### HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

BILL #: CS/CS/HB 1007 Nicotine Dispensing Devices

SPONSOR(S): Commerce Committee and Appropriations Committee. Overdorf and others

TIED BILLS: IDEN./SIM. BILLS: CS/CS/SB 1006

FINAL HOUSE FLOOR ACTION: 105 Y's 5 N's GOVERNOR'S ACTION: Approved

#### **SUMMARY ANALYSIS**

CS/HB 1007 passed the House on March 1, 2024. The bill was amended in the Senate on March 5, 2024, and was returned to the House. The House concurred in the Senate amendment and passed the bill as amended on March 7, 2024.

#### The bill:

- Grants authority to the Attorney General (AG) to create a directory (AG Directory) of all nicotine manufacturers that sell nicotine dispensing devices which the AG has deemed attractive to minors.
- Provides that nicotine dispensing devices that are either single-use or disposable electronic cigarettes, or devices that use sealed, prefilled, and disposable cartridge of nicotine in a solution may be reviewed for inclusion on the AG Directory.
- Sets standards for the AG, and reviewing courts, to use to determine how to evaluate whether a device should be included in the AG Directory and allows review of such determination under the Florida Administrative Procedure Act (APA).
- Prohibits manufacturers, retailers, wholesalers and distributors from selling, shipping, or distributing nicotine dispensing devices that are listed on the AG Directory.
- Requires the Department of Legal Affairs in the Attorney General's Office (Department) to make the AG Directory publicly available on its website by January 1, 2025.
- Provides that the AG Directory determination does not apply to a nicotine dispensing device that has received a Federal Food and Drug Administration (FDA) marketing granted order.
- Allows retailers and wholesalers holding a nicotine dispensing device which is on the AG Directory 60 days to sell or remove the product before it is considered contraband.
- Allows a nicotine product manufacturer to be fined \$1,000 per day that it offers to sell a nicotine dispensing device that is on the AG Directory in violation of these provisions after March 1, 2025.
- Provides that it is a first-degree misdemeanor for a retailer, a wholesaler, or a distributor who sells, ships, or otherwise distributes a nicotine dispensing device on the AG Directory under certain circumstances.
- Provides that selling, shipping or distributing nicotine dispensing devices on the AG Directory is deemed an unfair and deceptive trade practice.
- Considers nicotine dispensing devices that are on the AG Directory to be contraband, and subject to seizure and destruction by court order under certain circumstances.
- Requires the Department to maintain detailed information and records related to seized nicotine dispensing devices.
- Provides agent of service procedures for a nonresident manufacturer of nicotine dispensing devices under certain circumstances.
- Provides that, in addition to current misdemeanor offenses for selling a nicotine products to a person under 21, any person who sells a nicotine product to a person under 21 for a third or subsequent time at any time after the first violation commits a third-degree felony.

The bill may have an indeterminate fiscal impact on state government and the private sector.

The bill was approved by the Governor on April 26, 2024, ch. 2024-127, L.O.F., and will become effective on July 1, 2024.

# I. SUBSTANTIVE INFORMATION

# A. EFFECT OF CHANGES:

# **Current Situation**

## **Federal Regulation of Tobacco Products**

The Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act) gives the U.S. Food and Drug Administration (FDA) authority to regulate the manufacture, distribution, and marketing of tobacco products to protect the public health. The Tobacco Control Act provides advertising and labeling guidelines, provides standards for tobacco products, and requires face-to-face transactions for tobacco sales with certain exceptions.<sup>1</sup>

On August 8, 2016, the FDA extended the definition of "tobacco products" regulated under the Act to **include electronic nicotine delivery systems** (ENDS). ENDS include e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers and electronic pipes. Additionally, the definition of tobacco products includes components and parts such as e-liquids, tanks, cartridges, pods, wicks, and atomizers. On April 14, 2022, the FDA's authority was further expanded to include tobacco products containing nicotine from any source, including synthetic nicotine.<sup>2</sup>

Federal law preempts states from providing additional or different requirements for tobacco products in regards to "standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products." However, federal law explicitly preserves the right of states, or any political subdivision of a state, to enact laws, rules, regulations or other measures related to prohibiting the sale, distribution, possession, exposure to, access to, advertising and promotion of tobacco products which are more stringent than federal requirements.<sup>3</sup>

## Registration by Manufacturers

Under federal law, manufacturers<sup>4</sup> are required initially, and annually thereafter, to register the name<sup>5</sup>, places of business, and all such establishments of that manufacturer in any State with the FDA.<sup>6</sup> These manufacturers are required to register any additional places which they own or operate and start to manufacture, prepare, compound, or process a tobacco product or tobacco products.<sup>7</sup>

FDA Premarket Review Application Process for Tobacco Products<sup>8</sup>

<sup>&</sup>lt;sup>1</sup> Federal Food, Drug, and Cosmetic Act, 21 USC § 351 et seq; 15 U.S.C. s. 1333, s. 1335; 21 U.S.C. s. 387g, s. 387f.

