HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1007 Nicotine Products
SPONSOR(S): Overdorf
TIED BILLS: **IDEN./SIM. BILLS:** 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			
3) Commerce Committee			

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 products manufacturer”, “wholesale nicotine products dealer", and “wholesale nicotine products dealer permit”.
- Requires manufacturers to certify nicotine products with the Division and provide evidence that they have sought approval with the Food and Drug Administration (FDA).
- Creates a new wholesale nicotine product permit and requires wholesalers who do not have tobacco permit to register, and only buy products on the directory.
- Provides that the Division is permitted to conduct unannounced inspections of nicotine product manufacturers who submitted their certification paperwork or are on the directory.
- 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 provides an effective date of October 1, 2024.

The bill may have an insignificant indeterminate fiscal impact on the state government.

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 product[s]"** 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. A request for an exemption (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] https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders

[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 Products 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 Products 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

[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).

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

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

Retail Nicotine Products 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 product" by providing that "each individual stock keeping unit is considered a separate nicotine product." The bill provides the following definitions:

- "Nicotine products manufacturer" means any person that manufactures nicotine products.
- "Wholesale nicotine products dealer" means 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" means a permit issued by the division under s. 569.316.

Nicotine Directory

Submission of Form and Applicable Copy Page for Certification

The bill requires every nicotine products manufacturer that sells nicotine products in Florida to execute and deliver a form, prescribed by the Division under penalty of perjury for each nicotine product sold that meets either of the following criteria:

- The nicotine product manufacturer has applied for a marketing order for the nicotine product derived from a tobacco source or nontobacco source by submitting a premarket tobacco product application to the FDA under certain conditions, AND

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

    - The premarket tobacco product application for the nicotine product remains under review by the FDA, and neither a marketing authorization nor a marketing denial order has been issued, OR
    - The FDA issued a marketing denial order for the nicotine product, but the FDA or a federal court issued a stay or an injunction during the pendency of the manufacturer's appeal of the marketing denial order or either the order has been appealed to the FDA or a challenge to the order has been filed with a federal court and the appeal or challenge is still pending
- The nicotine products manufacturer has received a marketing authorization or other authorization, such as the SE or EX REQ, for the nicotine product from the FDA.

The Division's form must require each nicotine products manufacturer to set forth:
- the name under which the nicotine products manufacturer transacts or intends to transact business,
- the address of the location of the nicotine products manufacturer's principal place of business,
- the nicotine products manufacturer's e-mail address,
- and any other information the division requires

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

In addition to completing the form prescribed by the Division each nicotine products manufacturer is required to provide a copy of the cover page of the premarket tobacco application with evidence of the receipt of the application by the FDA, or a copy of the cover page of the marketing authorization or other authorization issued by the FDA, whichever is applicable.

After the nicotine manufacturer submits the form and the applicable cover page ("the certification") as prescribed under the bill to the Division, nicotine manufacturer must notify the Division of any material change to the certification, including, but not limited to, issuance by the FDA of any of the following:
- A market authorization or authorization;
- An marketing order requiring a nicotine products manufacturer to remove a product from the market either temporarily or permanently;
- Any notice of action taken by the FDA affecting the ability of the nicotine product to be introduced or delivered in this state for commercial distribution;
- Any change in policy which results in a nicotine product no longer being exempt from federal enforcement oversight; or
- Any other change deemed material by the division pursuant to a rule of the Division.

The bill provides that a nicotine products 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 products 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, and update the directory as necessary.

The bill provides that a determination by the Division not to include or remove from the directory a nicotine products manufacturer or nicotine product is subject to review under 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 nicotine product on the directory until conclusion of the hearing.

Process for Removal from the Directory

The bill requires that the Division provide a nicotine products manufacturer notice and an opportunity to cure deficiencies before removing the manufacturer or its nicotine product from the directory. The Division may not remove the nicotine products manufacturer or its nicotine product from the directory until at least 15 days after the nicotine products manufacturer has been given notice of an intended action. Notice is sufficient and deemed immediately received by a nicotine products 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. The bill provides that the nicotine products manufacturer has 15 days from the date of service of the notice of the Division's intended action to establish that the nicotine products manufacturer or its nicotine product should be included in the directory.

The bill provides a process for retailers and wholesalers if a nicotine product is removed from the directory. Each retailer and wholesaler have 21 days from when the such product is removed from the directory to remove the product from its inventory and return the nicotine product to the nicotine products manufacturer. Each nicotine products manufacturer shall provide to the division information regarding the return of such product and how the returned product was disposed of within 21 days after receipt. After 21 days following removal from the directory, the product identified in the notice of removal is contraband.

