

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 6 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 6 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 6 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 2. Exemption from the United States Food and Drug Administration; or
- 3 3. A safe harbor certification;
- 4 (b) Cigar; or
- 5 (c) Pipe tobacco;
- 6 (2) "Cigar" means any roll of tobacco wrapped in leaf tobacco or in any substance
- 7 containing tobacco, other than a little cigar, or any roll of tobacco which is a
- 8 cigarette as defined in KRS 138.130;
- 9 (3) "Pipe tobacco" means any tobacco which, because of its appearance, type,
- 10 packaging, or labeling, is suitable for use and likely to be offered to or purchased
- 11 by consumers as tobacco to be smoked in a pipe;
- 12 (4) (a) "Safe harbor certification" means a certification provided by a
- 13 manufacturer establishing that a product falls within a safe harbor
- 14 established by the United States Food and Drug Administration by timely
- 15 pursuing one (1) of the following paths to market:
- 16 1. For any nicotine product containing tobacco-derived nicotine and was
- 17 on the market in the United States as of August 8, 2016, by submitting
- 18 a substantial equivalence report, or an exemption from substantial
- 19 equivalence request on or before March 11, 2011, to the United States
- 20 Food and Drug Administration, that:
- 21 a. Remains under review, but has not received either a marketing
- 22 denial order or a marketing grant order;
- 23 b. Has received a marketing denial order, but remains under a stay
- 24 by an agency or injunction by a court of competent jurisdiction;
- 25 or
- 26 c. Has had a marketing denial order that has been rescinded by the
- 27 United States Food and Drug Administration or vacated by a

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court of competent jurisdiction;

2. For any nicotine product containing tobacco-derived nicotine and was on the market in the United States as of August 8, 2016, by submitting a premarket tobacco product application, substantial equivalence report, or an exemption from substantial equivalence request on or before September 9, 2020, to the United States Food and Drug Administration, that:

a. Remains under review, but has not received either a marketing denial order or a marketing grant order;

b. Has received a marketing denial order, but remains under a stay by an agency or injunction by a court of competent jurisdiction;
or

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

3. For any nicotine product containing nontobacco-derived nicotine and was on the market in the United States as of April 14, 2022, by submitting a premarket tobacco product application, on or before May 14, 2022, to the United States Food and Drug Administration, that:

a. Remains under review, but has not received either a marketing denial order or a marketing grant order;

b. Has received a marketing denial order, but remains under a stay or injunction by either the agency or a court; or

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

(b) Safe harbor certifications shall contain a copy of the first page of the

1 communication from the United States Food and Drug Administration
2 reflecting an acceptance for review or the submission tracking number or, if
3 on appeal, a copy of the first page of the document filed with the applicable
4 agency or court.

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

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

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

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

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

17 2. The manufacturer has a safe harbor certification.

18 (6)

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

21 (1) A manufacturer of Tobacco Control Act covered products shall only sell
22 authorized products to wholesalers and retailers.

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

26 (3) It shall be a violation of this section for a manufacturer to provide false or
27 misleading information in a safe harbor certification.

1 (4) A manufacturer that violates this section shall be subject to a fine of twenty-five
 2 thousand dollars (\$25,000) for a first violation, fifty thousand dollars (\$50,000)
 3 for a second violation, and seventy-five thousand dollars (\$75,000) for the third
 4 or subsequent violation.

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

7 (1) A wholesaler shall not sell:

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

10 or

11 (b) Unauthorized products.

12 (2) Any wholesaler that violates this section shall be subject to a fine of five thousand
 13 dollars (\$5,000) for a first violation of fifteen thousand dollars (\$15,000) for
 14 second and subsequent violations.

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

17 (1) A retailer shall be prohibited from selling:

18 (a) Unauthorized products to any person; and

19 (b) Authorized products to a person under twenty-one (21) years of age.

20 (2) (a) Any retailer that violates this section shall be subject to a fine of one
 21 thousand dollars (\$1,000) for a first violation and five thousand dollars
 22 (\$5,000) for a second or subsequent violation not subject to paragraph (b) of
 23 this subsection.