<sup>&</sup>lt;sup>2</sup> "NTN is the term used to describe nicotine that did not come from a tobacco plant. NTN includes 'synthetic' nicotine." U.S. Food and Drug Administration. *Regulation and Enforcement of Non-Tobacco Nicotine (NTN) Products*, U.S. Food and Drug Administration, <a href="www.fda.gov/tobacco-products/products-ingredients-components/regulation-and-enforcement-non-tobacco-nicotine-ntn-products">www.fda.gov/tobacco-products/products-ingredients-components/regulation-and-enforcement-non-tobacco-nicotine-ntn-products</a> (last visited Jan. 19, 2024).

<sup>&</sup>lt;sup>3</sup> 21 U.S.C. § 387p.

<sup>&</sup>lt;sup>4</sup> "The term 'manufacture, preparation, compounding, or processing' shall include repackaging or otherwise changing the container, wrapper, or labeling of any tobacco product package in furtherance of the distribution of the tobacco product from the origin al place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user." 21 USCA § 387e(a)(1).

<sup>&</sup>lt;sup>5</sup> "The term 'name' shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation." 21 USCA § 387e(a)(2).

<sup>&</sup>lt;sup>6</sup> 21 USCA § 387e(b)(c).

<sup>&</sup>lt;sup>7</sup> 21 USCA § 387e(d).

<sup>&</sup>lt;sup>8</sup> See generally, 21 U.S.C. § 387j.

Before a new tobacco product<sup>9</sup> can be distributed into interstate commerce, the manufacturer is required to submit a marketing application to the FDA and receive authorization. <sup>10</sup> These applications are reviewed by the FDA to determine whether the product meets the proper requirements to receive marketing authorization. Marketing authorization can be achieved through a Premarket Tobacco Product Application (PMTA), Substantial Equivalence (SE) Report, or Exemption from Substantial Equivalence Request (EX REQ).<sup>11</sup> The FDA may issue a marketing granted order, temporarily suspend a marketing order, withdraw a marketing granted order, or issue a marketing denial order.<sup>12</sup> Preexisting tobacco products were required to submit marketing applications to the FDA and receive authorization by a particular date depending on the kind of tobacco product. A tobacco manufacturer may challenge the FDA's marketing denial.<sup>13</sup> Manufactures must hold onto records that show their tobacco products are legally on the market.

An applicant may submit a PMTA to demonstrate that a new tobacco product meets the requirements to receive a marketing granted order. The PMTA must contain certain information for the FDA to ascertain whether there are any applicable grounds for a marketing denial order. A PMTA must demonstrate the new tobacco product would be appropriate for the protection of the public health and takes into account the increased or decreased likelihood that existing users of tobacco products will stop using such products, as well as the increased or decreased likelihood that those who do not use tobacco products will start using such products.

A SE Report can be submitted by the tobacco manufacturer to seek an FDA substantially equivalent order. The applicant must provide information on the new tobacco product's characteristics and compare its characteristics to another tobacco product.<sup>17</sup> The SE Report must contain certain information to allow the FDA to determine whether the new tobacco product is substantially equivalent to a tobacco product that was commercially marketed in the United States as of February 15, 2007.<sup>18</sup>

On the other hand, FDA may exempt from the requirements relating to the demonstration that a tobacco product is substantially equivalent tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive if certain conditions are met. An EX REQ from the requirement of showing a substantial equivalence may be made only by the manufacturer of a legally marketed tobacco product for a minor modification to that tobacco product.<sup>19</sup>

<sup>&</sup>lt;sup>9</sup> "A 'new tobacco product' is defined as any product not commercially marketed in the U.S. as of Feb. 15, 2007, or the modification of a tobacco product where the modified product was commercially marketed in the U.S. after Feb. 15, 2007." 21 U.S.C. § 387j(1).

<sup>&</sup>lt;sup>10</sup> Market and Distribute a Tobacco Product, U.S. Food and Drug Administration, <u>www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product</u> (last visited Jan. 19, 2024).

