The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Fiscal Policy

BILL:	CS/CS/SB 1006
INTRODUCER:	Appropriations Committee on Agriculture, Environment, and General Government; Regulated Industries Committee; and Senator Perry
SUBJECT:	Nicotine Products and Dispensing Devices
DATE:	February 26, 2024 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Oxamendi	Imhof	RI	**Fav/CS**
2.	Oxamendi/Davis	Betta	AEG	**Fav/CS**
3.	Oxamendi	Yeatman	FP	**Pre-meeting**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 1006 provides for the regulation of the wholesale and the retail sale of nicotine dispensing devices (NDDs) products such as electronic cigarettes. The bill:

- Requires manufacturers of NDDs to register with the Division of Alcoholic Beverages and Tobacco (division) within the Department of Business and Professional Regulation by December 1, 2024, and annually thereafter, any of its products that are sold in Florida and which have received an order from the U.S. Food and Drug Administration (FDA) authorizing the marketing of such products or has applied for such a marketing order.
- Requires manufacturers to certify under penalty of perjury the NDDs with the division and provide evidence specified in the bill of such approval from the FDA or that they have sought approval from the FDA.
- Requires the division to create a directory containing the registered NDDs.
- Requires wholesale dealers of a NDD to have a permit issued by the division.
- Requires manufacturers of NDDs to maintain certain records for a period of three years, including identifying information regarding to whom the products were sold.
- Prohibits wholesale dealers and retail dealers of NDDs from selling NDDs that are not on the division's directory of NDDs.
- Prohibits the shipment into Florida of NDDs that the FDA has ordered removed from the market, that have not been submitted for approval by the FDA, or that have not been registered with the division.

- Prohibits the sale, shipment, or distribution of NDDs if the FDA does not accept a premarket application, denies an application, or other FDA or court action negatively affects the ability of the product to be introduced or delivered into interstate commerce for commercial distribution in the United States.
- Creates the following criminal violations and penalties:
  - Third degree felony for falsely misrepresenting any of the information required to register a NDD with the division.
  - First degree misdemeanor for nicotine product manufacturers who knowingly ships or receives a NDD that the FDA has ordered removed from the market, that have not been submitted for approval by the FDA, or that have not been registered with the division;
  - Second degree misdemeanor for any person who knowingly ships or receives unregistered NDDs;
  - Second degree misdemeanor for any person who knowingly ships or receives NDDs from a manufacturer that does not have a permit issued by the division; and
- Provides administrative fines for violations and for the suspension and revocation of permits.
- Provides that all NDDs sold, delivered, possessed, or distributed in contrary to the provisions in the bill are contraband and are subject to seizure and confiscation under the Florida Contraband Forfeiture Act.
- Requires non-resident manufacturers of NDDs sold in Florida to have a registered agent in Florida to accept service of process.

The bill has a significant, negative fiscal impact on state expenditures. See Section V., Fiscal Impact Statement.

The bill provides an effective date of October 1, 2024.

II. Present Situation:

Florida Regulation of Tobacco Products and Nicotine Dispensing Devises

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.

Tobacco Products Definitions

Section 210.01(1), F.S., defines the term "cigarette" to mean:

> 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.

Section 569.002(6), F.S., defines the term "tobacco products" to 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, in the context of the taxation of cigarettes under part I of ch. 210, F.S.

Section 210.25(12), F.S., provides a separate definition for the term "tobacco products" in the context of the taxation of tobacco products other than cigarettes or cigars. It provides for the licensing of tobacco product manufacturers, importers, exporters, distributing agents, or wholesale dealers under part II of ch. 210, F.S. In this context, the term "tobacco products" means:

> 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; but "tobacco products" does not include cigarettes, as defined by s. 210.01(1), or cigars.

The definition of "tobacco products" in s. 569.002(6), F.S., is limited to the regulation of tobacco products by the division under ch. 569, F.S., and does not affect the taxation of such products under ch. 210, F.S.

Nicotine Products

Section 569.31(3), F.S., defines the term "nicotine dispensing device" to mean:

> 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.

Section 569.31(4), F.S., defines the term "nicotine product" to mean:

> any product that contains nicotine, including liquid nicotine, which is intended for human consumption, whether inhaled, chewed, absorbed, dissolved, or ingested by any means. The term also includes any nicotine dispensing device. The term does not include a:
> (a) Tobacco product, as defined in s. 569.002;
> (b) Product regulated as a drug or device by the United States Food and Drug Administration under Chapter V of the Federal Food, Drug, and Cosmetic Act; or
> (c) Product that contains incidental nicotine.
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> (Emphasis added.)

