

1 AN ACT relating to nicotine products.

2 *Be it enacted by the General Assembly of the Commonwealth of Kentucky:*

3 ➔SECTION 1. A NEW SECTION OF KRS 438.305 TO 438.340 IS CREATED
4 TO READ AS FOLLOWS:

5 *(1) Each business entity shall, upon organizational filing or application for*
6 *certificate of authority to the Secretary of State and upon its annual report, state*
7 *whether it is involved in the retail sale of Tobacco Control Act covered products.*

8 *(2) The Secretary of State shall:*

9 *(a) Create a list of the retailers that sell the products identified in this section;*
10 *and*

11 *(b) Share the list of retailers monthly to the Department of Alcoholic Beverage*
12 *Control and the Department of Revenue.*

13 ➔SECTION 2. A NEW SECTION OF KRS 438.305 TO 438.340 IS CREATED
14 TO READ AS FOLLOWS:

15 *The Department of Alcoholic Beverage Control shall:*

16 *(1) Enforce Sections 1 to 8 of this Act;*

17 *(2) On the first day of each month, update and publish online the retailers that are*
18 *involved in the retail sale of the products identified in Section 1 of this Act; and*

19 *(3) Develop, maintain, and utilize a coordinated tobacco noncompliance database*
20 *and reporting system to identify the retailers that have violated Sections 1 to 8 of*
21 *this Act and to publish that information online on the first day of each month.*

22 ➔SECTION 3. A NEW SECTION OF KRS 438.305 TO 438.340 IS CREATED
23 TO READ AS FOLLOWS:

24 *As used in Sections 1 to 8 of this Act:*

25 *(1) "Authorized product" means:*

26 *(a) A Tobacco Control Act covered product for which the manufacturer has*
27 *obtained:*

- 1 1. Authorization from the United States Food and Drug Administration
2 or
3 2. A safe harbor certification;
4 (b) Cigars;
5 (c) Pipe tobacco; or
6 (d) Tobacco Control Act covered products exempt from the substantial
7 equivalence or premarket tobacco product authorization process with the
8 United States Food and Drug Administration due to having been
9 commercially marketed in the United States of America as of February 15,
10 2007;
11 (2) "Cigar" means any roll of tobacco wrapped in leaf tobacco or in any substance
12 containing tobacco, other than a little cigar, or any roll of tobacco which is a
13 cigarette as defined in KRS 138.130;
14 (3) "Pipe tobacco" means any tobacco which, because of its appearance, type,
15 packaging, or labeling, is suitable for use and likely to be offered to or purchased
16 by consumers as tobacco to be smoked in a pipe;
17 (4) (a) "Safe harbor certification" means a certification provided by a
18 manufacturer establishing that a product falls within a safe harbor
19 established by the United States Food and Drug Administration by timely
20 pursuing one (1) of the following paths to market:
21 1. For any nicotine product containing tobacco-derived nicotine that
22 commercially marketed in the United States of America after February
23 15, 2007, but as of March 11, 2011, by submitting a substantial
24 equivalence report, on or before March 11, 2011, to the United States
25 Food and Drug Administration, that:
26 a. Remains under review, but has not received a substantial
27 equivalence authorization; or

- 1 **b. Has been denied substantial equivalence authorization, but**
2 **remains under a stay by the United States Food and Drug**
3 **Administration or continues to be subject to an appeal to or**
4 **review by a court of competent jurisdiction;**
- 5 **2. For any nicotine product containing tobacco-derived nicotine that was**
6 **on the market in the United States of America as of August 8, 2016,**
7 **and submitted a premarket tobacco product application on or before**
8 **September 9, 2020, to the United States Food and Drug**
9 **Administration, that:**
- 10 **a. Remains under review, but has not received either a marketing**
11 **denial order or a marketing grant order;**
- 12 **b. Has received a marketing denial order, but remains under a stay**
13 **by the United States Food and Drug Administration or continues**
14 **to be subject to an appeal to or review by a court of competent**
15 **jurisdiction; or**
- 16 **c. Has had a marketing denial order that has been rescinded by the**
17 **United States Food and Drug Administration or vacated by a**
18 **court of competent jurisdiction; or**
- 19 **3. For any nicotine product containing nontobacco-derived nicotine that**
20 **was on the market in the United States of America as of April 14,**
21 **2022, and submitted a premarket tobacco product application, on or**
22 **before May 14, 2022, to the United States Food and Drug**
23 **Administration, that:**
- 24 **a. Remains under review, but has not received either a marketing**
25 **denial order or a marketing grant order;**
- 26 **b. Has received a marketing denial order, but remains under a stay**
27 **by the United States Food and Drug Administration or continues**

1 to be subject to an appeal to or review by a court of competent
2 jurisdiction; or

3 c. Has had a marketing denial order that has been rescinded by the
4 United States Food and Drug Administration or vacated by a
5 court of competent jurisdiction.