<sup>&</sup>lt;sup>11</sup> *Tobacco Products Marketing Orders*, U.S. Food and Drug Administration, <u>www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders</u> (last visited Jan. 19, 2024).

<sup>&</sup>lt;sup>12</sup> 21 U.S.C. § 387j.

<sup>&</sup>lt;sup>13</sup> See Melissa Kress, Bat to Challenge FDA's Marketing Denial Order for Flavored Vuse Products, Convenience Store News, (Oct. 13, 2023), <a href="https://csnews.com/bat-challenge-fdas-marketing-denial-order-flavored-vuse-products">https://csnews.com/bat-challenge-fdas-marketing-denial-order-flavored-vuse-products</a> (last visited Jan. 20, 2024).

<sup>14</sup> 21 CFR 1114.5.

<sup>&</sup>lt;sup>15</sup> The PMTA must include information, such as, full reports of investigations of health risks, effect on the population as a whole, product formulation, statement of compliance and certification, and manufacturing. *See* 21 CFR § 1114.7(a). <sup>16</sup> *Supra* note 9.

<sup>&</sup>lt;sup>17</sup> See 21 CFR 1107.16 and 21 CFR 1107.18.

<sup>&</sup>lt;sup>18</sup> 21 CFR 1107.18.

<sup>&</sup>lt;sup>19</sup> 21 CFR 1107.1.

The FDA receives millions of applications.<sup>20</sup> "To date, the FDA has authorized marketing of 45 products, including 23 tobacco-flavored e-cigarette products and devices."<sup>21</sup> However, the FDA tobacco premarket application process has been challenged. In 2022, the Eleventh Circuit Court of Appeals set aside FDA marketing order denials as arbitrary and capricious<sup>22</sup> because FDA failed to consider relevant factors in evaluating the applications submitted by the six tobacco companies.<sup>23</sup> In 2024, the Fifth Circuit Court of Appeals stated in reference to the tobacco premarketing application process, that "[o]ver several years, the Food and Drug Administration sent manufacturers of flavored ecigarette products on a wild goose chase."<sup>24</sup>

# Florida Regulation of Tobacco and Nicotine Products

The Division of Alcoholic Beverages and Tobacco (Division) within the Department of Business and Professional Regulation (DBPR) is the state agency responsible for the regulation and enforcement of tobacco products under part I of Ch. 569, F.S., and nicotine products under part II of Ch. 569, F.S. Under Florida law, tobacco products and nicotine products have different definitions. This differs from federal law where tobacco products include nicotine products.

# Regulation of Tobacco Products

"Tobacco products" include loose tobacco leaves, and products made from tobacco leaves, in whole or in part, and cigarette wrappers, which can be used for smoking, sniffing, or chewing.<sup>25</sup>

Section 210.25(11), F.S., relating to the tax on tobacco products other than cigarettes or cigars, defines the term "tobacco products" differently as "loose tobacco suitable for smoking; snuff; snuff flour; cavendish; plug and twist tobacco; fine cuts and other chewing tobaccos; shorts; refuse scraps; clippings, cuttings, and sweepings of tobacco, and other kinds and forms of tobacco prepared in such manner as to be suitable for chewing."

"Tobacco products" in either definition does not include nicotine products or nicotine dispensing devices.

Under Section 210.01, F.S.:

"Wholesale dealer" means any person located inside or outside this state who sells cigarettes<sup>26</sup> to retail dealers or other persons for purposes of resale only. Such term shall not include any cigarette

<sup>&</sup>lt;sup>20</sup> "FDA Makes Determinations on More than 99% of the 26 Million Tobacco." U.S. Food and Drug Administration, <a href="https://www.fda.gov/tobacco-products/ctp-newsroom/fda-makes-determinations-more-99-26-million-tobacco-products-which-applications-were-submitted">www.fda.gov/tobacco-products/ctp-newsroom/fda-makes-determinations-more-99-26-million-tobacco-products-which-applications-were-submitted</a> (last visited Jan. 24, 2024).

<sup>&</sup>lt;sup>21</sup> "Premarket Tobacco Product Marketing Granted Orders", U.S. Food and Drug Administration, (updated as of Jan. 9, 2024), <a href="https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders">www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders</a> (last visited Jan. 24, 2024).