Nicotine products, including nicotine dispensing devises such as electronic cigarettes (also commonly known as "vapes"), may contain nicotine, which comes from tobacco, but they do not

contain tobacco. It is a non-tobacco "e-liquid" that is heated and aerosolized for inhalation by the user of the device.[1]

Heated Tobacco Products

Heated tobacco products heat a compressed stick or pod of tobacco and produce an inhalable vapor or aerosol. These products do not produce smoke because the tobacco is not burned or ignited.[2] It is not clear that heated tobacco products are subject to taxation under ch. 210, F.S., as cigarettes or other tobacco products because the definitions for the terms cigarettes and tobacco products under ch. 210, F.S., do not appear to describe heated tobacco products, e.g., heated tobacco products are not smoked or chewed.

Retail Tobacco Products Dealer Permits

A person must obtain a retail tobacco products dealer permit from the division for each place of business where tobacco products are sold, including sales made through a vending machine.[3] The fee for an annual permit is established by the division in rule at an amount to cover the regulatory costs of the program, not to exceed $50. The fees are deposited into the Alcoholic Beverage and Tobacco Trust Fund within the DBPR.[4]

Retail Nicotine Products Dealer Permit

A retail nicotine products dealer permit from the division is required for each place of business where nicotine products are sold, including sales made through a vending machine.[5] There is no fee for the permit. A person must be 21 years of age to qualify for a retail nicotine products dealer permit.[6]

Taxation of Tobacco Products Other than Cigarettes or Cigars

Part II of ch. 210, F.S., imposes a tax and a surcharge tax on tobacco products other than cigarettes or cigars. Cigarettes are taxed under part I of ch. 210, F.S. Cigars are not subject to a tax.

DBPR Annual Report

The DBPR is required to submit an annual report to the Governor, the President of the Senate, and the Speaker of the House regarding the enforcement of tobacco products, including:[7]

- 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

[1] American Cancer Society, What Do We Know About E-cigarettes? at: https://www.cancer.org/cancer/risk-prevention/tobacco/e-cigarettes-vaping/what-do-we-know-about-e-cigarettes.html (last visited Feb. 7, 2024).
[2] Campaign for Tobacco Free Kids, *Heated Tobacco Products, Definition and Global Market*, available at: https://assets.tobaccofreekids.org/global/pdfs/en/HTP_definition_en.pdf (last visited Feb. 7, 2024).
[3] Section 569.003, F.S.
[4] Section 569.003(1)(c), F.S.
[5] Section 569.32, F.S.
[6] Section 569.32(2)(a), F.S.
[7] Section 569.19, F.S.

- The number of people under the age of 21 cited, including sanctions imposed as a result of citation.

The DBPR is required to submit a comparable annual report to the Legislature regarding compliance with the age restriction on the sale of nicotine dispensing devices.[8]

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.[9]

On August 8, 2016, the FDA extended the definition of the term "tobacco product" regulated under the Tobacco Control Act to include "electronic nicotine delivery systems" (ENDS). ENDS include nicotine delivery devices such as e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes. The definition of tobacco products also 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.[10]

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.[11]

Registration by Manufacturers

Under federal law, tobacco product manufacturers[12] are required initially and annually thereafter to register with the FDA the name,[13] places of business, and all such establishments of that manufacturer in any state.[14] These manufacturers are required to register any additional places

[8] Section 569.44, F.S.
[9] 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.
[10] "Non-Tobacco Nicotine" (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 Feb. 7, 2024).
[11] 21 U.S.C. § 387p.
[12] The term "manufacture, preparation, compounding, or processing" includes "the 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).
[13] The term "name" includes the name of each partner in the case of a partnership 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).
[14] 21 USCA § 387e(b)(c).

which they own or operate and start to manufacture, prepare, compound, or process a tobacco product or tobacco products.[15]

FDA Premarket Review Application Process for Tobacco Products[16]

Before a new tobacco product[17] can be distributed into interstate commerce, the manufacturer is required to submit a marketing application to the FDA and receive authorization.[18] 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).[19] The FDA may issue a marketing granted order, temporarily suspend a marketing order, withdraw a marketing granted order, or issue a marketing denial order.[20]

Preexisting tobacco products, i.e., tobacco products that were 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. before Feb. 15, 2007, may voluntarily submit an application to the FDA by May 14, 2022,[21] to receive a determination that the product is a pre-existing tobacco product. A tobacco manufacturer may challenge the FDA's determination.[22] Manufactures must hold onto records that show their tobacco products are legally on the market.

