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HOUSE FLOOR AMENDMENTS

2023 Regular Session

Amendments proposed by Representative Hughes to Engrossed House Bill No. 179 by Representative Wheat

1 AMENDMENT NO. 1

- 2 Delete the set of House Floor Amendments by Representative Wheat (#3135)
- 3 AMENDMENT NO. 2
- 4 On page 1, line 2, after "R.S. 26:911(A)(7)" and before the comma "," insert "and 926"
- 5 AMENDMENT NO. 3
- On page 1, line 6, after "R.S. 26:911(A)(7)" and before "hereby" delete "is" and insert "and
 926 are"
- 8 AMENDMENT NO. 4
- 9 On page 1, line 13, after "products" insert a comma "," and insert "<u>in each case, only if the</u> 10 <u>e-liquid or vapor products contain nicotine from any source</u>,"
- 11 <u>AMENDMENT NO. 5</u>

12 On page 1, at the end of line 19, insert "<u>This paragraph shall not apply to any e-liquid or</u> 13 <u>vapor product that has received a marketing order from the U.S. Food and Drug</u>

- 14 Administration pursuant to 21 U.S.C. 387(j)."
- 15 AMENDMENT NO. 6
- 16 On page 1, after line 20, add the following:
- 17 "§926. Vapor product and alternative nicotine product directory

A. Beginning October 1, 2023, 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 secretary, a certification to the secretary certifying, 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 (FDA); and either of the following is true:

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

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1	(ii) The FDA has issued a no marketing order for the vapor product or
2	alternative nicotine product from the FDA; however, the agency or a federal court
3	has issued a stay order or injunction during the pendency of the manufacturer's
4	appeal of the no marketing order.
5	(2) The manufacturer has received a marketing order or other authorization
6	under 21 U.S.C. §387j for the vapor product or alternative nicotine product from the
7	FDA.
8 9 10 11 12	B. In addition to the requirements of Subsection A 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.
13	C. Any manufacturer submitting a certification pursuant to Subsection A
14	shall notify the secretary within 30 days of any material change to the certification,
15	including issuance by the FDA of any of the following:
16	(1) A market order or other authorization pursuant to 21 U.S.C. §387j.
17 18	(2) An order requiring a manufacturer to remove a product from the market either temporarily or permanently.
19 20 21	(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.
22 23	(4) Any change in policy that results in a product no longer being exempt from federal enforcement oversight.
24	D. The secretary shall develop and maintain a directory listing all vapor
25	product manufacturers and alternative nicotine product manufacturers that have
26	provided certifications that comply with Subsection A and all products that are listed
27	in those certifications.
28	E. The secretary shall do all of the following:
29 30	(1) Make the directory available for public inspection on its website by November 1, 2023.
31	(2) Update the directory as necessary in order to correct mistakes and to add
32	or remove vapor product manufacturers and alternative nicotine product
33	manufacturers or products manufactured by those manufacturers consistent with the
34	requirements of Paragraphs (1) and (2) of this Subsection on a monthly basis.
35	(3) Send monthly notifications to each wholesale dealer, retail dealer, or
36	manufacturer of vapor products and manufacturer of alternative nicotine products
37	that have qualified or registered with the department, by electronic communication,
38	containing a list of all changes that have been made to the directory in the previous
39	month. In lieu of sending monthly notifications, the secretary may make the
40	information available in a prominent place on the department's public website.
41	F. Notwithstanding Subsection A of this Section, if a vapor product
42	manufacturer or alternative nicotine product manufacturer can demonstrate to the
43	secretary that the FDA has issued a rule, guidance, or any other formal statement that
44	temporarily exempts a vapor product or alternative nicotine product from the federal
45	premarket tobacco application requirements, the vapor product or alternative product
46	may be added to the directory upon request by the manufacturer if the manufacturer

provides suffic	cient evidence that the va	apor product or alterna	ative nicotine product is
compliant with	n the federal rule, guida	nce, or other formal s	tatement, as applicable.

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<u>G. Beginning November 1, 2023, or on the date that the department first</u> makes the directory available for public inspection on its website as provided in Subsection F of this Section, whichever is later, 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 dollars 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.

11H. No wholesale dealer or retail dealer shall be permitted to remit tax with12respect to a vapor product or alternative nicotine product unless such vapor product13or alternative nicotine product is listed on the directory, and the sale, possession, or14transportation of such vapor products or alternative nicotine products by any person,15including a permitted wholesale dealer or retail dealer, shall be subject to provisions16of R.S. 47:858. 859, and 860 as if such wholesale dealer or retail dealer did not17possess a valid permit.

- 18 <u>I. Any other violation of this Section shall result in a fine of five hundred</u>
 <u>dollars per offense.</u>
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 J. The secretary shall adopt rules for the implementation and enforcement of

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 this Section."