6 (b) Safe harbor certifications shall contain a copy of the first page of the
7 communication from the United States Food and Drug Administration
8 reflecting an acceptance for review or the submission tracking number or, if
9 on appeal, a copy of the first page of the document filed with the applicable
10 agency or court.

11 (c) Safe harbor certifications may be provided and maintained in hard copy or
12 in electronic form;

13 (5) "Tobacco Control Act covered product" means products covered by the Family
14 Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31; and

15 (6) (a) "Unauthorized product" means any Tobacco Control Act covered product
16 that has not been authorized by the United States Food and Drug
17 Administration.

18 (b) "Unauthorized product" does not include a Tobacco Control Act covered
19 product for which:

20 1. The manufacturer has received a marketing grant order or other
21 authorization to market from the United States Food and Drug
22 Administration; or

23 2. The manufacturer has a safe harbor certification.

24 ➔SECTION 4. A NEW SECTION OF KRS 438.305 TO 438.340 IS CREATED
25 TO READ AS FOLLOWS:

26 (1) A manufacturer of Tobacco Control Act covered products shall only sell
27 authorized products.

1 (2) A manufacturer shall provide a safe harbor certification to a wholesaler or
2 retailer when selling a product that has not been authorized by the United States
3 Food and Drug Administration.

4 (3) If the United States Food and Drug Administration or a court of competent
5 jurisdiction takes final action which removes a product from the safe harbor or
6 authorized to market status, the manufacturer shall provide notice of the final
7 action to any wholesaler or retailer which has purchased the product from the
8 manufacturer within thirty (30) days of the final action being taken.

9 (4) It shall be a violation of this section for a manufacturer to provide false or
10 misleading information in a safe harbor certification or other notice to retailers
11 or wholesalers.

12 (5) A manufacturer that violates this section shall be subject to a fine of twenty-five
13 thousand dollars (\$25,000) for a first citation issued for a violation of this section,
14 fifty thousand dollars (\$50,000) for a second citation issued for a violation of this
15 section, and seventy-five thousand dollars (\$75,000) for a third or subsequent
16 citation issued for a violation of this section.

17 ➔SECTION 5. A NEW SECTION OF KRS 438.305 TO 438.340 IS CREATED
18 TO READ AS FOLLOWS:

19 (1) A wholesaler shall not sell:

20 (a) Authorized products to a retailer until the wholesaler verifies that the
21 retailer is not in the tobacco noncompliance database and reporting system;

22 or

23 (b) Unauthorized products.

24 (2) Any wholesaler that violates this section shall be subject to a fine of five thousand
25 dollars (\$5,000) for a first citation issued for a violation of this section and fifteen
26 thousand dollars (\$15,000) for a second or subsequent citation issued for a
27 violation of this section.

1 ➔SECTION 6. A NEW SECTION OF KRS 438.305 TO 438.340 IS CREATED
2 TO READ AS FOLLOWS:

3 *(1) A retailer shall be prohibited from selling authorized products to any person*
4 *under twenty-one (21) years of age.*

5 *(2) It shall be an affirmative defense for a retailer for a violation of selling*
6 *authorized product to a person under twenty-one (21) years of age if the retailer*
7 *meets the standards set forth in KRS 244.080.*

8 *(3) (a) For the first citation issued for a violation of this section, a retailer shall be*
9 *subject to a fine of not less than one hundred dollars (\$100) nor more than*
10 *five hundred dollars (\$500).*

11 *(b) A retailer shall be subject to fine of one thousand dollars (\$1000) for the*
12 *second citation issued for a violation of this section, and a fine of five*
13 *thousand dollars (\$5000) for a third or subsequent citation issued for a*
14 *violation of this section not subject to paragraph (c) of this subsection.*

15 *(c) For any fourth or subsequent citation issued for a violation of this section*
16 *within a two (2) year period, a retailer shall be placed in the tobacco*
17 *noncompliance database and reporting system and lose the ability to sell*
18 *Tobacco Control Act covered products for one (1) year.*

19 *(3) Any retailer with unpaid fines that are more than sixty (60) days overdue shall*
20 *become ineligible to sell Tobacco Control Act covered products until the fines are*
21 *paid.*

22 ➔SECTION 7. A NEW SECTION OF KRS 438.305 TO 438.340 IS CREATED
23 TO READ AS FOLLOWS:

24 *(1) A retailer shall be prohibited from selling unauthorized products to any person.*

25 *(2) Any retailer selling Tobacco Control Act products shall obtain from the*
26 *manufacturer a safe harbor certification. The retailer shall maintain a copy*
27 *thereof at the physical location where the product is being sold.*

