

A BILL TO BE ENTITLED

AN ACT

relating to the sale, design, and manufacture 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. 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 move a patient's teeth or jaw or correct a misalignment; and

(B) manufactured to address the specific orthodontic needs of an individual patient.

(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 or provide 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) A person may not sell a clear aligner or provide a

1 service related to the design or manufacture of a clear aligner to a
2 patient in this state who has not received:

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

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

10 (A) untreated caries;

11 (B) gingivitis and periodontal disease;

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

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

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

17 or

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

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

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

24 (B) the dentist who:

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

27 (ii) has either:

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

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

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

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

12 (d) The required counsel under Subsection (c)(4) is valid
13 only if the patient acknowledges and verifies in writing, with the
14 patient's signature, that the patient received the counsel. The
15 dentist providing the required counsel shall attach and maintain
16 the patient's written acknowledgment of counsel in the patient's
17 file.

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

23 (f) A dentist may not require a patient to agree to use a
24 particular type of clear aligner as a condition of performing the
25 examination or review described by Subsections (c)(1) and (2).

26 (g) A dentist described by Subsection (c)(3)(A) shall
27 provide any records collected under Subsections (c)(1) and (2) to

1 another dentist in accordance with Section 258.109, Occupations
2 Code, if:

3 (1) disclosure of a dental record is authorized under
4 Subchapter C, Chapter 258, Occupations Code; and

5 (2) the other dentist requests the records.

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

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