September 9, 2020, was the deadline for submitting a PMTA application for other new deemed tobacco products that were on the market as of August 8, 2016.[23]

An applicant may submit a PMTA to demonstrate that a new tobacco product meets the requirements to receive a marketing granted order.[24] The PMTA must contain information[25] for the FDA to ascertain whether there are any applicable grounds for a marketing denial order. To receive a marketing granted order:

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[15] 21 USCA § 387e(d).
[16] *See generally*, 21 U.S.C. § 387j.
[17] "A 'new tobacco product' is defined as any product not commercially marketed in the United States as of February 15, 2007, or the modification of a tobacco product where the modified product was commercially marketed in the U.S. after February 15, 2007." 21 U.S.C. § 387j(1).
[18] U.S. Food and Drug Administration, *Market and Distribute a Tobacco Product*, www.fda.gov/tobacco-products/products-guidance-regulations/market-and-distribute-tobacco-product (last visited Feb 7, 2024).
[19] U.S. Food and Drug Administration, *Tobacco Products Marketing Orders*, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders Last visited Feb. 7, 2024).
[20] 21 U.S.C. § 387j.
[21] U.S. Food and Drug Administration, *Reminder: Electronic Submission of Premarket Applications for Non-Tobacco Nicotine Products due May 14*, https://www.fda.gov/tobacco-products/ctp-newsroom/reminder-electronic-submission-premarket-applications-non-tobacco-nicotine-products-due-may-14 (last visited Feb. 7, 2024).
[22] *See* U.S. Food and Drug Administration, *Pre-Existing Tobacco Products*, June 15, 2023, at https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/pre-existing-tobacco-products (last visited February 16, 2024).
[23] FDA, Submit Tobacco Product Applications for Deemed Tobacco Products, Sept. 9, 2020, at: https://www.fda.gov/tobacco-products/manufacturing/submit-tobacco-product-applications-deemed-tobacco-products (last visited Feb 7, 2024).
[24] 21 CFR 1114.5.
[25] 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).

> 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.[26]

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.[27] The SE Report must contain 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.[28]

The 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. A tobacco product may only receive an exemption from the requirement of showing a substantial equivalence (Ex Req) if it is for a minor modification to a tobacco product that can legally be sold as a legally marketed tobacco product.[29]

The FDA made determinations on more than 99 percent of the nearly 26 million products for which PMTSs have been submitted.[30] As of March 15, 2023, the FDA has authorized the marketing of 45 products, including 23 tobacco-flavored e-cigarette products and devices.[31]

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 because the FDA failed to consider relevant factors in evaluating the applications submitted by the six tobacco companies.[32] In 2024, the Fifth Circuit Court of Appeals stated, in reference to the tobacco premarketing application process, that over several years, the FDA had "sent manufacturers of flavored e-cigarette products on a wild goose chase."[33]

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[26] *Supra* note 16.
[27] *See* 21 CFR 1107.16 and 21 CFR 1107.18.
[28] 21 CFR 1107.18.
[29] 21 CFR 1107.1.
[30] U.S. Food and Drug Administration, *FDA Makes Determinations on More than 99% of the 26 Million Tobacco*, www.fda.gov/tobacco-products/ctp-newsroom/fda-makes-determinations-more-99-26-million-tobacco-products-which-applications-were-submitted (last visited Feb 7, 2024); and U.S. Food and Drug Administration, *Premarket Tobacco Product Marketing Granted Orders*," updated as of Jan. 9, 2024, www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders (last visited Feb 7, 2024).
[31] *Id.*
[32] *See*, *Bidi Vapor LLC v. U.S. Food & Drug Admin*., 47 F.4th 1191, 1205 (11th Cir. 2022), in which the FDA issued marketing denial orders that specifically stated that it did not consider the marketing or sales-access-restriction plans in the PMTSs submitted by six tobacco companies which included their proposed marketing and sales-access restrictions in their applications.
[33] *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).

III. Effect of Proposed Changes:

Definitions

Section 1 revises the meaning of the term "nicotine dispensing device" (NDD) in s. 569.31, F.S., to provide that "each individual stock keeping unit is considered a separate nicotine dispensing device."

