HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 1007 Nicotine Products
SPONSOR(S): Commerce Committee, Appropriations Committee, Overdorf and others
TIED BILLS: **IDEN./SIM. BILLS:** CS/CS/SB 1006

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Regulatory Reform & Economic Development Subcommittee	11 Y, 1 N	Larkin	Anstead
2) Appropriations Committee	19 Y, 9 N, As CS	Helpling	Pridgeon
3) Commerce Committee	16 Y, 0 N, As CS	Larkin	Hamon

SUMMARY ANALYSIS

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.

The bill:

- Provides definitions for “nicotine product manufacturer”, “wholesale nicotine products dealer", and “wholesale nicotine products dealer permit”.
- Requires manufacturers to certify nicotine dispensing devices with the Division and provide evidence that they have sought approval with the Food and Drug Administration (FDA).
- Requires the Division to develop and maintain an online directory that lists:
  - nicotine product manufacturers that sell nicotine dispensing devices in this state; and
  - nicotine dispensing devices certified by those manufacturers with the Division which comply with this requirement.
- Creates a new wholesale nicotine product dealer permit and requires wholesalers who do not have a tobacco permit to register, and only buy products on the directory.
- Authorizes the Division to conduct unannounced inspections of nicotine product manufacturers.
- Provides administrative fines and imposes criminal penalties for violations of certain provisions.
- Mandates retail nicotine product permit holders, other than nicotine manufacturers selling direct to consumers, to purchase only from permitted wholesalers and only purchase registered products.
- Modifies retail nicotine product dealer permit requirements.
- Allows law enforcement to seize and destroy non-registered nicotine products.

The bill may have an indeterminate fiscal impact on state government and the private sector. *See* Fiscal Analysis and Economic Impact Statement.

Except as otherwise provided, the effective date of the bill is October 1, 2024.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED 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.[1]

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.[2]

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.[3]

Registration by Manufacturers

Under federal law, manufacturers[4] are required initially, and annually thereafter, to register the name[5], places of business, and all such establishments of that manufacturer in any State with the FDA.[6] 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.[7]

FDA Premarket Review Application Process for Tobacco Products[8]

Before a new tobacco product[9] can be distributed into interstate commerce, the manufacturer is required to submit a marketing application to the FDA and receive authorization.[10] These applications

[1] 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.
[2] "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, www.fda.gov/tobacco-products/products-ingredients-components/regulation-and-enforcement-non-tobacco-nicotine-ntn-products (last visited Jan. 19, 2024).
[3] 21 U.S.C. § 387p.
[4] "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 original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user." 21 USCA § 387e(a)(1).
[5] "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).
[6] 21 USCA § 387e(b)(c).
[7] 21 USCA § 387e(d).
[8] *See generally*, 21 U.S.C. § 387j.

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).[11] The FDA may issue a marketing granted order, temporarily suspend a marketing order, withdraw a marketing granted order, or issue a marketing denial order.[12] 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.[13] 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.[14] The PMTA must contain certain information[15] 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.[16]

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.[17] 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.[18]

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.[19]

The FDA receives millions of applications.[20] **"To date, the FDA has authorized marketing of 45 products, including 23 tobacco-flavored e-cigarette products and devices."[21]** However, the FDA tobacco premarket application process has been challenged. In 2022, the Eleventh Circuit Court of

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[9] "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).

[10] *Market and Distribute a Tobacco Product*, U.S. Food and Drug Administration, www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product (last visited Jan. 19, 2024).

[11] *Tobacco Products Marketing Orders,* U.S. Food and Drug Administration, www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders (last visited Jan. 19, 2024).

[12] 21 U.S.C. § 387j.

[13] *See* Melissa Kress, *Bat to Challenge FDA's Marketing Denial Order for Flavored Vuse Products*, Convenience Store News, (Oct. 13, 2023), https://csnews.com/bat-challenge-fdas-marketing-denial-order-flavored-vuse-products (last visited Jan. 20, 2024).

[14] 21 CFR 1114.5.

[15] 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).

[16] *Supra* note 9.