Nicotine Products Not Listed on the Directory

The bill 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 that offers for sale a nicotine product not listed on the directory is subject to a fine of $1,000 per day for each nicotine product 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.

Unannounced Inspections

The bill 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

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

Maintenance and inspection of nicotine product records

The bill provides that each nicotine products manufacturer must keep for a period of 3 years, at the address listed on the certification:

- a complete and accurate record of the sales of each nicotine product sold or the amount of nicotine products delivered to a wholesaler in Florida, and
- to whom each nicotine product was sold on a wholesale basis, 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. Such records may be kept 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 agent. They must keep a record of the amount of each nicotine product received, delivered, or sold in Florida and to whom each nicotine

product was sold or delivered or from whom they received each nicotine product, 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 are allowed to kept in electronic or paper format.

Upon request by the Division, a nicotine products manufacturer, including a nicotine products manufacturer selling 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. The bill provides that the Division is allowed to examine such records, issue subpoenas to such persons or entities; administer oaths; and take depositions of witnesses within or outside of Florida. The For each violation regarding maintenance and inspection of records, the Division may assess an administrative fine of up to $1,000. The Division shall deposit all fines collected into the General Revenue Fund. An order imposing an administrative fine becomes effective 15 days after the date of the order.

Shipment of unregistered nicotine products into Florida

The bill prohibits a nicotine products manufacturer from distributing nicotine products in Florida which:

- there is an FDA order requiring the nicotine products manufacturer to remove the product from the market either temporarily or permanently;
- has not submitted a premarket tobacco product application; or
- has not submitted the certification required for the nicotine product.

The bill states that a nicotine products manufacturer who knowingly distributes an unregistered nicotine product, which is described above, commits a first degree misdemeanor. The Division may also impose an administrative fine up to $5,000 for each violation. The Division shall deposit all fines collected into the General Revenue Fund. An order imposing an administrative fine becomes effective 15 days after the date of the order.

Wholesale nicotine products dealer

The bill creates a wholesale nicotine products dealer permit which is issued by the Division. The bill language for a wholesale nicotine products dealer permits mirrors the requirements for a retail tobacco dealer and a retail nicotine dealer. 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 products distributor, which deals, at wholesale, in nicotine products is subject to, and must be in compliance with Chapter 569 regarding nicotine and tobacco.

The bill requires that wholesale nicotine products dealer may only purchase and sell nicotine products contained on the directory created by the Division. The Division may 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 shall deposit all fines collected into the General Revenue Fund. 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 products dealer

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 forbids the Division from granting an exemption from the permit fees for any applicant.

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 misdemeanor of the second degree.

The bill provides that on or after January 1, 2025, it is unlawful for a retail nicotine products dealer to purchase nicotine products from a wholesaler, manufacturer, or other source that is not a wholesale nicotine products 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 products in violation of this section commits a misdemeanor of the second degree. The Division may suspend or revoke a retail nicotine products permit and may also assess an administrative fine of up to $1,000 for each violation.

Seizure and destruction of contraband nicotine products

The bill declares all nicotine products sold in contravention of Chapter 569 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 products. The bill requires that the Division document the place where the contraband was seized, the kind and quantities of contraband seized, the cost of destruction, the time, place, and manner of destruction, the chain of custody of the contraband, and the cost of destruction.

B. SECTION DIRECTORY:

Section 1: amending s. 569.31, F.S., relating to definitions.
Section 2: creating s. 569.311, F.S., relating to nicotine directory.
Section 3: creating s. 569.312, F.S., relating to maintenance and inspection of nicotine product records.
Section 4: creating s. 569.313, F.S., relating to shipment of unregistered nicotine products.
Section 5: creating s. 569.316, relating to wholesale nicotine products dealer permits.
Section 6: creating s. 569.317, relating to wholesale nicotine products dealer permitholder and administrative penalties.
Section 7: amending s. 569.32, F.S., relating to retail nicotine products dealer permits.
Section 8: amending s. 569.33, F.S., relating to consent to inspection and search without warrant.
Section 9: amending s. 569.34, F.S., relating to operating without a retail nicotine products dealer permit.
Section 10: creating s. 569.345, F.S., relating to contraband nicotine products.
Section 11: amending s. 569.31, F.S., relating to definitions.
Section 12: providing effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Indeterminate. This may slightly increase revenues because wholesale nicotine dealers would have to obtain a permit from DBPR.

2. Expenditures:

   Indeterminate. There may be an increase in expenditures for DBPR to create a nicotine directory and enforce the provisions of this bill.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   Indeterminate.

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:

None.

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:

There are parts of the bill that have unclear language or misuse legal terms. The bill also uses the term “certification” and “registration” interchangeably.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES