

1 AN ACT relating to nicotine products.

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

3 ➔Section 1. KRS 438.305 is amended to read as follows:

4 As used in KRS 438.305 to 438.340, unless the context requires otherwise:

- 5 (1) (a) "Alternative nicotine product" means a noncombustible product containing
6 nicotine that is intended for human consumption, whether chewed, absorbed,
7 dissolved, or ingested by any other means.
- 8 (b) "Alternative nicotine product" does not include any product regulated as a
9 drug or device by the United States Food and Drug Administration under
10 Chapter V of the Food, Drug, and Cosmetic Act;
- 11 (2) **"Authorized vapor product" means a vapor product containing nicotine for**
12 **which the manufacturer has obtained:**
- 13 **(a) Authorization from the FDA; or**
- 14 **(b) A safe harbor certification;**
- 15 **(3) "Department" means the Department of Alcoholic Beverage Control;**
- 16 **(4) "FDA" means the United States Food and Drug Administration;**
- 17 **(5)** "Manufacturer" means any person who manufactures or produces tobacco products
18 within or without this Commonwealth;
- 19 ~~(6)~~~~(3)~~ "Nonresident wholesaler" means any person who purchases cigarettes or other
20 tobacco products directly from the manufacturer and maintains a permanent
21 location or locations outside this state at which Kentucky cigarette tax evidence is
22 attached or from which Kentucky cigarette tax is reported and paid;
- 23 ~~(7)~~~~(4)~~ "Proof of age" means a driver's license or other documentary or written
24 evidence of an individual's age;
- 25 ~~(8)~~~~(5)~~ "Resident wholesaler" means any person who purchases at least seventy-five
26 percent (75%) of all cigarettes or other tobacco products purchased by that person
27 directly from the cigarette manufacturer on which the cigarette tax provided for in

1 KRS 138.130 to 138.205 is unpaid, and who maintains an established place of
2 business in this state at which the person attaches cigarette tax evidence or receives
3 untaxed cigarettes;

4 (9) "Retailer" means any person, online or in person, who sells tobacco products,
5 alternative nicotine products, or vapor products to a consumer for any purpose
6 other than resale;

7 (10) "Safe harbor certification":

8 (a) Means a certification provided by a manufacturer establishing that a vapor
9 product:

10 1. Falls within a safe harbor established by the FDA by the
11 manufacturer's timely pursuing the path to market described in
12 subparagraph 2. of this paragraph; and

13 2. Is a nicotine product containing tobacco-derived nicotine that was
14 commercially marketed in the United States as of August 8, 2016, for
15 which the manufacturer submitted a premarket tobacco product
16 application on or before September 9, 2020, to the FDA that:

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

19 b. Has received a marketing denial order, but remains under a stay
20 by the FDA or continues to be subject to an appeal to or review
21 by a court of competent jurisdiction; or

22 c. Has had a marketing denial order that has been rescinded by the
23 FDA or vacated by a court of competent jurisdiction;

24 (b) Shall contain a copy of the first page of the communication from the FDA
25 reflecting an acceptance for review or the submission tracking number or, if
26 on appeal, a copy of the first page of the document filed with the applicable
27 agency or court; and

1 **(c) May be provided and maintained in hard copy or in electronic form;**

2 ~~(11)~~~~(6)~~ "Sample" means a tobacco product, alternative nicotine product, or vapor
3 product distributed to members of the general public at no cost;

4 ~~(12)~~~~(7)~~ "Subjobber" means any person who purchases tobacco products, on which the
5 Kentucky cigarette tax has been paid, from a wholesaler licensed pursuant to KRS
6 138.195, and makes them available to a retail establishment for resale;

7 **(13) "Tobacco noncompliance database and reporting system" means the database of**
8 **retailers that have violated Section 6 or 7 of this Act developed and maintained by**
9 **the department under Section 3 of this Act;**

10 ~~(14)~~~~(8)~~ (a) "Tobacco product" means any cigarette, cigar, snuff, smokeless tobacco
11 product, smoking tobacco, chewing tobacco, and any kind or form of tobacco
12 prepared in a manner suitable for chewing or smoking, or both, or any kind or
13 form of tobacco that is suitable to be placed in a person's mouth. "Tobacco
14 product" also means any product made or derived from tobacco that is
15 intended for human consumption, including any component, part, or accessory
16 of a tobacco product, except for raw materials other than tobacco used in
17 manufacturing any component, part, or accessory of a tobacco product, in
18 accordance with the federal Tobacco Control Act, Pub. L. No. 111-31;