[17] *See* 21 CFR 1107.16 and 21 CFR 1107.18.

[18] 21 CFR 1107.18.

[19] 21 CFR 1107.1.

[20] "FDA Makes Determinations on More than 99% of the 26 Million Tobacco." U.S. Food and Drug Administration, www.fda.gov/tobacco-products/ctp-newsroom/fda-makes-determinations-more-99-26-million-tobacco-products-which-applications-were-submitted (last visited Jan. 24, 2024).

[21] "Premarket Tobacco Product Marketing Granted Orders", U.S. Food and Drug Administration, (updated as of Jan. 9, 2024), www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders (last visited Jan. 24, 2024).

Appeals set aside FDA marketing order denials as arbitrary and capricious[22] because FDA failed to consider relevant factors in evaluating the applications submitted by the six tobacco companies.[23] 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 e-cigarette products on a wild goose chase."[24]

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.[25]

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[26] to retail dealers or other persons for purposes of resale only. Such term shall not include any cigarette manufacturer, export warehouse proprietor, or importer with a valid permit [27]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.[28]

"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

[22] 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).
[23] *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.).
[24] *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).
[25] S. 569.002(6), F.S.
[26] "'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 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.
[27] 26 U.S.C. s. 5712.
[28] S. 210.01(6), F.S.

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.[29]

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.[31]

Retail Tobacco Product Dealers

In order to sell tobacco products at retail or operate a tobacco products 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 machines 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.[34]

DBPR is required to submit an annual report to the Governor and Legislature regarding the enforcement of tobacco products, including:[35]

- 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.

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.[36]

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

[29] S. 210.01(14), F.S.
[30] S. 210.40, F.S.
[31] S. 210.15, F.S.
[32] S. 569.003, F.S.
[33] S. 569.003, F.S.
[34] S. 569.005, F.S.
[35] S. 569.19, F.S.
[36] Ss. 210.011, 210.02, 210.276, and 210.30, F.S.; DBPR, Alcoholic Beverages & Tobacco – Tax & Reporting Information For Licensees, http://www.myfloridalicense.com/DBPR/alcoholic-beverages-and-tobacco/tax-and-reporting-information-for-licensees/#1510753842753-25986d10-086f (last visited Jan. 20, 2024).

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.

Administrative Penalties

The Division may suspend or revoke the permit of the retail tobacco products dealer or retail nicotine product dealer upon sufficient cause appearing of the violation of chapter 569. The Division may also assess and accept administrative fines of up to $1,000 against a dealer for each violation. The Division shall deposit all fines collected into the General Revenue Fund as collected. An order imposing an administrative fine becomes effective 15 days after the date of the order. The Division may suspend the imposition of a penalty against a dealer, conditioned upon the dealer's compliance with terms the Division considers appropriate.[37]

Consent to inspection and search without warrant

The place or premises covered by a permit for a retail tobacco products dealer or a permit for a retail nicotine product dealer is subject to inspection and search without a search warrant by the Division or its authorized assistants, and by sheriffs, deputy sheriffs, or police officers, to determine compliance with requirements for and dealing.[38]

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:

- "Sell" or "sale" means any sale, transfer, exchange, barter, gift, or offer for sale and distribution, in any manner or by any means whatsoever.
- "Timely filed premarket tobacco product application" means either:
  - An application under to 21 U.S.C. s. 387j for a nicotine dispensing device containing or using nicotine derived from tobacco marketed in the United States as of August 8, 2016, which was submitted to the FDA on or before September 9, 2020, and accepted for filing; or
  - An application under to 21 U.S.C. s. 387j for a nicotine dispensing device containing or using nicotine derived from a non-tobacco source that is not a single use or disposable electronic cigarette, an electronic cigar, an electronic cigarillo, an electronic pipe, or any other similar device and that does not use a sealed, prefilled, and disposable cartridge of nicotine in a solution.
- "Nicotine product manufacturer" means any person that manufactures nicotine products.
- "Wholesale nicotine product dealer" means the holder of a wholesale nicotine products dealer permit who purchases nicotine dispensing devices or nicotine products from any nicotine product manufacturer.
- "Wholesale nicotine product dealer permit" means a permit issued by the Division under s. 569.316.

