By: Johnson, et al. (Senate Sponsor - Campbell) H.B. No. 4070

(In the Senate - Received from the House May 14, 2025; May 21, 2025, read first time and referred to Committee on Health & Human Services; May 26, 2025, reported favorably by the following vote: Yeas 8, Nays 0; May 26, 2025, sent to printer.)

COMMITTEE VOTE

| | Yea | Nay | Absent | PNV |
|---|---|---|---|---|
| Kolkhorst | X | | | |
| Perry | X | | | |
| Blanco | X | | | |
| Cook | X | | | |
| Hall | X | | | |
| Hancock | X | | | |
| Hughes | | | X | |
| Miles | X | | | |
| Sparks | X | | | |

A BILL TO BE ENTITLED
AN ACT

relating to the sale, design, and manufacture of orthodontic devices.

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. ORTHODONTIC DEVICES. (a) In this section:

(1) "Orthodontic device" means any class II or class III medical device, as defined by the United States Food and Drug Administration under 21 U.S.C. Section 360c and 21 C.F.R. Section 860.3, 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 or malposition; 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 an orthodontic device to a patient in this state or provide a service related to the design or manufacture of an orthodontic device 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 an orthodontic device or provide a service related to the design or manufacture of an orthodontic device 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;

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

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

(3) a prescription for an orthodontic device 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) 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 received the counsel. The dentist providing the required counsel shall attach and maintain the patient's written acknowledgment of counsel in the patient's file.

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

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

(g) A dentist described by Subsection (c)(3)(A) shall provide any records collected under Subsections (c)(1) and (c)(2) to another dentist in accordance with Section 258.109, Occupations Code, if:

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

(2) the other dentist requests the records.

SECTION 2. Section 431.024, Health and Safety Code, as added by this Act, applies only to services related to the design or manufacture of an orthodontic device that are provided or an orthodontic device sold on or after the effective date of this Act. Services related to the design or manufacture of an orthodontic device that are provided or an orthodontic device sold before the effective date of this Act are governed by the law in effect immediately before the effective date of this Act, and that law is continued in effect for that purpose.

SECTION 3. This Act takes effect September 1, 2025.

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