19 (b) "Tobacco product" does not include any alternative nicotine product, vapor
20 product, or product regulated as a drug or device by the United States Food
21 and Drug Administration under Chapter V of the Food, Drug, and Cosmetic
22 Act;~~and~~

23 **(15) "Unauthorized vapor product":**

24 **(a) Means any vapor product that has not been authorized by the FDA; and**

25 **(b) Does not include a vapor product for which the manufacturer has received:**

26 **1. A marketing granted order or other authorization to market from the**
27 **FDA; or**

1 **2. A safe harbor certification; and**

2 ~~(16)~~~~(9)~~ (a) "Vapor product" means any noncombustible product that employs a
 3 heating element, battery, power source, electronic circuit, or other electronic,
 4 chemical, or mechanical means, regardless of shape or size and including the
 5 component parts and accessories thereto, that can be used to deliver vaporized
 6 nicotine or other substances to users inhaling from the device. "Vapor
 7 product" includes but is not limited to any device deemed to be an electronic
 8 nicotine delivery system by the United States Food and Drug Administration,
 9 any electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe,
 10 or similar product or device and every variation thereof, regardless of whether
 11 marketed as such, and any vapor cartridge or other container of a liquid
 12 solution or other material that is intended to be used with or in an electronic
 13 cigarette, electronic cigar, electronic cigarillo, electronic pipe, or other similar
 14 product or device.

15 (b) "Vapor product" does not include any product regulated as a drug or device
 16 by the United States Food and Drug Administration under Chapter V of the
 17 Food, Drug, and Cosmetic Act.

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

20 **(1) Each retailer shall, upon organizational filing or application for certificate of**
 21 **authority to the Secretary of State and upon its annual report, state whether it is**
 22 **involved in the retail sale of authorized vapor products.**

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

24 **(a) Create a list of retailers that sell authorized vapor products; and**

25 **(b) Provide the list of retailers created under paragraph (a) of this subsection to**
 26 **the department and the Department of Revenue on a monthly basis.**

27 ➔SECTION 3. A NEW SECTION OF KRS 438.305 TO 438.340 IS CREATED

1 TO READ AS FOLLOWS:

2 **The department shall:**

3 **(1) (a) Enforce Sections 4, 5, 6, and 7 of this Act; and**

4 **(b) Not enforce Sections 4, 5, and 7 of this Act against manufacturers,**
5 **distributors, and wholesalers of vapor products that are not intended for**
6 **resale in this state;**

7 **(2) On the first day of each month, update and publish online the list of retailers of**
8 **authorized vapor products provided by the Secretary of State under Section 2 of**
9 **this Act; and**

10 **(3) Develop, maintain, and utilize a coordinated tobacco noncompliance database**
11 **and reporting system to:**

12 **(a) Identify the retailers that have violated Section 6 or 7 of this Act; and**

13 **(b) Publish that information online on the first day of each month.**

14 ➔SECTION 4. A NEW SECTION OF KRS 438.305 TO 438.340 IS CREATED

15 TO READ AS FOLLOWS:

16 **(1) A manufacturer of vapor products shall only sell authorized vapor products.**

17 **(2) A manufacturer shall provide an applicable safe harbor certification to a**
18 **wholesaler or retailer when selling a vapor product that has not been authorized**
19 **by the FDA.**

20 **(3) If the FDA or a court of competent jurisdiction takes final action that removes a**
21 **vapor product from safe harbor certification or authorized to market status, the**
22 **manufacturer shall provide notice of the final action to any wholesaler or retailer**
23 **that has purchased the vapor product from the manufacturer within thirty (30)**
24 **days of the final action being taken.**

25 **(4) A manufacturer that provides false or misleading information in a safe harbor**
26 **certification or other notice to retailers or wholesalers violates this section and**
27 **shall be subject to a fine of:**

1 (a) Twenty-five thousand dollars (\$25,000) for a first citation issued for a
2 violation of this section;

3 (b) Fifty thousand dollars (\$50,000) for a second citation issued for a violation
4 of this section; and

5 (c) Seventy-five thousand dollars (\$75,000) for a third or subsequent citation
6 issued for a violation of this section.

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

9 (1) A wholesaler shall not sell:

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

12 or

13 (b) Unauthorized vapor products.