The bill defines the following terms:

- "FDA" to mean the United States Food and Drug Administration.
- "Nicotine products manufacturer" to mean any person who manufactures nicotine products.
- "Sell" or "sale" to mean in addition to its common usage meaning, any sale, transfer, exchange, theft, barter, gift, or offer for sale and distribution, in any manner or by any means whatsoever.
- "Timely filed premarket tobacco product application" to mean an application pursuant to 21 U.S.C. s. 387j for either:
  - A nicotine dispensing device containing or utilizing nicotine derived from tobacco marketed in the United States as of August 8, 2016, which was submitted to the U.S. Food and Drug Administration (FDA) on or before September 9, 2020, and accepted for filing; or
  - A nicotine dispensing device containing or utilizing 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 other similar device and that does not use a sealed, prefilled, and disposable cartridge of nicotine in a solution.
- "Wholesale nicotine products dealer" to mean the holder of a wholesale nicotine products dealer permit who purchases nicotine dispensing devices or nicotine products from any nicotine products manufacturer.
- "Wholesale nicotine products dealer permit" to mean a permit issued by the division under s. 569.316, F.S, as created by the bill.

The definition for the term "timely filed premarket tobacco product application" is limited to NDDs required to file an application under 21 U.S.C. s. 387j., i.e., a new deemed tobacco product, and for which September 9, 2020, was the deadline for submitting a Premarket Tobacco Product Application (PMTA) application for new deemed tobacco products that were on the market as of August 8, 2016.[34] This term does not apply to tobacco products that are "preexisting tobacco products," i.e., tobacco products that were commercially marketed in the U.S. as of February 15, 2007, or the modification of a tobacco product where the modified product was commercially marketed in the U.S. before February 15, 2007, that are not required to submit marketing applications to the FDA by May 14, 2022, and not required to receive a marketing order to permit the continued sale of the tobacco product.[35]

[34] *Supra* note 23.
[35] *Supra* note 21.

Nicotine Product Directory

Section 2 creates s. 569.311, F.S., to provide a certification requirement for nicotine product manufacturers.

Section 561.311(1), F.S., requires every nicotine product manufacturer who sells NDDs in Florida to execute and deliver a form, which s. 569.311(4), F.S., refers to as a "certification," prescribed by the Division of Alcoholic Beverages and Tobacco (division), under penalty of perjury for each NDD sold that meets either of the following criteria:

- The nicotine product manufacturer has submitted a timely filed PMTA for a NDD; and
  - the PMTA remains stayed by a court order, or the 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 the court; or
- The nicotine products manufacturer has received a marketing granted order, such as the Substantial Equivalence (SE) or Exemption from Substantial Equivalence Request (EX REQ), for the NDD from the FDA.

Although the bill requires all NND's to be registered or "certified" with the division if they meet the specified criteria, the criteria for registration are limited to new deemed tobacco products under 21 U.S.C. s. 387j., which are required to submit a PMTA with the FDA. Registration requirements for pre-existing NDDs are not specified in the bill.

The form must be submitted to the division by December 1, 2024, and annually thereafter.

Section 569.311(2), F.S., requires 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;
- The brand name of the nicotine dispensing device, the device's category (e.g., e-liquid, power unit, device, e-liquid cartridge, e-liquid pod, disposable), the device's name; and
- Any flavor utilized with the device that is sold in this state.

The bill provides that the division may allow a nicotine product manufacturer to group its nicotine dispensing devices on its certification.

Section 569.311(3), F.S., 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 for each device,
- The acceptance letter issued by the FDA pursuant to 21 U.S.C. s. 387j for a timely filed premarket tobacco product application for each 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 device.

Section 569.311(4), F.S., requires a 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 market authorization as a preexisting or new tobacco product;
- A marketing order requiring a nicotine product manufacturer to remove a NDD from the market either temporarily or permanently;
- Any notice of action taken by the FDA affecting the ability of the NDD to be introduced or delivered in this state for commercial distribution;
- Any change in policy which results in a NDD no longer being an FDA enforcement priority; or
- Any other change deemed material by the division pursuant to a rule of the division.

Directory

Section 569.311(5), F.S., requires the division to develop and maintain a directory listing all the NDDs certified with the division which comply with the requirements discussed above. On January 1, 2025, the division must make the directory available on the DBPR website or the website of the division, and update the directory as necessary. The bill requires the division to establish a process to provide retailers, distributors, and wholesalers notice of the initial publication of the directory and changes made to the directory in the prior month.

Process for Removal from the Directory

Section 569.311(6), F.S., requires the division to establish by rule a process to provide a nicotine product manufacturer a notice and an opportunity to cure deficiencies before removing the manufacturer or its NDD from the directory. The division may not remove the nicotine product manufacturer or its NDD from the directory until at least 30 days after the nicotine product manufacturer has been given 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 products manufacturer in its most recent certification filed.

Section 569.311(6)(b), F.S., 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 its NDD should be included in the directory.