24 (b) For any third or subsequent violation within a two (2) year period, a retailer
 25 shall be placed in the tobacco noncompliance database and reporting
 26 system and lose the ability to sell Tobacco Control Act covered products for
 27 one (1) year.

- 1 (3) A retailer on the tobacco noncompliance database and reporting system found to
2 be selling Tobacco Control Act covered products that are not authorized products
3 shall be subject to a fine of ten thousand dollars (\$10,000) per unlawful
4 transaction.
- 5 (4) Any retailer with unpaid fines that are more than sixty (60) days overdue shall
6 become ineligible to sell Tobacco Control Act covered products until the fines are
7 paid.
- 8 (5) It shall be an affirmative defense for a retailer for a violation of selling
9 unauthorized product if any of the following exists:
- 10 (a) Official proof that there has been a material change in the status of a
11 product under review by the United States Food and Drug Administration
12 within forty-five (45) days of the issuance of the citation; or
- 13 (b) A safe harbor certification exists onsite at the retail location at the time the
14 citation was issued.
- 15 (6) Any retailer selling Tobacco Control Act products shall obtain from the
16 manufacturer a safe harbor certification. The retailer shall maintain a copy
17 thereof at the physical location where the product is being sold.
- 18 (7) A retailer is not required to obtain a safe harbor certification for Tobacco Control
19 Act products if those products were purchased from a Kentucky-licensed tobacco
20 wholesaler.
- 21 (8) It shall be an affirmative defense for a retailer for a violation of selling
22 authorized product to a person under twenty-one (21) years of age if the retailer
23 can meet the standards set forth in KRS 244.080.
- 24 (9) All certified peace officers with general law enforcement authority and
25 investigators of the Department of Alcoholic Beverage Control may issue a
26 uniform citation for a violation of Section 1 to 6 of this Act. A citation shall not
27 be issued to a minor and an arrest of a minor shall not be made for a violation of

1 **Sections 1 to 6 of this Act.**

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

4 **(11) Nothing in Sections 1 to 6 of this Act shall affect the provisions of KRS 438.310.**

5 ➔Section 7. KRS 241.060 is amended to read as follows:

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

- 7 (1) To promulgate reasonable administrative regulations governing procedures relative
 8 to the applications for and revocations of licenses, the supervision and control of the
 9 use, manufacture, sale, transportation, storage, advertising, and trafficking of
 10 alcoholic beverages, and all other matters over which the board has jurisdiction.
 11 The only administrative regulation that shall be promulgated in relation to the direct
 12 shipper license is to establish the license application, as set forth in KRS
 13 243.027(4). To the extent any administrative regulation previously promulgated is
 14 contrary to the provisions of KRS 13A.120(2), the board shall repeal or amend the
 15 administrative regulation as necessary by January 1, 2022. Administrative
 16 regulations need not be uniform in their application but may vary in accordance
 17 with reasonable classifications;
- 18 (2) To limit in its sound discretion the number of licenses of each kind or class to be
 19 issued in this state or any political subdivision, and restrict the locations of licensed
 20 premises. To this end, the board may make reasonable division and subdivision of
 21 the state or any political subdivision into districts. Administrative regulations
 22 relating to the approval, denial, and revocation of licenses may be different within
 23 the several divisions or subdivisions;
- 24 (3) To hold hearings in accordance with the provisions of KRS Chapter 13B. The
 25 department may pay witnesses the per diem and mileage provided in KRS 421.015;
- 26 (4) To conduct hearings and appeals under KRS 241.150, 241.200, 241.260, 243.470,
 27 ~~and~~ 243.520, **438.340, and Sections 1 to 6 of this Act** and render final orders upon

- 1 the subjects of the hearings and appeals;
- 2 (5) To order the destruction of evidence in the department's possession after all
- 3 administrative and judicial proceedings are conducted;
- 4 (6) To suspend, revoke, or cancel for cause, after a hearing in accordance with KRS
- 5 Chapter 13B, any license; and
- 6 (7) To prohibit the issuance of a license for the premises until the expiration of two (2)
- 7 years from the time the offense was committed if a violation of KRS Chapters 241
- 8 to 244 has taken place on the premises which the owner knew of or should have
- 9 known of, or was committed or permitted in or on the premises owned by the
- 10 licensee.