14 (2) Any wholesaler that violates this section shall be subject to a fine of:

15 (a) Five thousand dollars (\$5,000) for a first citation issued for a violation of
16 this section; and

17 (b) Fifteen thousand dollars (\$15,000) for a second or subsequent citation
18 issued for a violation of this section.

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

21 (1) A retailer shall not sell, give away, or distribute an authorized vapor product or
22 tobacco product to any person under twenty-one (21) years of age. A retailer who
23 sells a tobacco product to a person under twenty-one (21) years of age shall be
24 subject to the penalties listed in KRS 438.310(4).

25 (2) (a) A retailer shall have an affirmative defense to a violation of subsection (1)
26 of this section if the sale was induced by the use of false, fraudulent, or
27 altered identification papers or other documents.

1 (b) Evidence to support an affirmative defense under this subsection may be
2 introduced either in mitigation of the violation or as a defense to the
3 violation itself.

4 (3) Any retailer that violates subsection (1) of this section regarding authorized vapor
5 products shall be:

6 (a) Subject to a fine of:

7 1. Not less than one hundred dollars (\$100) nor more than five hundred
8 dollars (\$500) for the first citation issued for a violation of this
9 section;

10 2. One thousand dollars (\$1,000) for the second citation issued for a
11 violation of this section; and

12 3. Five thousand dollars (\$5,000) for a third or subsequent citation
13 issued for a violation of this section that is not subject to paragraph (b)
14 of this subsection; and

15 (b) For a fourth or subsequent citation issued for a violation of this section
16 within a two (2) year period, placed in the tobacco noncompliance database
17 and reporting system and lose the ability to lawfully sell vapor products for
18 one (1) year.

19 (4) Any retailer with unpaid fines under this section that are more than sixty (60)
20 days overdue shall lose the ability to lawfully sell vapor products until the fines
21 are 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 not sell an unauthorized vapor product to any person.

25 (2) Except as provided in subsection (3) of this section, any retailer selling vapor
26 products shall obtain from the manufacturer an applicable safe harbor
27 certification and shall maintain a copy of the certification at the physical location

1 where the vapor product is being sold.

2 (3) A retailer is not required to obtain a safe harbor certification for vapor products
3 if those products were purchased from a Kentucky-licensed resident wholesaler.

4 (4) Any retailer that violates this section shall be:

5 (a) Subject to a fine of:

6 1. One thousand dollars (\$1,000) for the first citation issued for a
7 violation of this section; and

8 2. Five thousand dollars (\$5,000) for a second or subsequent citation
9 issued for a violation of this section; and

10 (b) Placed in the tobacco noncompliance database and reporting system and
11 lose the ability to lawfully sell vapor products for one (1) year for any third
12 or subsequent citation issued for a violation within a two (2) year period.

13 (5) A retailer in the tobacco noncompliance database and reporting system that sells
14 vapor products that are unauthorized vapor products shall be subject to a fine of
15 ten thousand dollars (\$10,000) per unlawful transaction.

16 (6) Any retailer with unpaid fines under this section that are more than sixty (60)
17 days overdue shall lose the ability to lawfully sell vapor products until the fines
18 are paid.

19 (7) A retailer shall have an affirmative defense to a violation of selling an
20 unauthorized vapor product if the retailer can establish:

21 (a) Proof of an official material change in the status of a vapor product under
22 review by the FDA within forty-five (45) days of the issuance of the citation;
23 or

24 (b) A safe harbor certification for the vapor product exists onsite at the retail
25 location at the time the 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 may issue a citation for a violation of Section 4, 5,
 3 6, or 7 of this Act.

4 (2) A citation shall not be issued to a minor, and a minor shall not be arrested, in
 5 connection with a retailer's violation of Section 6 or 7 of this Act.

6 (3) (a) All citations issued pursuant to Sections 4, 5, 6, and 7 of this Act shall be
 7 reported to and enforced by the department.

8 (b) Multiple violations found during one (1) visit shall be reported on a single
 9 citation and shall be considered to be one (1) violation for purposes of the
 10 penalties set 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 438.310 is amended to read as follows:

14 (1) No person shall sell or cause to be sold any tobacco product or^[,] alternative
 15 nicotine product~~[, or vapor product]~~ at retail to any person under the age of twenty-
 16 one (21), or solicit any person under the age of twenty-one (21) to purchase any
 17 tobacco product or^[,] alternative nicotine product~~[, or vapor product]~~ at retail.