Section 569.311(6)(c), F.S., provides that a determination by the division not to include or remove a nicotine product manufacturer or NDD on the directory is subject to review under ch. 120, F.S., the Florida Administrative Procedure Act. If a nicotine products manufacturer seeks review of the decision to remove it from the directory, the division must keep the NDD on the directory until entry of a final order.

Section 569.311(6)(d), F.S., provides that retailers and wholesalers have 30 days from when the product is removed from the directory to remove the product from their inventory and return the NDD to the nicotine product manufacturer.

Section 569.311(6)(d), F.S., also provides that a NDD identified in the notice of removal is considered contraband 30 days after its removal from the directory, and is subject to s. 569.345, F.S., relating to the seizure and destruction of contraband nicotine products.

Nicotine Products Not Listed on the Directory

Section 569.311(7), F.S., provides that, beginning March 1, 2025, or on the date that the division first makes the directory available for public inspection on its or the DBPR's website, whichever is later, a nicotine products manufacturer who offers for sale a NDD not listed on the directory is subject to a fine of $1,000 per day for each NDD offered for sale in violation of this section until the offending product is removed from the market or until the offending product is properly listed on the directory. In addition, within 60 days from the date that the division first makes the directory available for inspection on its public website, each retailer and each nicotine product manufacturer must sell products that were in its inventory and not included on the directory or remove those products from inventory.

False Representation

Section 569.311(8), F.S., provides that a nicotine product manufacturer who falsely represents any of the information required to be provided to the division commits a felony of the third degree[36] for each false representation.

Unannounced Inspections

Section 569.311(9), F.S., provides that each retail nicotine products dealer and wholesale nicotine products dealer is subject to unannounced inspections or audit checks 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 checks of all noncompliant retail nicotine products dealers or wholesale nicotine products dealers within 30 days after a violation. The bill requires the division to publish the results of all inspections at least annually and make the results available to the public on request.

Renew Certification

Section 569.311(10), F.S., authorizes the division to adopt by rule a procedure to allow nicotine product manufacturers to renew certifications without having to resubmit all the information for the certification process.

Enforcement

Section 569.311(11), F.S., provides that a nicotine product manufacturer's failure to provide required information or documents to the division may result in a NDD not being included on the directory or the removal of a NDD from the directory.

The bill authorizes the division to assess an administrative fine of up to $1,000 for each NDD offered for sale in Florida if a nicotine product manufacturer fails to provide notice to the division of a material change to its certification within 30 days after that material change. The

[36] Section 775.082, F.S., provides that a felony of the third degree is punishable by a term of imprisonment not to exceed five years. Section 775.083, F.S., provides that a felony of the third degree is punishable by a fine not to exceed $5,000.

bill requires the division to deposit all fines collected into the General Revenue Fund. Under the bill, an order imposing an administrative fine becomes effective 15 days after the date of the order.

Maintenance and Inspection of Nicotine Product Records

Section 3 creates s. 569.312, F.S., to require nicotine product manufacturers who sell a NDD in Florida to maintain specified records.

Section 569.312(1), F.S., requires nicotine product manufacturers to keep for a period of three years, at the address listed on the certification:

- A complete and accurate record of the number of NDD sold or delivered to a wholesaler in Florida; and
- To whom each NDD was sold on a wholesale basis.

The records must include the business name, license number, shipping and business addresses, e-mail address, and telephone number for the person or entity to which each product was sold. Such records may be kept in an electronic or paper format.

Section 569.312(2), F.S., provides that retail nicotine product dealers, wholesale nicotine product dealers, wholesale dealers of cigarettes, and distributing agents of cigarettes must keep a record of the amount of each NDD received, delivered, or sold in Florida and to whom each NDD was sold or delivered or from whom they received each NDD, including the business name, license number, shipping and business addresses, e-mail address, and telephone number for the person or entity to which each product was sold or delivered or from which each product was received. The records may be kept in electronic or paper format.

Section 569.312(3), F.S., provides that retail nicotine product dealers, wholesale nicotine product dealers, wholesale dealers of cigarettes, and distributing agents of cigarettes, who sell directly to consumers, are not required to keep and maintain these identifying records of the consumers who purchase or receive NDDs.

Section 569.312(4), F.S., requires nicotine product manufacturers that sell NDDs in Florida, including nicotine products manufacturers selling nicotine products directly to consumers, retail nicotine products dealers; wholesale nicotine products dealers, wholesale dealers of cigarettes, and distributing agents of cigarettes to provide these records within seven calendar days of receiving a request by the division.