[37] Ss. 569.006 and 569.35, F.S.
[38] Ss. 569.004 and 569.33, F.S.

Nicotine Dispensing Device Directory

Submission of Form and Applicable Copy Page for Certification

By December 1, 2024, and annually thereafter, the bill requires any nicotine product manufacturer who sells nicotine dispensing devices to a person for retail sale in this state to execute a form, prescribed by the Division, under penalty of perjury, for each such nicotine dispensing device sold that meets either of the following criteria:

- The nicotine product manufacturer has submitted a timely filed premarket tobacco product application for the nicotine dispensing device under to 21 U.S.C. s. 387j to the FDA and remains stayed by a court order, or the nicotine product manufacturer has filed a timely request for supervisory review with the FDA which remains under review, or the order has been rescinded by the FDA or vacated by a court; or
- The nicotine product manufacturer has received a granted marketing order under 21 U.S.C. s. 387j for the nicotine dispensing device from the FDA.

The bill requires such form to be delivered by the nicotine product manufacturer to the Division.

The Division's form must require each nicotine product manufacturer to set forth:

- the name under which the nicotine product manufacturer transacts or intends to transact business;
- the address of the location of the nicotine product manufacturer's principal place of business;
- the nicotine product manufacturer's e-mail address; and
- the brand name of the nicotine dispensing device, the device's category, such as, e-liquid, power unit, device, e-liquid cartridge, e-liquid pod, disposable, the device's name, and any flavor used with the device that is sold in Florida.

The bill provides that the Division may allow a nicotine product manufacturer to group its nicotine products on its certification.

In addition to completing the form prescribed by the Division, the bill requires each nicotine product manufacturer to provide to the Division a copy of:

- the cover page of the granted marketing order issued by the FDA under 21 U.S.C. s. 387j for each nicotine dispensing device;
- the acceptance letter issued by the FDA under 21 U.S.C. s. 387j for a timely filed premarket tobacco product application for each nicotine dispensing device; or
- a document issued by the FDA or by a court confirming that the premarket tobacco product application has been received and denied, but the order is not yet in effect for each nicotine dispensing device.

After the nicotine product manufacturer who submits certification as prescribed under the bill to the Division, the bill requires the nicotine product manufacturer to notify the Division within 30 days after any material change to the certification, including, but not limited to, issuance by the FDA of any of the following:

- A denial of a market authorization or authorization under 21 U.S.C. s. 387j;
- An order requiring a nicotine product manufacturer to remove a nicotine dispensing device or nicotine product from the market either temporarily or permanently;
- Any notice of action taken by the FDA affecting the ability of the nicotine dispensing device to be introduced or delivered in this state for commercial distribution;
- Any change in policy which results in a nicotine dispensing device becoming an FDA enforcement priority; or
- Any other change deemed material by the Division pursuant to a rule of the Division.

The bill provides that a nicotine product manufacturer that falsely represents any of the information in the form prescribed by the Division or the applicable copy page in the certification process commits a felony of the third degree for each false representation.

Directory

The bill requires the Division to develop and maintain a directory listing all the:

- nicotine product manufacturers who sell nicotine dispensing devices in this state; and
- nicotine dispensing devices certified by those manufacturers with the Division which comply with this requirement.

The bill requires the Division to:

- Make the directory available January 1, 2025, on its or DBPR's website.
- Update the directory as necessary.
- Establish a process to provide retailer nicotine product dealers, wholesale nicotine product dealers, and distributing agents, as defined in section 210.01(14), F.S., notice of the initial publication of the directory and changes made to the directory in the prior month.

Process for Removal from the Directory

The bill requires the Division to establish by rule a process to provide a nicotine product manufacturer notice and an opportunity to cure deficiencies before removing the nicotine product manufacturer or any of the manufacturer's nicotine dispensing devices from the directory.