<sup>&</sup>lt;sup>22</sup> Arbitrary and capricious means "founded on prejudice or preference rather than on reason or fact." ARBITRARY, Black's Law Dictionary (11th ed. 2019); see also, "...[A]n agency action is lawful only if it rests on a consideration of the relevant factors. An agency rule would be arbitrary and capricious if the agency ... entirely failed to consider an important aspect of the problem." Bidi Vapor LLC v. U.S. Food & Drug Admin., 47 F.4th 1191, 1202 (11th Cir. 2022).

<sup>&</sup>lt;sup>23</sup> See, Bidi Vapor LLC v. U.S. Food & Drug Admin., 47 F.4th 1191, 1205 (11th Cir. 2022) (where 6 tobacco companies included their proposed marketing and sales-access restrictions in their application, and the FDA marketing denial orders specifically stated that it did not consider the marketing or sales-access-restriction plans in the companies' applications.).

<sup>&</sup>lt;sup>24</sup> Wages & White Lion Investments, L.L.C. v. Food & Drug Admin., 90 F.4th 357 (5th Cir. 2024) (the court held that the FDA's denial of marketing orders was arbitrary and capricious because FDA failed to give manufacturers fair notice of the rules, did not explain or admit a change in position regarding application requirements, and disregarded the tobacco manufacturers' good faith reliance on previous FDA guidance).

<sup>&</sup>lt;sup>25</sup> S. 569.002(6), F.S.

<sup>&</sup>lt;sup>26</sup> "Cigarette" means any roll for smoking, except one of which the tobacco is fully naturally fermented, without regard to the kind of tobacco or other substances used in the inner roll or the nature or composition of the material in which the roll is wrapped, which is

manufacturer, export warehouse proprietor, or importer with a valid permit <sup>27</sup>if such person sells or distributes cigarettes in this state only to dealers who are agents and who hold valid and current permits under s. 210.15, F.S. or to any cigarette manufacturer, export warehouse proprietor, or importer who holds a valid and current permit under 26 U.S.C. s. 5712.<sup>28</sup>

"Distributing agent" means every person, firm or corporation in this state who acts as an agent for any person, firm or corporation outside or inside the state by receiving cigarettes in interstate or intrastate commerce and storing such cigarettes subject to distribution or delivery upon order from said principal to wholesale dealers and other distributing agents inside or outside this state.<sup>29</sup>

Cigarette and Tobacco Product Wholesalers, Distributors, and Manufacturers

A person must obtain a permit from the Division in order to distribute tobacco products, not including cigarettes or cigars. A person must obtain a permit for each place of business. The fee for such permit is \$25.30

A person must obtain a cigarette permit from the Division in order to import, export, manufacture, deal at wholesale, or distribute cigarettes in the state. A person must obtain a permit for each place of business in the state or its principal place of business if the person does not have a business in this state. The fee for such permit is \$100. The Division may only issue permits to persons who are 18 years or older or corporations with officers who are 21 years or older.<sup>31</sup>

### Retail Tobacco Product Dealers

In order to sell tobacco products at retail or operate a tobacco product vending machine in Florida, a person must obtain a retail tobacco products dealer permit from the Division. A tobacco products dealer permit holder is allowed to sell nicotine products and nicotine dispensing devices, in addition to tobacco products. A person must obtain a permit for each place of business or premises where tobacco products are sold. Any person who owns, leases, furnishes, or operates a vending machine that dispense tobacco products must also obtain a permit for each machine. The fee for such permit is \$50.32 The Division may only issue permits to persons who are 21 years or older or corporations with officers who are 21 years or older.33

Anyone who deals in tobacco products at retail or allows a vending machine on the premises without a permit is subject to a \$500 fine.<sup>34</sup>

DBPR is required to submit an annual report to the Governor and Legislature regarding the enforcement of tobacco products, including:<sup>35</sup>

- The number and results of compliance visits by the Division;
- The number of violations for failure of a retailer to hold a valid license;
- The number of violations for selling tobacco products to anyone under the age of 21 and the results of administrative hearings on such violations; and
- The number of people under the age of 21 cited, including sanctions imposed as a result of such citation, for misrepresenting their age, purchasing tobacco products underage, and misrepresenting military service for the purpose of obtaining tobacco products underage.

made wholly or in part of tobacco irrespective of size or shape and whether such tobacco is flavored, adulterated or mixed with any other ingredient. S. 210.01(1), F.S.

<sup>&</sup>lt;sup>27</sup> 26 U.S.C. s. 5712.

<sup>&</sup>lt;sup>28</sup> S. 210.01(6), F.S.

<sup>&</sup>lt;sup>29</sup> S. 210.01(14), F.S.

<sup>&</sup>lt;sup>30</sup> S. 210.40, F.S.