Section 569.312(5), F.S., provides that the division is allowed to examine such records, issue subpoenas to persons or entities, administer oaths, and take depositions of witnesses within or outside of Florida.

Section 569.312(6), F.S., provides that the division may assess an administrative fine of up to $1,000 for each violation regarding maintenance and inspection of records. The division must deposit all fines collected into the General Revenue Fund. Under the bill, an order imposing an administrative fine becomes effective 15 days after the date of the order.

Shipment of Unregistered Nicotine Products into Florida

Section 4 creates s. 569.313, F.S., to prohibit the unregistered shipment of NDDs into Florida.

Section 569.313(1), F.S., prohibits nicotine product manufacturers from distributing nicotine products in Florida for which the manufacturer has:

- Been ordered by the FDA to remove the product from the market either temporarily or permanently and the order has not been stayed;
- Not submitted a timely filed PMTA for a NDD;
- Had a timely filed PMTA not accepted by the FDA, denied by the FDA, or the FDA or a court has taken an action that negatively affects the ability of the product to be introduced or delivered into interstate commerce for commercial distribution in the United States; or
- Not submitted the certification required for any of the NDD intended for eventual retail sale to a consumer in Florida.

Section 569.313(2), F.S., provides that any person who knowingly ships and receives an unregistered NDD in violation of s. 569.313, F.S., commits a first degree misdemeanor.[37]

Section 569.313(3), F.S., authorizes the division to impose an administrative fine of up to $5,000 for each violation. The division must deposit all fines collected into the General Revenue Fund. Under the bill, an order imposing an administrative fine becomes effective 15 days after the date of the order.

Wholesale Nicotine Products Dealers

Section 5 creates a wholesale nicotine products dealer permit which is issued by the division.

Section 561.316(1)(a), F.S., requires each person, firm, association, or corporation that seeks to deal, at wholesale, in nicotine products that will be sold at retail within this state, or to sell nicotine products or NDDs to any retail nicotine products dealer who intends to sell nicotine products in Florida, must obtain a wholesale nicotine products dealer permit for each place of business or premises at which nicotine products are sold.

Section 561.316(1)(b), F.S., specifies the identifying information that must be provided to the division on the application form, adopted by the rule of the division, for the permit. A permit is required for each place of business. The application must be signed and verified by the owner, if a sole proprietor; or, if the owner is a firm, association, or partnership, by the members or partners; if the owner is a corporation, by an executive officer of the corporation or by a person authorized by the corporation to sign the application. Written evidence of the authority to sign the application must be provided.

Section 561.316(2), F.S., sets forth the qualification for a wholesale nicotine products dealer permit. The permit may only be issued to a person who is 21 years of age or older or to a

[37] Section 775.082, F.S., provides that a misdemeanor of the first degree is punishable by a term of imprisonment not to exceed one year. Section 775.083, F.S. provides that a misdemeanor of the first degree is punishable by a fine not to exceed $1,000.

corporation whose officers are 21 years of age or older. In addition, a permit may not be issued to any to any person, firm, association, or corporation whose permit has been revoked by any jurisdiction; to any corporation an officer of which has had such permit revoked by any jurisdiction; or to any person who is or has been an officer of a corporation whose permit has been revoked by any jurisdiction.

Section 561.316(3), F.S., provides that, once issued, a wholesale nicotine products dealer permit is only valid for the person and place of business for which it was issued.

Section 561.316(4), F.S., exempts wholesale dealers of cigarettes and distributing agents of cigarettes from the requirement to have a wholesale nicotine products dealer permit for each place of business, but such persons must comply with the requirements in ch. 569, F.S. However, distributors of tobacco products other than cigarettes are not specifically exempted from the permit requirements, thus are required to have a wholesale nicotine products dealer permit for each place of business. However, it is not clear that such persons are subject to the records maintenance requirements in s. 569.312, F.S., which references the requirements as applicable to wholesale dealers and distributing agent of cigarettes, but does not reference the permittees under part II of ch. 210, F.S.

Wholesale Nicotine Products Dealer Permitholders

Section 6 creates s. 569.317, F.S., to provide that a wholesale nicotine products dealer permitholder may only purchase and sell for retail in Florida NDDs contained on the division's NDD directory. It authorizes the division to suspend or revoke the permit of a wholesale nicotine products dealer if the dealer fails to comply. The division may also impose an administrative fine up to $5,000 for each violation. The division must deposit all fines collected into the General Revenue Fund. Under the bill, an order imposing an administrative fine becomes effective 15 days after the date of the order.

