

1-1 By: Kolkhorst S.B. No. 384
1-2 (In the Senate - Filed January 12, 2023; February 15, 2023,
1-3 read first time and referred to Committee on Health & Human
1-4 Services; March 20, 2023, reported adversely, with favorable
1-5 Committee Substitute by the following vote: Yeas 8, Nays 1;
1-6 March 20, 2023, sent to printer.)

1-7 COMMITTEE VOTE

	Yea	Nay	Absent	PNV
1-8				
1-9	Kolkhorst	X		
1-10	Perry	X		
1-11	Blanco	X		
1-12	Hall	X		
1-13	Hancock		X	
1-14	Hughes	X		
1-15	LaMantia	X		
1-16	Miles	X		
1-17	Sparks	X		

1-18 COMMITTEE SUBSTITUTE FOR S.B. No. 384 By: Hall

1-19 A BILL TO BE ENTITLED
1-20 AN ACT

1-21 relating to the sale, design, and manufacture of clear aligners.
1-22 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:
1-23 SECTION 1. Subchapter B, Chapter 431, Health and Safety
1-24 Code, is amended by adding Section 431.024 to read as follows:
1-25 Sec. 431.024. CLEAR ALIGNERS. (a) In this section:
1-26 (1) "Clear aligner" means a medical device, excluding
1-27 a retainer used to keep teeth in a fixed position, that is:
1-28 (A) used in orthodontic treatment to move a
1-29 patient's teeth or jaw or correct a misalignment; and
1-30 (B) manufactured to address the specific
1-31 orthodontic needs of an individual patient.
1-32 (2) "Dentist" means a person licensed to practice
1-33 dentistry in this state under Subtitle D, Title 3, Occupations
1-34 Code.
1-35 (b) A person may not sell a clear aligner to a patient in
1-36 this state or provide a service related to the design or manufacture
1-37 of a clear aligner unless the person:
1-38 (1) is a dentist who has provided the services
1-39 prescribed by Subsection (c) to the patient; or
1-40 (2) receives written or electronic confirmation from a
1-41 dentist who has provided the services prescribed by Subsection (c)
1-42 to the patient.
1-43 (c) A person may not sell a clear aligner or provide a
1-44 service related to the design or manufacture of a clear aligner to a
1-45 patient in this state who has not received:
1-46 (1) an in-person intraoral dental examination and an
1-47 examination of the patient's head and neck;
1-48 (2) a review of recently performed x-rays, panoramic
1-49 x-rays, computed tomography, bone imaging scans, or other
1-50 appropriate diagnostic imaging sufficient to allow the dentist to
1-51 detect patient conditions that preclude or contraindicate the
1-52 provision of safe orthodontic treatment, including:
1-53 (A) untreated caries;
1-54 (B) gingivitis and periodontal disease;
1-55 (C) issues with the roots of teeth in the
1-56 periodontium, including short roots;
1-57 (D) the presence of an osseointegrated dental
1-58 implant or other fixed dental appliance;
1-59 (E) fractured, cracked, or split teeth or roots;
1-60 or

2-1 (F) any other oral pathology or condition that
2-2 precludes orthodontic treatment;
2-3 (3) a prescription for a clear aligner issued by:
2-4 (A) the dentist who provided the examination
2-5 described by Subdivision (1) and reviewed the appropriate
2-6 diagnostic imaging described by Subdivision (2); or
2-7 (B) the dentist who:
2-8 (i) will conduct and monitor the patient's
2-9 orthodontic treatment; and
2-10 (ii) has either:
2-11 (a) received a referral from the
2-12 patient's dentist described by Paragraph (A); or
2-13 (b) requested, received, and
2-14 maintained clearance for orthodontic treatment from the patient's
2-15 dentist described by Paragraph (A);
2-16 (4) subject to Subsection (d), counsel by a dentist
2-17 described by Subdivision (3) regarding available orthodontic
2-18 treatment options and the risks associated with those treatments;
2-19 and
2-20 (5) a review of the patient's medical and dental health
2-21 histories.
2-22 (d) The required counsel under Subsection (c)(4) is valid
2-23 only if the patient acknowledges and verifies in writing, with the
2-24 patient's signature, that the patient received the counsel. The
2-25 dentist providing the required counsel shall attach and maintain
2-26 the patient's written acknowledgment of counsel in the patient's
2-27 file.
2-28 (e) A person who sells a clear aligner to a patient or
2-29 provides a service related to the design or manufacture of a clear
2-30 aligner shall maintain any documents received under Subsection (c)
2-31 for not less than seven years after the date of sale or provision of
2-32 services.

2-33 SECTION 2. Section 431.024, Health and Safety Code, as
2-34 added by this Act, applies only to services related to the design or
2-35 manufacture of a clear aligner that are provided or a clear aligner
2-36 sold on or after the effective date of this Act. Services related
2-37 to the design or manufacture of a clear aligner that are provided or
2-38 a clear aligner sold before the effective date of this Act is
2-39 governed by the law in effect immediately before the effective date
2-40 of this Act, and that law is continued in effect for that purpose.

2-41 SECTION 3. This Act takes effect September 1, 2023.

2-42 * * * * *