<sup>&</sup>lt;sup>31</sup> S. 210.15, F.S.

<sup>&</sup>lt;sup>32</sup> S. 569.003, F.S.

<sup>&</sup>lt;sup>33</sup> S. 569.003, F.S.

<sup>&</sup>lt;sup>34</sup> S. 569.005, F.S.

<sup>&</sup>lt;sup>35</sup> S. 569.19, F.S.

Florida also has an excise tax and surcharge on cigarettes and other tobacco products, not including cigars. The tax and surcharge for cigarettes is \$0.1695 to \$0.42375 per pack and a surcharge of \$0.50 to \$1.25 per pack depending on the number of cigarettes in the pack. The excise tax for tobacco products is 25 percent of the wholesale price and the surcharge is 60 percent of the wholesale price. There is no excise tax or surcharge for nicotine products or nicotine dispensing devices.<sup>36</sup>

# Nicotine Regulations

"Nicotine dispensing device" means any product that employs an electronic, chemical, or mechanical means to produce vapor or aerosol from a nicotine product, including, but not limited to, an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or other similar device or product, any replacement cartridge for such device, and any other container of nicotine in a solution or other form intended to be used with or within an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or other similar device or product.

"Nicotine product" means any product that contains nicotine, including liquid nicotine, which is intended for human consumption, whether inhaled, chewed, absorbed, dissolved, or ingested by any means.

## Retail Nicotine Product Dealers

The regulations for the sale of nicotine products and nicotine dispensing devices mirror the regulations for the sale of tobacco products. However, nicotine products **do not** have a tax or permit fee similar to tobacco products.

# **Advertising to Minors**

### Hemp

In 2023, the Governor signed Senate Bill 1676, which only allows the distribution and sale of hemp<sup>37</sup> in Florida if the product is distributed and sold in a container that is not "attractive to children." Under this law, "attractive to children" means manufactured in the shape of humans, cartoons, or animals; manufactured in a form that bears any reasonable resemblance to an existing candy product that is familiar to the public as a widely distributed, branded food product such that a product could be mistaken for the branded product, especially by children; or containing any color additives.<sup>38</sup>

### Lawsuits Against Juul Labs, Inc.

Juul Labs faced over 5,000 lawsuits, with most alleging the company engaged in deceptive marketing or failed to warn about the risks of its product. Multiple states also sued Juul Labs, Inc. (Juul) <sup>39</sup> regarding its marketing of its nicotine products. <sup>40</sup>

However, many of these lawsuits have been settled:

 In April 2023, Juul settled with six states and the District of Columbia for \$462 million for how products were marketed.

<sup>&</sup>lt;sup>36</sup> Ss. 210.011, 210.02, 210.276, and 210.30, F.S.; DBPR, Alcoholic Beverages & Tobacco – Tax & Reporting Information For Licensees, <a href="http://www.myfloridalicense.com/DBPR/alcoholic-beverages-and-tobacco/tax-and-reporting-information-for-licensees/#1510753842753-25986d10-086">http://www.myfloridalicense.com/DBPR/alcoholic-beverages-and-tobacco/tax-and-reporting-information-for-licensees/#1510753842753-25986d10-086</a> (last visited Jan. 20, 2024).

<sup>&</sup>lt;sup>37</sup> "Hemp" means the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof, and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers thereof, whether growing or not, that has a total delta-9-tetrahydrocannabinol concentration that does not exceed 0.3 percent on a dry-weight basis, with the exception of hemp extract, which may not exceed 0.3 percent total delta-9-tetrahydrocannabinol on a wet-weight basis. S. 581.217(3)(e), F.S.

<sup>&</sup>lt;sup>38</sup> S. 581.217(3)(a), F.S.

<sup>&</sup>lt;sup>39</sup>Juul manufactures electronic cigarettes and other accessories.

<sup>&</sup>lt;sup>40</sup> Christy Bieber, *Juul Lawsuit Update March* 2024, Forbes Magazine (Nov. 1, 2023), <a href="www.forbes.com/advisor/legal/product-liability/juul-lawsuit-update/">www.forbes.com/advisor/legal/product-liability/juul-lawsuit-update/</a> (last visited Mar. 12, 2024).