18 (2) Any person who sells tobacco products or^[,] alternative nicotine products~~[, or vapor~~
 19 ~~products]~~ at retail shall cause to be posted in a conspicuous place in his or her
 20 establishment a notice stating that it is illegal to sell tobacco products, alternative
 21 nicotine products, or vapor products to persons under age twenty-one (21).

22 (3) Any person selling tobacco products, alternative nicotine products, or vapor
 23 products shall require proof of age from a prospective buyer or recipient if the
 24 person has reason to believe that the prospective buyer or recipient is under the age
 25 of twenty-one (21).

26 (4) A person who violates subsection (1) or (2) of this section shall be subject to a fine
 27 of not less than one hundred dollars (\$100) nor more than five hundred dollars

1 (\$500) for a first violation and a fine of not less than five hundred dollars (\$500)
2 nor more than one thousand dollars (\$1,000) for any subsequent violation. The fine
3 shall be administered by the Department of Alcoholic Beverage Control using a
4 civil enforcement procedure.

5 ➔Section 10. KRS 438.313 is amended to read as follows:

6 (1) No wholesaler, retailer, or manufacturer of cigarettes, tobacco products, or
7 alternative nicotine products,~~[or vapor products]~~ may distribute cigarettes, tobacco
8 products, or alternative nicotine products,~~[or vapor products]~~ including samples
9 thereof, free of charge or otherwise, to any person under the age of twenty-one (21).

10 (2) Any person who distributes cigarettes, tobacco products, or alternative nicotine
11 products,~~[or vapor products]~~ including samples thereof, free of charge or
12 otherwise shall require proof of age from a prospective buyer or recipient if the
13 person has reason to believe that the prospective purchaser or recipient is under the
14 age of twenty-one (21).

15 (3) Any person who violates the provisions of this section shall be fined not less than
16 one thousand dollars (\$1,000) nor more than two thousand five hundred dollars
17 (\$2,500) for each offense. The fine shall be administered by the Department of
18 Alcoholic Beverage Control using a civil enforcement procedure for persons
19 eighteen (18) years of age or older.

20 (4) All peace officers with general law enforcement authority and employees of the
21 Department of Alcoholic Beverage Control may issue a uniform citation, but may
22 not make an arrest, or take a child into custody, for a violation of this section.

23 ➔Section 11. KRS 241.060 is amended to read as follows:

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

25 (1) To promulgate reasonable administrative regulations governing procedures relative
26 to the applications for and revocations of licenses, the supervision and control of the
27 use, manufacture, sale, transportation, storage, advertising, and trafficking of

- 1 alcoholic beverages, and all other matters over which the board has jurisdiction.
- 2 The only administrative regulation that shall be promulgated in relation to the direct
- 3 shipper license is to establish the license application, as set forth in KRS
- 4 243.027(4). To the extent any administrative regulation previously promulgated is
- 5 contrary to the provisions of KRS 13A.120(2), the board shall repeal or amend the
- 6 administrative regulation as necessary by January 1, 2022. Administrative
- 7 regulations need not be uniform in their application but may vary in accordance
- 8 with reasonable classifications;
- 9 (2) To limit in its sound discretion the number of licenses of each kind or class to be
- 10 issued in this state or any political subdivision, and restrict the locations of licensed
- 11 premises. To this end, the board may make reasonable division and subdivision of
- 12 the state or any political subdivision into districts. Administrative regulations
- 13 relating to the approval, denial, and revocation of licenses may be different within
- 14 the several divisions or subdivisions;
- 15 (3) To hold hearings in accordance with the provisions of KRS Chapter 13B. The
- 16 department may pay witnesses the per diem and mileage provided in KRS 421.015;
- 17 (4) To conduct hearings and appeals under KRS 241.150, 241.200, 241.260, 243.470,
- 18 ~~and~~ 243.520, **438.340 and Sections 4, 5, 6, and 7 of this Act** and render final
- 19 orders upon the subjects of the hearings and appeals;
- 20 (5) To order the destruction of evidence in the department's possession after all
- 21 administrative and judicial proceedings are conducted;
- 22 (6) To suspend, revoke, or cancel for cause, after a hearing in accordance with KRS
- 23 Chapter 13B, any license; and
- 24 (7) To prohibit the issuance of a license for the premises until the expiration of two (2)
- 25 years from the time the offense was committed if a violation of KRS Chapters 241
- 26 to 244 has taken place on the premises which the owner knew of or should have
- 27 known of, or was committed or permitted in or on the premises owned by the

1 licensee.

2 ➔Section 12. This Act takes effect January 1, 2025.