Retail Nicotine Products Dealer Permit

Section 7 amends s. 569.32, F.S., to provide that permits must be issued annually. The holder of a permit may renew each year. A dealer that does not timely renew must pay a $5 late fee for each month or portion of a month occurring after expiration and before renewal of the permit. The bill forbids the division from granting an exemption from the permit fees for any applicant.

The bill also requires the division to establish by rule a renewal procedure.

Section 569.32(2)(b), F.S., provides that the division may refuse to issue a retail nicotine products dealer permit if the person, including as an officer in a corporation, has had a permit revoked by another jurisdiction. Current law provides a basis for the division to deny an application for a prior revocation but not on the basis of a revocation by another jurisdiction.

Section 8 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. Currently, this inspection and search provision only applies to retail nicotine products dealer permitholders.

Section 9 creates s. 569.34(4), F.S., to provide that on or after March 1, 2025, it is unlawful for a person, a firm, an association, or a corporation in Florida to deal, at retail, in NDDs that are not listed on the division's NDD directory. Any person who knowingly ships or receives such NDDs in violation of this prohibition commits a misdemeanor of the second degree.[38]

Section 569.34(5), F.S., provides that on or after January 1, 2025, it is unlawful for a retail nicotine products dealer in Florida to purchase NDDs from a source that is not a wholesale nicotine products dealer permitholder, a wholesale dealer of cigarettes, a distributing agent of cigarettes, or a tobacco products distributor of tobacco products other than cigarettes. The bill exempts from this prohibition nicotine product manufacturers who have a permit as a retail nicotine products dealer and sell their own products directly to consumers.

Under the bill, a person who knowingly ships or receives NDDs in violation of s. 569.34(5), F.S., prohibition commits a misdemeanor of the second degree.

Section 569.34(6), F.S., authorizes the division to suspend or revoke a retail nicotine products permit for a violation of part II of ch. 569, F.S., and to assess an administrative fine of up to $1,000 for each violation. The division must deposit all fines collected into the General Revenue Fund. Under the bill, an order imposing an administrative fine becomes effective 15 days after the date of the order.

Seizure and Destruction of Contraband Nicotine Products

Section 10 creates s, 569.345, F.S., to provide that all NDDs sold, delivered, possessed, or distributed contrary to the provisions of ch. 569, F.S., are contraband and are subject to seizure and confiscation under the Florida Contraband Forfeiture Act.[39] The bill requires the court having jurisdiction to order the destruction and forfeiture of contraband NDDs.

Section 569.345(2), F.S., requires that the division keep a full and complete record of:
- The exact kinds, quantities, and forms of such nicotine products or nicotine dispensing devices;
- The persons from whom they were received and to whom they were delivered;
- By whose authority they were received, delivered, and destroyed; and
- The dates of the receipt, disposal, or destruction.

Under the bill, this record must be open to inspection by all persons charged with the enforcement of tobacco and nicotine product laws.

[38] Section 775.082, F.S., provides that a misdemeanor of the second degree is punishable by a term of imprisonment not to exceed 60 days. Section 775.083, F.S., provides that a misdemeanor of the second degree is punishable by a fine not to exceed $500.
[39] Sections 932.701-932.7062, F.S., comprise the Florida Contraband Forfeiture Act, which provides for the seizure and civil forfeiture of property related to criminal and non-criminal violations of law.

Section 569.345(3), F.S., provides that the cost of seizure, confiscation, and destruction of contraband NDDs must be borne by the person from whom the contraband NDDs are seized.

Agent for Service of Process

Section 11 creates s. 569.346, F.S., to require non-resident manufacturers of NDDs to have a registered agent in Florida to accept service of process. The manufacturer must have such an agent for service of process in Florida in order to register a product with the division's NDD directory. The manufacturer must provide the name, address, telephone number, and proof of the appointment and availability of such agent to the division. The manufacturer must notify the division with 30 days of any change related to the agent, including notice to the division of any termination within five calendar days of an existing agency appointment with proof to the satisfaction of the division of the appointment of a new agent.

If an agent is not appointed by a manufacturer whose NDD is sold in Florida, the Secretary of State is deemed to be the agent. However, the appointment of the Secretary of State does not satisfy the condition precedent for inclusion or retention in the directory.

Conforming Provision

Section 12 amends s. 569.002, F.S., to conform a cross-reference changed in the bill.

Effective Date

Section 13 provides that the bill takes effect October 1, 2024.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Manufacturers, distributers, and retail dealers of nicotine products will incur costs related to complying with the registration and permitting requirements in the bill. Additionally, retail dealers of nicotine products would have to pay a $5 dollar late renewal fee for nicotine products retail dealer permit.