- In January 2023, U.S. District Judge William Orrick in San Francisco approved a \$255 million settlement resolving the class action alleging the company deceptively marketed the product, downplaying addiction and marketed to minors.
- In December 2022, Juul agreed to a settlement reportedly between \$1.2 and \$1.7 billion with 10,000 plaintiffs in 5,000 cases in California in regard to marketing and addiction to the product. The deal involves school district plaintiffs. Judge Orrick has yet to approve this but did call it fair and reasonable.
- In September 2022, Juul tentatively agreed to pay more than \$438 million to settle
  investigations by nearly three dozen states over how it may have marketed to teenagers. The
  company did not admit any wrongdoing.

On October 4, 2023, Florida Attorney General Ashley Moody filed a lawsuit against Juul alleging that it was intentionally marketing its products to minors. According to the complaint, Juul relentlessly marketed to underage users with launch parties, advertisements using trendy-looking and young models, social media posts, and free samples. It created a technology-focused, sleek design that could be easily concealed and sold its product in flavors known to be attractive to underage users. Juul also manipulated the chemical composition of its product to make the vapor less harsh on the throats of the young and inexperienced consumers it courted. To preserve its young customer base, Juul relied on age-verification techniques that it knew were ineffective. Juul indicated in a response that AG Moody had decided against participating in the settlement between the company and 48 other states and territories. It also pointed to steps the company has taken, including ceasing distribution of non-tobacco, non-menthol products in advance of FDA guidance on flavors, halting mass market product advertising, and restructuring our entire company with an emphasis on combating underage use. In part, due to these efforts, we have seen underage use of Juul products cut by 95%."

# **Emergency Rules**

Agencies are authorized to respond to immediate dangers to the public health, safety, or welfare by adopting emergency rules. Emergency rule adoption follows different procedures. The notice of the emergency rule and its text is published in the first available issue of the Florida Administrative Code (FAR). There is no requirement that an emergency rule be published in the FAC. The agency must publish prior to, or contemporaneous with, the rule's promulgation the specific facts and reasons for finding an immediate danger to the public health, safety, or welfare. Emergency rules are effective immediately, or on a date less than 20 days after filing if specified in the rule, but are effective for no longer than 90 days. An emergency rule is not renewable, except when the agency has initiated rulemaking to adopt rules relating to the subject of the emergency rule and either a challenge to the proposed rules has been filed and remains pending or the proposed rule is awaiting ratification by the Legislature. The validity of an emergency rule may be challenged at DOAH subject to an expedited filing and hearing schedule.

<sup>&</sup>lt;sup>41</sup> See Office of the Attorney General. State of Florida, Department of Legal Affairs v. Juul Labs, Inc. Compl., <a href="https://www.myfloridalegal.com/sites/default/files/2023-10/dkt-1-complaint.pdf">https://www.myfloridalegal.com/sites/default/files/2023-10/dkt-1-complaint.pdf</a>. The lawsuit is still pending.

<sup>&</sup>lt;sup>42</sup> WUSF, Health News Florida, *Florida attorney general's lawsuit claims Juul improperly marketed to children*, October 5, 2023, <a href="https://www.wusf.org/courts-law/2023-10-05/florida-attorney-generals-lawsuit-claims-juul-improperly-marketed-to-children">https://www.wusf.org/courts-law/2023-10-05/florida-attorney-generals-lawsuit-claims-juul-improperly-marketed-to-children</a> (last visited Mar. 12, 2024).

 $<sup>^{43}</sup>$  *Id*.

<sup>&</sup>lt;sup>44</sup> S. 120.54(4), F.S.

<sup>&</sup>lt;sup>45</sup> S. 120.54(4)(a)1., F.S.

<sup>&</sup>lt;sup>46</sup> S. 120.54(4)(a)3., F.S.

<sup>&</sup>lt;sup>47</sup> Id.

<sup>&</sup>lt;sup>48</sup> S. 120.54(4)(d), F.S.

<sup>&</sup>lt;sup>49</sup> S. 120.54(4)(c), F.S.

<sup>&</sup>lt;sup>50</sup> *Id*.

<sup>&</sup>lt;sup>51</sup> *Id*.

# Effect of the Bill

## **Definitions**

The bill modifies the definition of "nicotine dispensing device" by providing that "each individual stock keeping unit is considered a separate nicotine product." The bill provides the following definitions:

- "FDA" means the United States Food and Drug Administration.
- "Sell" or "sale" means any sale, transfer, exchange, barter, gift, or offer for sale and distribution, in any manner or by any means whatsoever.
- "Nicotine product manufacturer" means any person or entity that manufactures nicotine products.

