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

AN ACT

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

Be it enacted by the Legislature of Louisiana:

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

§926.1. Vapor product and alternative nicotine product directory

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

~~I.~~ J.(1) The sale, possession, or transportation of vapor products or alternative nicotine products not listed on the directory by any person, including a permitted wholesale dealer or retail dealer, shall be subject to provisions of R.S. 47:858, 859, and 860 as if such wholesale dealer or retail dealer did not possess a valid permit.

(2) Each unit of vapor product or alternative nicotine product sold or offered for sale, possessed, or transported shall constitute a separate violation for purposes of Paragraph (1) of this Subsection.

~~J.~~ K. Any other violation of this Section shall result in a fine of five hundred dollars per offense.

~~K.~~ L. The commissioner shall adopt rules for the implementation and enforcement of this Section.

DIGEST

The digest printed below was prepared by House Legislative Services. It constitutes no part of the legislative instrument. The keyword, one-liner, abstract, and digest do not constitute part of the law or proof or indicia of legislative intent. [R.S. 1:13(B) and 24:177(E)]

HB 412 Original 2025 Regular Session Romero

Abstract: Provides that each alternative nicotine product manufacturer provide proof that a copy of the cover page of its premarket tobacco application was submitted on are before April 14, 2022, along with evidence that the product was on the market in the U.S. as of May 14, 2022.

Present law provides that every vapor product manufacturer and alternative nicotine product manufacturer shall execute and deliver a certification detailing certain information to the commissioner of alcohol and tobacco prior to selling its products in the state.

Present law provides that every vapor product manufacturer and alternative nicotine product manufacturer whose products are sold in this state shall deliver a copy of the cover page of its premarket tobacco application indicating that it was submitted to the FDA on are before Sept. 9, 2020, along with evidence that the product was on the market in the U.S. as of Aug. 8, 2016.

Proposed law retains present law with regard to vapor product manufacturers.

Present law provides that every alternative nicotine product manufacturer whose products are sold in this state shall deliver a copy of the cover page of its premarket tobacco application indicating that it was submitted to the FDA on are before May 14, 2022, along with evidence that the product was on the market in the U.S. as of April 14, 2022.

(Amends R.S. 26:926.1)