C. Government Sector Impact:

The Division of Alcoholic Beverages and Tobacco (division) will incur costs in implementing, administering, and enforcing the requirements in the bill, including the creation of the nicotine products directory. According to the Department of Business and Professional Regulation (DBPR), the division estimates that it will need an additional nine positions with $562,497 of budget authority ($65,553 nonrecurring) to implement the bill.[40]

Modifications to DBPR's licensing system (Versa: Regulation) and online system (Versa: Online) related to creating and maintaining online accounts and changes to licensure processes, are required. The DBPR states these changes can be made using existing resources.[41]

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. 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 the DBPR in their legislative budget request.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

[40] See Department of Business and Professional Regulation, *2024 Agency Legislative Bill Analysis for SB 1006* (Dec. 20, 2023) (on file with the Senate Regulated Industries Committee). The analysis indicated a need of 16 FTE and $1,304,523 of budget authority ($111,378 nonrecurring) to implement the bill; however, an updated estimate was provided by the DBPR legislative affairs staff via a phone call on February 11, 2024.
[41] *Id.*

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 569.002, 569.31, 569.32, 569.33, and 569.34.

This bill creates the following sections of the Florida Statutes: 569.311, 569.312, 569.313, 569.316, 569.317, 569.345, and 569.346.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS/CS by Appropriations Committee on Agriculture, Environment, and General Government on February 20, 2024:
The committee substitute:

- Revises the definition for the term "timely filed premarket product application" to include application under 21. U.S.C. s. 387j for a nicotine dispensing device (NDD) containing nicotine derived a non-tobacco source that is not a single use or disposable electronic cigarette, an electronic cigar, an electronic cigarillo, an electronic pipe, or other similar device and that does not use a sealed, prefilled, and disposable cartridge of nicotine in a solution.
- Provides that the division must keep the NDD on the directory until entry of a final order (instead of after the conclusion of an administrative hearing) following review under the APA.
- Prohibits the sale, shipment, or distribution of NDDs if the U.S. Food and Drug Administration (FDA) does not accept a premarket application, denies an application, or other FDA or court action negatively affects the ability of the product to be introduced or delivered into interstate commerce for commercial distribution in the United States.
- In s. 569.313(1)(B), F.S., removes the reference to a pending premarket tobacco application that has not been timely filed.
- Removes from the bill the requirement for the division to "establish by rule a renewal procedure that, to the greatest extent feasible, combines the application and the permitting procedure for permits with the application and licensing system for alcoholic beverages."

CS by Regulated Industries on February 5, 2024:
The committee substitute:

- Changes the title from an act relating to nicotine products to an act relating to nicotine products and nicotine dispensing devices.
- Provides that each individual stock keeping unit is a considered a separate "nicotine dispensing device" (instead of a separate "nicotine product").
- Defines the terms "sell," "sale," and "timely filed premarket tobacco product application."
- Amends the requirements for the directory in s. 569.311, F.S., to apply to nicotine dispensing devices (NDDs) instead of nicotine products, requires manufacturers and

retailers of NDDs to submit the required form by December 1, 2024, and annually thereafter, and revises the criteria for the types of products that must be registered, including deleting products derived from a non-tobacco source.

- Requires additional information be include in the registration application to include brand name of the NDD, the device's category (e.g., e-liquid, power unit, device, e-liquid cartridge, e-liquid pod, disposable), the device's name, and flavor utilized with the device.
- Requires the Division of Alcoholic Beverages and Tobacco (division) to establish a process to provide retailers, distributors, and wholesalers' notice of the initial publication of the directory and changes made to the directory in the prior month.
- Prohibits retailers from selling or having in inventory the products that have been removed from the directory 30 days after (instead of 21 days after) such removal.
- Requires retailers and distributors, within 60 days after the initial posting of the directory, to sell or remove from inventory the products that are not included in the directory.
- Provides an administrative fine of up to $1,000 for each NDD offered for sale in Florida if a NDD manufacturer fails to provide notice to the division of a material change to its certification within 30 days after that material change.
- Requires permitholders to respond to a records request from the division with 7 calendar days of a request (instead of upon a request).
- Disqualifies persons, including officers of a corporation, for a wholesale nicotine products dealer permit and a retail nicotine products dealer permit if a permit has been revoked in any jurisdiction.
- Requires non-resident manufacturers of NDDs sold in Florida to have a registered agent in Florida to accept service of process.

B. Amendments:

None.