# Legislative Intent

The bill provides that information, testings, approvals, or scientific evidence may, from time to time, indicate that certain nicotine dispensing devices have a greater potential to be attractive to and be abused by minors than was evident when such devices were allowed on the market. The bill states that the intent of the Legislature to quickly provide a method to allow Florida to seek removal of such items from the market.

## AG Directory of Nicotine Products Attractive to Minors

The bill empowers the Attorney General (AG) to adopt rules to create a directory which lists nicotine dispensing devices that are attractive to minors.

The bill states that if the nicotine dispensing device has features that are significantly appealing to minors as compared to the legitimate benefits those features offer to lawful users of the product, a nicotine dispensing device is deemed attractive to minors, and the AG shall include it on the directory.

In order to determine whether a nicotine dispensing device is attractive to minors, the AG and the reviewing court must consider:

- Surveys or other data sources indicating that the nicotine dispensing device is being used by minors at a higher rate than other nicotine dispensing devices.
- Complaints, reports, or other information related to the use of a nicotine dispensing device by
  minors from other minors, parents, teachers, school employees, school boards, law
  enforcement officers, retailers, and other industry related officials as compared to other nicotine
  dispensing devices.
- The extent to which the nicotine dispensing device:
  - Is designed to be attractive to minors, such as through the use of bright colors or cartoon characters.
  - Is designed so that it is easy for minors to use and to conceal.
  - Uses or resembles the trade dress of a branded food product, consumer food product, or logo of a food product.
  - o Is marketed in a manner that uniquely appeals to minors.
  - Uses actual copyrights, service marks, or trademarks or fake or actual copyrights, service marks, or trademarks that resemble consumer or food products popular with minors, including the names of candy or cereal products.
- Any reports of physical harm to minors from using the nicotine dispensing device or evidence that the nicotine dispensing device presents unique risks to minors.
- Whether the manufacturer of the nicotine dispensing device submitted a timely filed premarket tobacco product application for the nicotine dispensing device pursuant to 21 103 U.S.C. s. 387j.A decision of the FDA regarding the nicotine dispensing device, if the decision was final and not subject to a stay, by a court or the agency, or subject to a timely petition for supervisory review, and the extent to which the FDA's decision was based on the risks to minors outweighing other benefits of the nicotine dispensing device.

The bill requires the Department of Legal Affairs (DLA) within the Office of the Attorney General to:

- Develop and maintain a directory listing all nicotine product manufacturers that sell nicotine dispensing devices in Florida which the AG has deemed attractive to minors.
- Make such directory publicly available January 1, 2025 on its website.
- Update such directory as necessary.
- Establish a process to provide retailers, distributors, and wholesalers notice of the initial publication of the directory and any changes made to the directory.

The bill states that a nicotine dispensing device may be subject to the AG directory if:

- The nicotine dispensing device is either a single-use or disposable electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or other similar device that is intended to be discarded after use, or
- An electronic cigarette, an electronic cigar, an electronic cigarillo, an electronic pipe, or other similar device that uses a sealed, prefilled, and disposable cartridge of nicotine in a solution.

The bill provides that the following nicotine dispensing devices are **not subject** to the AG directory if:

- It has received a marketing granted order from the FDA 21 U.S.C. s. 387j; or
- It is an electronic cigarette, an electronic cigar, an electronic cigarillo, an electronic pipe, or
  other similar device that is an open system where a consumer fills a vial or other container with
  nicotine in a solution.

# AG's Rulemaking Authority and Review of Determination

The bill requires that AG's rulemaking to be in accordance with the procedural requirements of the APA, including the emergency rule provisions, except that the petition to initiate rulemaking subsection under s. 120.54(7), F.S. does not apply.

The AG's determination to include a nicotine dispensing device in the directory is subject to review under the APA.

# Retailers, Wholesalers, Distributors, and Nicotine Product Manufacturers

The bill provides that when a nicotine dispensing device is added to the directory, each retailer, wholesaler, and distributor holding nicotine dispensing devices for eventual sale in Florida has 60 days from the day such product is added to the directory to sell the product or remove the product from its inventory. After the 60 days has expired, the product identified in the directory is contraband, and is subject to seizure and destruction.

### Potential Fine for Nicotine Product Manufacturer

The bill states that beginning on March 1, 2025, or on the date DLA first makes the directory publicly available on its website, whichever is later, a nicotine product manufacturer that offers a nicotine dispensing device which is listed on the AG directory for sale in Florida is subject to a fine of \$1,000 per day for each individual nicotine dispensing device offered for sale until the offending product is removed from the market or until the offending product is no longer listed on the directory.

