the sale of a clear aligner unless the expressed requirements are satisfied. In this change, an individual in a contract to sell a clear aligner to a patient cannot deliver the medical device until they have received confirmation that the outlined requirements were fulfilled.

These stipulations were revised to include a review of an individual's medical and dental history. C.S.S.B. 384 also describes the extent of the mandated dental examination, in which a dentist must review a person's mouth, tongue, gums, lips, teeth, jaws, head, and neck.

C.S.S.B. 384 amends the definition of clear aligner to include the services necessary to design and manufacture these devices.

C.S.S.B. 384 amends current law relating to the sale, design, and manufacture of clear aligners.

RULEMAKING AUTHORITY

This bill does not expressly grant any additional rulemaking authority to a state officer, institution, or agency.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Subchapter B, Chapter 431, Health and Safety Code, by adding Section 431.024, as follows:

Sec. 431.024. CLEAR ALIGNERS. (a) Defines "clear aligner" and "dentist."

(b) Prohibits a person from selling a clear aligner to a patient in this state or providing a service related to the design or manufacture of a clear aligner unless the person:

(1) is a dentist who has provided the services prescribed by Subsection (c) to the patient; or

(2) receives written or electronic confirmation from a dentist who has provided the services prescribed by Subsection (c) to the patient.

(c) Prohibits a person from selling a clear aligner or providing a service related to the design or manufacture of a clear aligner to a patient in this state who has not received:

(1) an in-person intraoral dental examination and an examination of the patient's head and neck;

(2) a review of recently performed x-rays, panoramic x-rays, computed tomography, bone imaging scans, or other appropriate diagnostic imaging sufficient to allow the dentist to detect patient conditions that preclude or contraindicate the provision of safe orthodontic treatment, including:

(A) untreated caries;

(B) gingivitis and periodontal disease;

(C) issues with the roots of teeth in the periodontium, including short roots;

(D) the presence of an osseointegrated dental implant or other fixed dental appliance; or

(E) fractured, cracked, or split teeth or roots;

(F) any other oral pathology or condition that precludes orthodontic treatment;

(3) a prescription for a clear aligner issued by:

(A) the dentist who provided the examination described by Subdivision (1) and reviewed the appropriate diagnostic imaging described by Subdivision (2); or

(B) the dentist who:

(i) will conduct and monitor the patient's orthodontic treatment; and

(ii) has either:

(a) received a referral from the patient's dentist described by Paragraph (A); or

(b) requested, received, and maintained clearance for orthodontic treatment from the patient's dentist described by Paragraph (A);

(4) subject to Subsection (d), counsel by a dentist described by Subdivision (3) regarding available orthodontic treatment options and the risks associated with those treatments; and

(5) a review of the patient's medical and dental health histories.

(d) Provides that the required counsel under Subsection (c)(4) is valid only if the patient acknowledges and verifies in writing, with the patient's signature, that the patient has received the counsel. Requires the dentist providing the required counsel to attach and maintain the patient's written acknowledgment of counsel in the patient's file.

(e) Requires a person who sells a clear aligner to a patient or provides a service related to the design or manufacture of a clear aligner to maintain any documents received under Subsection (c) for not less than seven years after the date of sale or provision of services.

SECTION 2. Makes application of Section 431.024, Health and Safety Code, as added by this Act, prospective.

SECTION 3. Effective date: September 1, 2023.