- 1 (3) A retailer is not required to obtain a safe harbor certification for Tobacco Control
2 Act products if those products were purchased from a Kentucky-licensed tobacco
3 wholesaler.
- 4 (4) (a) Any retailer that receives a citation issued for a violation of this section
5 shall be subject to a fine of one thousand dollars (\$1,000) for a first
6 violation and five thousand dollars (\$5,000) for a second or subsequent
7 citation issued for a violation not subject to paragraph (b) of this subsection.
- 8 (b) For any third or subsequent citation issued for a violation within a two (2)
9 year period, a retailer shall be placed in the tobacco noncompliance
10 database and reporting system and lose the ability to sell Tobacco Control
11 Act covered products for one (1) year.
- 12 (5) A retailer on the tobacco noncompliance database and reporting system found to
13 be selling Tobacco Control Act covered products that are not authorized products
14 shall be subject to a fine of ten thousand dollars (\$10,000) per unlawful
15 transaction.
- 16 (6) Any retailer with unpaid fines that are more than sixty (60) days overdue shall
17 become ineligible to sell Tobacco Control Act covered products until the fines are
18 paid.
- 19 (7) It shall be an affirmative defense for a retailer for a violation of selling
20 unauthorized product if any of the following exists:
- 21 (a) Official proof that there has been a material change in the status of a
22 product under review by the United States Food and Drug Administration
23 within forty-five (45) days of the issuance of the citation; or
- 24 (b) A safe harbor certification exists onsite at the retail location at the time the
25 citation was issued.

26 ➔SECTION 8. A NEW SECTION OF KRS 438.305 TO 438.340 IS CREATED
27 TO READ AS FOLLOWS:

1 (1) All certified peace officers with general law enforcement authority and
2 investigators of the Department of Alcoholic Beverage Control may issue a
3 uniform citation for a violation of Sections 1 to 8 of this Act.

4 (2) A citation shall not be issued to a minor and an arrest of a minor shall not be
5 made for a violation of Sections 1 to 8 of this Act.

6 (3) (a) All citations issued pursuant to Sections 1 to 8 of this Act shall be reported
7 to and enforced by the Department of Alcoholic Beverage Control.

8 (b) Multiple violations found during one (1) visit shall be reported on a single
9 citation and shall result in one (1) violation for purposes of the penalties set
10 forth in Sections 6 and 7 of this Act.

11 (c) Each violation shall be specific to the physical location in which the
12 violation occurred.

13 ➔Section 9. KRS 241.060 is amended to read as follows:

14 The board shall have the following functions, powers, and duties:

15 (1) To promulgate reasonable administrative regulations governing procedures relative
16 to the applications for and revocations of licenses, the supervision and control of the
17 use, manufacture, sale, transportation, storage, advertising, and trafficking of
18 alcoholic beverages, and all other matters over which the board has jurisdiction.

19 The only administrative regulation that shall be promulgated in relation to the direct
20 shipper license is to establish the license application, as set forth in KRS
21 243.027(4). To the extent any administrative regulation previously promulgated is
22 contrary to the provisions of KRS 13A.120(2), the board shall repeal or amend the
23 administrative regulation as necessary by January 1, 2022. Administrative
24 regulations need not be uniform in their application but may vary in accordance
25 with reasonable classifications;

26 (2) To limit in its sound discretion the number of licenses of each kind or class to be
27 issued in this state or any political subdivision, and restrict the locations of licensed

- 1 premises. To this end, the board may make reasonable division and subdivision of
2 the state or any political subdivision into districts. Administrative regulations
3 relating to the approval, denial, and revocation of licenses may be different within
4 the several divisions or subdivisions;
- 5 (3) To hold hearings in accordance with the provisions of KRS Chapter 13B. The
6 department may pay witnesses the per diem and mileage provided in KRS 421.015;
- 7 (4) To conduct hearings and appeals under KRS 241.150, 241.200, 241.260, 243.470,
8 ~~and 243.520, **438.340, and Sections 1 to 8 of this Act**~~ and render final orders upon
9 the subjects of the hearings and appeals;
- 10 (5) To order the destruction of evidence in the department's possession after all
11 administrative and judicial proceedings are conducted;
- 12 (6) To suspend, revoke, or cancel for cause, after a hearing in accordance with KRS
13 Chapter 13B, any license; and
- 14 (7) To prohibit the issuance of a license for the premises until the expiration of two (2)
15 years from the time the offense was committed if a violation of KRS Chapters 241
16 to 244 has taken place on the premises which the owner knew of or should have
17 known of, or was committed or permitted in or on the premises owned by the
18 licensee.
- 19 ➔Section 10. This Act takes effect January 1, 2025.