

2025 Regular Session

HOUSE BILL NO. 412

BY REPRESENTATIVE ROMERO

Prefiled pursuant to Article III, Section 2(A)(4)(b)(i) of the Constitution of Louisiana.

TOBACCO/TOBACCO PRODUCTS: Provides relative to alternative nicotine products

1 AN ACT

2 To amend and reenact R.S. 26:926.1, relative to alternative nicotine products; to provide for
3 submission of marketing approval of alternative nicotine products to the
4 commissioner of the alcohol and tobacco commission; and to provide for related
5 matters.

6 Be it enacted by the Legislature of Louisiana:

7 Section 1. R.S. 26:926.1 is hereby amended and reenacted to read as follows:

8 §926.1. Vapor product and alternative nicotine product directory

9 A. Every vapor product manufacturer ~~and alternative nicotine product~~
10 ~~manufacturer~~ whose products are sold in this state, whether directly or through a
11 wholesale dealer, retail dealer, or similar intermediary or intermediaries, shall
12 execute and deliver on a form prescribed by the commissioner a certification to the
13 commissioner affirming, under penalty of perjury, either of the following:

14 (1) The product was on the market in the United States as of August 8, 2016,
15 and the manufacturer has applied for a marketing order pursuant to 21 U.S.C. 387j
16 for the vapor product or alternative nicotine product by submitting a premarket
17 tobacco product application on or before September 9, 2020, to the United States
18 Food and Drug Administration, hereinafter referred to in this Section as "FDA", and
19 either of the following is true:

20 (a) The premarket tobacco product application for the vapor product or
21 alternative nicotine product remains under review by the FDA.

1 (b) The FDA has issued a no marketing order for the vapor product or
2 alternative nicotine product, but the agency or a federal court has issued a stay order
3 or injunction during the pendency of the manufacturer's appeal of the no marketing
4 order, or the order has been appealed either to the FDA or a challenge to the order
5 filed with a federal court and the appeal or challenge is still pending.

6 (2) The manufacturer has received a marketing order or other authorization
7 under 21 U.S.C. 387j for the vapor product or alternative nicotine product from the
8 FDA.

9 B. Every alternative nicotine product manufacturer whose products are sold
10 in this state, whether directly or through a wholesale dealer, retail dealer, or similar
11 intermediary or intermediaries, shall execute and deliver on a form prescribed by the
12 commissioner a certification to the commissioner affirming, under penalty of
13 perjury, either of the following:

14 (1) The product was on the market in the United States as of April 14, 2022,
15 and the manufacturer has applied for a marketing order pursuant to 21 U.S.C. 387j
16 for the vapor product or alternative nicotine product by submitting a premarket
17 tobacco product application on or before May 14, 2022, to the FDA, and either of
18 the following is true:

19 (a) The premarket tobacco product application for the alternative nicotine
20 product remains under review by the FDA.

21 (b) The FDA has issued a no marketing order for the alternative nicotine
22 product, but the agency or a federal court has issued a stay order or injunction during
23 the pendency of the manufacturer's appeal of the no marketing order, or the order has
24 been appealed either to the FDA or a challenge to the order filed with a federal court
25 and the appeal or challenge is still pending.

26 (2) The manufacturer has received a marketing order or other authorization
27 under 21 U.S.C. 387j for the alternative nicotine product from the FDA.

28 ~~B. C.~~ In addition to the requirements of Subsection A and B of this Section,
29 each manufacturer shall provide a copy of the cover page of the premarket tobacco

1 application with evidence of receipt of the application by the FDA or a copy of the
2 cover page of the marketing order or other authorization issued pursuant to 21 U.S.C.
3 387j, whichever is applicable.

4 ~~C.~~ D. Any manufacturer submitting a certification pursuant to Subsection A
5 of this Section shall notify the commissioner within thirty days of any material
6 change to the certification, including issuance by the FDA of any of the following:

7 (1) A market order or other authorization pursuant to 21 U.S.C. 387j.

8 (2) An order requiring a manufacturer to remove a product from the market
9 either temporarily or permanently.

10 (3) Any notice of action taken by the FDA affecting the ability of the new
11 product to be introduced or delivered into interstate commerce for commercial
12 distribution.

13 (4) Any change in policy that results in a product no longer being exempt
14 from federal enforcement oversight.

15 ~~D.~~ E. The commissioner shall develop and maintain a directory listing all
16 vapor product manufacturers and alternative nicotine product manufacturers that
17 have provided certifications that comply with Subsection A and B of this Section and
18 all products that are listed in those certifications.

19 ~~E.~~ F. The commissioner shall do all of the following:

20 (1) Make the directory available for public inspection on the public website
21 of the office of alcohol and tobacco control.

22 (2) Update the directory as necessary in order to correct mistakes and to add
23 or remove vapor product manufacturers and alternative nicotine product
24 manufacturers or products manufactured by those manufacturers.

25 (3) Send monthly notifications to each wholesale dealer, retail dealer, and
26 manufacturer of vapor products and manufacturer of alternative nicotine products
27 that has qualified or registered with the commissioner, by electronic communication,
28 containing a list of all changes that have been made to the directory in the previous
29 month. In lieu of sending monthly notifications, the commissioner may make the

1 information available in a prominent place on the public website of the office of
2 alcohol and tobacco control.

3 F: G. Notwithstanding Subsection A of this Section, if a vapor product
4 manufacturer or alternative nicotine product manufacturer can demonstrate to the
5 commissioner that the FDA has issued a rule, guidance, or any other formal
6 statement that temporarily exempts a vapor product or alternative nicotine product
7 from the federal premarket tobacco application requirements, the vapor product or
8 alternative product may be added to the directory upon request by the manufacturer
9 if the manufacturer provides sufficient evidence that the vapor product or alternative
10 nicotine product is compliant with the federal rule, guidance, or other formal
11 statement, as applicable.

12 G: H. Each certifying vapor product manufacturer or alternative nicotine
13 product manufacturer shall pay an initial fee of one hundred dollars per product stock
14 keeping unit or SKU to offset the costs incurred by the commissioner for processing
15 the certifications and operating the directory. The commissioner shall collect an
16 annual renewal fee of one hundred dollars per product stock keeping unit or SKU to
17 offset the costs associated with maintaining the directory and satisfying the
18 requirements of this Section. The fees received pursuant to this Section by the
19 commissioner shall be used by the office of alcohol and tobacco control exclusively
20 for processing the certifications and operating and maintaining the directory.

21 H: I. Beginning on the date that the commissioner makes the directory
22 available for public inspection on the public website of the office of alcohol and
23 tobacco control as provided in Subsection E of this Section, a vapor product
24 manufacturer or alternative nicotine product manufacturer who offers for sale a
25 vapor product or alternative nicotine product not listed on the directory is subject to
26 a one thousand dollar daily fine for each vapor product or alternative nicotine
27 product offered for sale in violation of this Section until the offending product is
28 removed from the market or until the offending product is properly listed on the
29 directory.