The bill prohibits the Division from removing the nicotine product manufacturer or any of manufacturer's nicotine dispensing devices from the directory until at least 30 days after the nicotine product manufacturer has been provided notice of an intended action. Notice is sufficient and deemed immediately received by a nicotine product manufacturer if the notice is sent either electronically or by facsimile to an e-mail address or facsimile number provided by the nicotine product manufacturer in the most recent certification.

The bill provides that the nicotine product manufacturer has 15 days from the date of service of the notice of the Division's intended action to establish that the nicotine product manufacturer or any of the manufacturer's nicotine dispensing devices should be listed on the directory.

The bill provides that a determination by the Division not to include a nicotine product manufacturer or any of the manufacturer's nicotine dispensing devices on, or to remove such manufacturer or any of such manufacturer's nicotine dispensing devices from, the directory is subject to review under chapter 120. If a nicotine product manufacturer seeks review, the Division must keep the nicotine product manufacturer or the manufacturer's nicotine dispensing device on the directory until entry of a final order.

The bill provides that if a nicotine dispensing device is removed from the directory:

- Each retailer nicotine product dealer and each wholesale nicotine product dealer holding nicotine dispensing devices for sale to consumers in this state has 30 days after the date such device is removed from the directory to sell the device or remove the device from the dealer's inventory.
- 30 days after removal of the device from the directory, the device identified in the notice of removal is contraband and subject to s. 569.345, F.S.

Nicotine Dispensing Devices Not Listed on the Directory

The bill provides that beginning March 1, 2025, or on the date that the Division or DBPR first makes the directory available for public inspection on its website, whichever is later, a nicotine product manufacturer who offers for sale to consumers in this state a nicotine dispensing device not listed on the directory is subject to a fine of $1,000 per day for each individual nicotine dispensing device offered for sale in violation of this section until the offending device is removed from the market or until the offending device is properly listed on the directory.

The bill gives each retailer nicotine product dealer 60 days after the date that the Division or DBPR first makes the directory publicly available its website to either sell the nicotine dispensing devices in the dealer's inventory but not listed on the directory or remove those devices from the dealer's inventory.

The bill gives each wholesale nicotine product dealer or distributing agent, as defined in section 210.01(14), has 60 days after the date that the Division or DBPR first makes the directory publicly available its website to remove from the dealer's inventory those nicotine dispensing devices intended for retail sale to consumers in this state.

Unannounced Inspections

The bill provides that each retail nicotine product dealer and wholesale nicotine product dealer is subject to unannounced inspections and audits by the Division for purposes of enforcing compliance with the certification process and the directory. The Division is required under the bill to conduct unannounced follow-up compliance inspections of all noncompliant retail nicotine product dealers or wholesale nicotine product dealers within 30 days after a violation. The bill requires the Division to publish the results of all inspections and audits at least annually and make the results available to the public upon request.

Certification Renewal

The bill gives the Division rule making authority to develop a procedure to allow nicotine product manufacturers to renew certifications without having to resubmit all the information for the certification process.

Failure to Provide Information

The bill provides if a nicotine product manufacturer fails to provide information or documents required, the Division may exclude or remove the manufacturer's nicotine dispensing devices from the directory.

The bill:

- Authorizes the Division to assess an administrative fine of up to $1,000 for each nicotine dispensing device offered for sale to consumers in this state if a nicotine product manufacturer fails to provide notice to the Division of a material change to the manufacturer's certification within 30 days after such change.
- Requires the Division to deposit all fines collected into the General Revenue Fund.

The bill specifies that an order imposing an administrative fine becomes effective 15 days after the date of the order.

Maintenance and Inspection of Nicotine Dispensing Device Records

The bill requires each nicotine product manufacturer who sells nicotine dispensing devices to consumers in this state to maintain for a period of 3 years, at the address listed on the certification:

- a complete and accurate record of the quantity of sales of nicotine dispensing devices sold or delivered to a wholesale nicotine product dealer in Florida; and
- to whom each device was sold on a wholesale basis, including the business name, license number, shipping and business addresses, e-mail address, and telephone number of the person or entity to which each nicotine dispensing device was sold. Such records may be maintained in an electronic or paper format.

