

By: Kolkhorst

S.B. No. 384

A BILL TO BE ENTITLED

AN ACT

relating to the sale of clear aligners.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subchapter B, Chapter 431, Health and Safety Code, is amended by adding Section 431.024 to read as follows:

Sec. 431.024. SALE OF CLEAR ALIGNERS. (a) In this section:

(1) "Clear aligner" means a medical device, excluding a retainer used to keep teeth in a fixed position, that is:

(A) used in orthodontic treatment to gradually move a patient's teeth or jaw and correct a misalignment; and

(B) manufactured to address the patient's unique orthodontic needs.

(2) "Dentist" means a person licensed to practice dentistry in this state under Subtitle D, Title 3, Occupations Code.

(b) A person may not sell a clear aligner to a patient in this state unless the person has received written or electronic confirmation from a dentist that the patient has received:

(1) an intraoral or extraoral dental examination;
(2) a review of new or recently conducted x-rays, panoramic x-rays, computed tomography, bone imaging scans, or other appropriate diagnostic imaging sufficient to allow the dentist to detect conditions in the patient that would preclude or contraindicate the provision of safe orthodontic treatment,

1 including:

2 (A) untreated caries;

3 (B) gingivitis and periodontal disease;

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

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

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

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

10 (A) the dentist who provided the examination
11 described by Subsection (b)(1) and reviewed the appropriate
12 diagnostic imaging described by Subsection (b)(2); or

13 (B) the dentist who:

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

16 (ii) has either:

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

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

22 (4) subject to Subsection (c), counsel by a dentist
23 described by Subdivision (3) regarding available orthodontic
24 treatment options and the risks associated with those treatments.

25 (c) The required counsel under Subsection (b)(4) is valid
26 only if the patient acknowledges and verifies in writing, with the
27 patient's signature, that the patient has received the counsel.

1 The dentist providing the required counsel shall attach and
2 maintain the patient's written acknowledgment of counsel in the
3 patient's file.

4 (d) A person who sells a clear aligner to a patient shall
5 maintain any documents received under Subsection (b) for not less
6 than seven years after the date of sale.

7 SECTION 2. Section 431.024, Health and Safety Code, as
8 added by this Act, applies only to a clear aligner sold on or after
9 the effective date of this Act. A clear aligner sold before the
10 effective date of this Act is governed by the law in effect
11 immediately before the effective date of this Act, and that law is
12 continued in effect for that purpose.

13 SECTION 3. This Act takes effect September 1, 2023.