# Violations

The bill prohibits a nicotine product manufacturer, a retail nicotine products dealer, a wholesaler, or a distributor from selling, shipping, or otherwise distribute nicotine dispensing devices for retail sale to consumers in Florida that is listed on the AG directory. Any person who knowingly sells, ships, or receives, a nicotine dispensing device listed on the AG directory commits a first-degree misdemeanor.

The bill states that a violation of this part is deemed an unfair and deceptive trade practice that can only be enforced by the DLA. The bill allows the DLA, when it has reason to believe that a person is selling devices that are listed on the AG directory, or bring an action against such person for an unfair or deceptive act or practice.<sup>52</sup>

In addition to the other remedies provided in Part II of Ch. 569, F.S. concerning nicotine products, the DLA is allowed to collect a civil penalty of up to \$1,000 per nicotine dispensing device sold, shipped, or otherwise distributed.

## Seizure and Destruction of Contraband Nicotine Dispensing Devices

The bill declares all nicotine dispensing devices sold in contravention of Ch. 569, F.S., to be contraband. The contraband may be searched and seized per the Florida Contraband Forfeiture Act.

### The bill requires:

- The cost of seizure and destruction of the contraband is to be borne by the person from whom such nicotine dispensing devices are seized.
- Court's having jurisdiction to order the destruction and forfeiture of contraband nicotine dispensing devices:
  - Upon a showing that more likely than not such devices were sold, delivered, possessed, or distributed contrary to any provision of Ch. 569, F.S.
  - Once any APA proceedings under Ch. 120, F.S. related to such devices have been completed.
  - A report by the officer who destroyed the contraband to document and return under oath to the court the following information:
    - The place where the contraband was seized,
    - The kind and quantity of such contraband seized,
    - o The time, place, and manner of destruction of such contraband,

## **DLA Records**

The bill requires the DLA to maintain a full and complete record of all nicotine dispensing devices showing:

- The exact types, kinds, and quantities, and forms of such nicotine devices.
- The persons from whom such nicotine dispensing devices were received, delivered, or destroyed.
- By whose authority such nicotine dispensing devices were received, delivered, or destroyed.
- The dates of the receipt, disposal, or destruction of such nicotine dispensing devices.
  - The bill requires such record to be available for inspection by all persons charged with the enforcement of tobacco and nicotine product laws.

### Agent for Service of Process

The bill requires a nonresident nicotine dispensing device manufacturer that has not registered to do business in Florida as a foreign corporation or business entity to, as a condition precedent to being listed on the nicotine directory, appoint and continually engage without interruption the services of an agent in this state to act as agent for the service of process on whom all process, and any action or proceeding against the manufacturer concerning or arising out of the enforcement of Ch. 569, F.S., may be served in any manner authorized by law.

### The bill:

 Provides that such service constitutes legal and valid service of process on the nonresident manufacturer.

<sup>&</sup>lt;sup>52</sup> For the purposes of bringing an action pursuant to this section, ss. 501.211 and 501.212, F.S. do not apply.

- Requires the nonresident manufacturer to provide the name, address, telephone number, and proof of the appointment and availability of such agent to the Division.
- Requires the nonresident nicotine dispensing device manufacturer to provide notice to the DLA 30 calendar days before termination of the appointment of an agent and further provide proof to the satisfaction of the DLA of the appointment of a new agent at least 5 calendar days before termination of the existing agent.
- Requires, if an agent terminates his or her existing appointment, the manufacturer to notify the DLA of the termination within 5 calendar days and include proof to the satisfaction of the DLA of the appointment of a new agent.
- Requires any manufacturer whose nicotine dispensing devices are sold in this state who has not
  appointed and engaged the services of an agent as required to be deemed to have appointed
  the Secretary of State as manufacturer's agent for service of process.

## Criminal Offense for Selling to Person Under 21

The bill provides that, in addition to current misdemeanor offenses for selling nicotine products to a person under 21, any person who sells a nicotine product to a person under 21 for a third or subsequent time at any time after the first violation commits a third-degree felony.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

## A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The bill establishes new fines and penalties that the DLA may impose. The revenue generated from these penalties will vary each year depending on the number of violations enforced.

2. Expenditures:

Indeterminate.

## B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

# C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Businesses that are selling, manufacturing or distributing nicotine products that the AG has deemed attractive to minors may be subject to fines and penalties under certain circumstances.

### D. FISCAL COMMENTS:

The impact to DLA is indeterminate, however, if after the bill becomes effective and additional resources are needed, DLA may request them as part of the LBR process.