The bill provides similar maintenance requirements for retail nicotine products dealers; wholesale nicotine products dealers; wholesale dealers, and distributing agents. They must maintain a record of the quantity of each nicotine dispensing device received, delivered, or sold in Florida and to which each

nicotine dispensing device was sold or delivered or from whom they received each nicotine dispensing device, including the business name, license number, shipping and business addresses, e-mail address, and telephone number of the person or entity to which each product was sold or delivered or from which each device was received. The records are allowed to kept in electronic or paper format.

However, the bill provides that nicotine product manufacturers, retail product dealers, wholesale nicotine product dealers, wholesale dealers, as defined in section 210.01(6), F.S., or distributing agents who sell or deliver nicotine dispensing devices directly to consumers are not required to maintain the name, address, e-mail address, and telephone number of consumers who purchase or receive nicotine dispensing devices.

The bill provides that within seven calendar days after receiving a request by the Division, a nicotine product manufacturer who sells nicotine dispensing devices in this state, including a nicotine product manufacturer who sells nicotine products directly to consumers; a retail nicotine products dealer; a wholesale nicotine products dealer; a wholesale dealer, and a distributing agent provide such records, must provide to the Division or its representative, copies of records related to the nicotine dispensing devices received, delivered, or sold in this state and to whom such nicotine dispensing devices were sold or delivered or from which they were received.

The bill allows the Division or any designated employee thereof to examine such records, issue subpoenas[39] to such persons or entities; administer oaths; and take depositions of witnesses within or outside of Florida. The laws of Florida regarding enforcing obedience to a subpoena lawfully issued by a judge or any other person duly authorized to issue subpoenas under the laws of Florida in civil cases applies to a subpoena issued by the Division, or any designated employee thereof.

The subpoena may be enforced by writ of attachment[40] issued by the Division or any designated employee thereof: [41]

- to compel a witness to appear before the Division or any designated employee thereof, and give his or her testimony, and
- to produce such records as may be required for examination.

The Division or any designated employee thereof may bring an action against a witness who refuses to appear or give testimony by citation before the circuit court, which must punish such witness for contempt as in cases of refusal to obey the orders and process of the circuit court.[42] The Division may, in such cases, pay attendance and mileage fees to witnesses as permitted in civil cases appearing before the circuit court.

For each violation regarding maintenance and inspection of records, the Division is authorized to assess an administrative fine of up to $1,000. The bill requires the Division to deposit all fines collected into the General Revenue Fund, and specifies that an order imposing an administrative fine becomes effective 15 days after the date of the order.

Shipment of Unregistered Nicotine Dispensing Devices

The bill prohibits a nicotine product manufacturer from distributing nicotine dispensing devices for retail sale to consumers in Florida, in which:

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[39] A subpoena is an order to compel someone to testify. *Subpoena*, Legal Information Institute, www.law.cornell.edu/wex/subpoena (last visited Feb. 19, 2024).

[40] According to Black's Law Dictionary, a writ of attachment can either mean an "arrest of a person who either is in contempt of court or is to be held as security for the payment of a judgment", or "a writ ordering legal seizure of property (esp. to satisfy a creditor's claim) or of a person." ATTACHMENT, Black's Law Dictionary (11th ed. 2019).

[41] "[A]n [state administrative agency] investigation does not determine guilt or innocence, but serves as the means by which agencies can collect the information needed to decide whether to file an action. Because liability will be determined in a later proceeding at which the defendant will be able to assert a vigorous defense, courts give agencies 'more latitude … in considering the foundation for a subpoena." Roger B. Handberg, The Enforcement of Investigative Subpoenas Issued by Administrative Agencies an Analysis of Common Defenses, Fla. B.J., October 2002, at 40, 40–42.

[42] "Failure by any person without adequate excuse to obey a subpoena served on that person may be deemed a contempt of the court from which the subpoena issued." Fla. R. Civ. P. 1.410(f).

- The FDA has entered an order requiring the nicotine product manufacturer to remove the nicotine dispensing device from the market either temporarily or permanently, and:
    - which order has not been stayed by the FDA or a court of competent jurisdiction,
    - the manufacturer has submitted a timely filed request for supervisory review with the FDA which remains under review, or
    - the order has been rescinded by the FDA or vacated by any court;
- The nicotine product manufacturer has not submitted a timely filed premarket tobacco product application for the nicotine dispensing device;
- The nicotine product manufacturer's timely filed premarket tobacco product application for the nicotine dispensing device is no longer pending because:
    - it was not accepted by the FDA,
    - it was denied by the FDA, or
    - it is subject to any other order or action by the FDA or any court that negatively affects the ability of the nicotine dispensing device to be introduced or delivered into interstate commerce for commercial distribution in the United States; or
- The nicotine product manufacturer has not submitted the certification required under this chapter for any of the nicotine dispensing devices intended for retail sale to consumers in Florida.

The bill states that a nicotine product manufacturer who knowingly ships or receives such nicotine dispensing devices, commits a first-degree misdemeanor. The bill:

- Authorizes the Division to impose an administrative fine up to $5,000 for each violation.
- Requires the Division to deposit all fines collected into the General Revenue Fund.

The bill specifies that an order imposing an administrative fine becomes effective 15 days after the date of the order.

Wholesale Nicotine Product Dealer

The bill creates a wholesale nicotine products dealer permit which is issued by the Division. The provisions of the bill that address a wholesale nicotine products dealer permit mirror the provisions for a retail tobacco dealer and a retail nicotine dealer. However, a wholesale nicotine products dealer includes dealing in nicotine products or nicotine dispending devices.

The bill provides that a wholesale dealer or a distributing agent is not required to have a separate or additional wholesale nicotine products dealer permit to deal, at wholesale, in nicotine products in Florida. Furthermore, the bill states that a wholesale dealer, a distributing agent, or a tobacco product distributor, which deals, at wholesale, in nicotine products is subject to, and must be in compliance with Ch. 569, F.S., regarding nicotine and tobacco.

The bill requires that wholesale nicotine product dealer may purchase and sell for retail in Florida only those nicotine dispensing devices listed on the directory created by the Division. The Division is authorized to:

- Suspend or revoke the permit of a wholesale nicotine product dealer if the dealer fails to comply.
- Impose an administrative fine up to $5,000 for each violation. The Division shall deposit all fines collected into the General Revenue Fund.

The bill specifies that an order imposing an administrative fine becomes effective 15 days after the date of the order.

The bill provides that the place or premises covered by a permit for a wholesale nicotine product dealer is subject to inspection and search without a search warrant by the Division or its authorized assistants, and by sheriffs, deputy sheriffs, or police officers, to determine compliance with requirements.

Retail Nicotine Product Dealer

The bill adds dealing at retail in nicotine dispensing devices to the criteria that requires a retail nicotine product dealer permit.

The bill requires that such permits be issued annually by the Division.

The bill provides that retail nicotine products dealer permits may be renewed each year. Under the bill, a retail nicotine products dealer that does not timely renew its permit must pay a late fee of $5 for each month or portion of a month occurring after expiration, and before renewal, of the dealer's permit.

The Division shall establish by rule a renewal procedure that, to the greatest extent feasible, combines the application and permitting procedure for permits with the application and licensing system for alcoholic beverages. The bill prohibits the Division from granting an exemption from the permit fees for any applicant.

The bill specifies that the Division's current authority to refuse to issue a permit is based on such revocations by any jurisdiction.

The bill provides that on or after March 1, 2025, it is unlawful for a person, a firm, an association, or a corporation to deal, at retail, in nicotine products that are not listed on the Division's directory. Any person who knowingly ships or receives such nicotine products commits a second-degree. Misdemeanor.

The bill provides that on or after January 1, 2025, it is unlawful for a retail nicotine product dealer to purchase nicotine dispensing devices from a wholesale nicotine product dealer, nicotine product manufacturer, or other source that is not a wholesale nicotine product dealer permitholder, a wholesale dealer, a distributing agent, or a tobacco products distributor. The bill states that any person who knowingly ships or receives nicotine dispensing devices in violation of this section commits a second-degree misdemeanor. The bill authorizes the Division to suspend or revoke a retail nicotine product permit and may also assess an administrative fine of up to $1,000 for each violation.

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 that a Judge order the destruction and forfeiture of contraband nicotine dispensing devices. The bill requires 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,
- the time, place, and manner of destruction of such contraband,
- the chain of custody of the contraband, and the cost of destruction.

The bill requires the Division 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.

The bill requires that the cost of seizure and destruction of the contraband is borne by the person from whom the such nicotine dispensing devices are seized.

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.
- 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 Division 30 calendar days before termination of the appointment of an agent and further provide proof to the satisfaction of the Division 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 Division of the termination within 5 calendar days and include proof to the satisfaction of the Division of the appointment of a new agent.
- Requires any nonresident nicotine dispensing device 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. The appointment of the Secretary of State as agent does not satisfy the condition precedent to be included or retained on the nicotine dispensing device directory.

The bill provides funding and positions to implement the act.

B. SECTION DIRECTORY:

Section 1: Amends s. 569.31, F.S., relating to definitions.

Section 2: Creates s. 569.311, F.S., relating to nicotine dispensing device directory.

Section 3: Creates s. 569.312, F.S., relating to maintenance and inspection of nicotine dispensing device records.

Section 4: Creates s. 569.313, F.S., relating to shipment of unregistered nicotine dispensing devices sold for retail sale in this state.

Section 5: Creates s. 569.316, F.S., relating to wholesale nicotine products dealer permits; application; qualifications; renewal; duplicates.

Section 6: Creates s. 569.317, F.S., relating to wholesale nicotine products dealer permitholder; administrative penalties.

Section 7: Amends s. 569.32, F.S., relating to retail nicotine products dealer permits.

Section 8: Amends s. 569.33, F.S., relating to consent to inspection and search without warrant.

Section 9: Amends s. 569.34, F.S., relating to operating without a retail nicotine products dealer permit.

Section 10: Creates s. 569.345, F.S., relating to seizure and destruction of contraband nicotine dispensing devices.

Section 11: Creates s. 569.346 Agent for service of process.

Section 12: Amends s. 569.31, F.S., relating to definitions.

Section 13: Provides appropriations.

Section 14: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

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

2. Expenditures:

The bill provides funding for four positions with a total salary rate of 180,000. Additionally, the bill provides $278,875 in recurring funds and $20,268 in nonrecurring funds from the Alcoholic Beverage and Tobacco Trust Fund to DBPR to implement the act.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Businesses that are distributing nicotine products and operating as manufacturers, retailers, or wholesales will be penalized by fines or a criminal offense if they are distributing nicotine products without being on the directory or without proper permitting.

D. FISCAL COMMENTS:

Collected fines established in the bill are to be deposited into the General Revenue Fund. However, the Division currently deposits fines and other revenues into the Alcoholic Beverage and Tobacco Trust Fund. These funds are used for the purposes of operating the Division as requested by DBPR in their legislative budget request.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to require counties or municipalities to spend funds or take action requiring the expenditures of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill empowers the Division to develop and maintain a directory listing all the certified nicotine products and to develop a procedure to allow nicotine products manufacturers to renew certifications

without having to resubmit all the information for the certification process. The bill provides that the Division must develop a form for the nicotine manufacturers to certify their businesses and nicotine products.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On February 8, 2024, the Appropriations Committee adopted one amendment and reported the bill favorably as a committee substitute. The amendment provided funding and positions to implement the act.

On February 22, 2024, the Commerce Committee adopted a proposed committee substitute with one amendment and reported the bill favorably as a committee substitute. The committee substitute:

- Clarified terminology related to nicotine dispensing devices.
- Removed the requirement that nicotine dispensing products must be approved by the FDA in order to be sold in Florida, and instead requires that such products need to be sent to the FDA for approval.
- Clarified the process for DBPR approval of nicotine dispensing devices.
- Clarified records requirements.

This analysis is drafted to the committee substitute as passed by the Commerce Committee.