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 Regulated Industries

BILL:	CS/SB 980
INTRODUCER:	Regulated Industries Committee and Senator Calatayud
SUBJECT:	Nicotine Dispensing Devices
DATE:	January 27, 2026 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Oxamendi	Imhof	RI	**Fav/CS**
2.			AEG	
3.			FP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 980 provides that the act may be cited as the "Florida Age Gate Act." The bill provides restrictions on the sale, advertising, promotion, and displaying for sale of non-FDA-authorized nicotine dispensing devices, which the bill defines as "any nicotine dispensing device, including any single use device, nonrefillable closed system cartridge device, or disposable device, which has not received a marketing authorization under 21 U.S.C. s. 387j from the United States Food and Drug Administration (FDA)."

21 U.S.C. s. 387j requires manufacturers of tobacco products that were on the market as of August 8, 2016, to submit a premarket application (PMTA) to the FDA by September 9, 2020, in order to be authorized to continue to legally market the product. Nicotine dispensing devices that contain nicotine not made or derived from tobacco, such as synthetic nicotine, must also receive a marketing authorization from the FDA. This market authorization does not apply to "pre-existing tobacco product," i.e., "grandfathered tobacco products" that were commercially marketed in the United States as of February 15, 2007.

The bill prohibits retail nicotine products dealers (dealers) who sell non-FDA-authorized nicotine dispensing devices and who allow persons younger than 21 years of age inside the licensed premises from advertising, promoting, or displaying for sale such devices in any open display unit inside the licensed location or that is visible to persons outside of the licensed premises. These advertising and display restrictions would not apply to nicotine dispensing devices that have received a marketing authorization from the FDA under 21 U.S.C. s. 387j.

The bill provides that an applicant for a retail nicotine products dealer permit or a retail tobacco products dealer permit, by accepting the permit, agrees that the place or premises covered by the permit is subject to inspection and search of the premises without a search warrant by the Department of Law Enforcement (FDLE) in addition to the Division of Alcoholic Beverages and Tobacco (division) within the Department of Business and Professional Regulation (DBPR) or its authorized assistants, and by sheriffs, deputy sheriffs, and police officers currently authorized to determine compliance with this part.

Under the bill, the division must conduct regular inspections of the licensed premises of dealers who sell nonapproved disposable devices to ensure compliance with this part.

The bill authorizes the division to assess the following administrative penalties for each violation involving the unlawful advertising, promotion, or display for sale of non-FDA-authorized nicotine dispensing devices:

- For a first violation, an administrative fine not to exceed $1,000 but not less than $500, a 7-day permit suspension, and an order requiring corrective action within 15 days;
- For a second violation within 36 months of a first violation, an administrative fine not to exceed $5,000 but not less than $2,500, a 14-day permit suspension, and an order requiring corrective action within 3 days; and
- For a third violation within 36 months of a first violation, an administrative fine not to exceed $20,000 but not less than $5,000, and revocation of the permit.

The bill also provides that, if a dealer, or a dealer's agent or employee, commits a third or subsequent violation within 12 weeks after the first violation, that person commits a misdemeanor of the second degree.

The bill requires that the division deposit all fines collected into the Division of Alcoholic Beverages and Tobacco Trust Fund of the DBPR. Under the bill, administrative fines must be used by the division and FDLE to increase enforcement personnel, fund compliance inspections and investigations, and develop and implement public awareness campaigns to reduce nicotine use by persons younger than 21 years of age.

The bill requires the division to adopt by rule guidelines for compliance audits and enforcement actions pertaining to the sale, advertising, promotion, and display for sale of non-FDA-authorized nicotine dispensing devices. The bill also requires that the annual report of the DBPR must list the number of dealers cited for violations of the restrictions in the bill on the advertising, promotion, or display of prohibited non-FDA-authorized nicotine dispensing devices, and the penalties imposed.

The bill takes effect July 1, 2026.

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.

Retail Tobacco Products Dealer Permits

A person must obtain a retail tobacco products[1] dealer permit from the division for each place of business where tobacco products are sold, including sales made through a vending machine.[2] 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.[3]

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.[4] There is no fee for the permit. A person must be 21 years of age to qualify for a retail nicotine products dealer permit.[5]

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.

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

[1] *See* s. 569.002(6), F.S., defining the term "tobacco products."
[2] Section 569.003, F.S.
[3] Section 569.003(1)(c), F.S.
[4] Section 569.32, F.S.
[5] Section 569.32(2)(a), F.S.

contain tobacco. It is a non-tobacco "e-liquid" that is heated and aerosolized for inhalation by the user of the device.[6]

Consent to Inspection and Search without Warrant

Applicants for a retail tobacco dealer permit, by accepting the permit when issued, agree that the place or premises covered by the permit 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 ch. 569, F.S. The implied consent also applies to inspections for compliance with regulation of the retail sale nicotine products under part II of ch. 569, F.S., including nicotine products sold by a vending machine to be located on the applicant's premises.[7]

An applicant for a retail nicotine products dealer permit, by accepting the permit when issued, agrees that the place or premises covered by the permit 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 part II of ch. 569, F.S. Current law does not state that the purpose of the inspection may be to determine compliance with part I of ch. 569, F.S., relating to tobacco products.[8]

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.

Restrictions on Sales to Minors

The sale, delivery, bartering, furnishing, or giving of tobacco products and nicotine products to persons under the age of 21 is prohibited.[9] A violation of this prohibition is a misdemeanor of the second degree.[10] A second violation within one year of the first violation is a first degree misdemeanor.[11] A third or subsequent violation of the prohibition against selling or giving a nicotine product to a person under 21 years of age is a felony of the third degree.[12]

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[6] American Cancer Society, E-cigarettes and Vaping at: https://www.cancer.org/cancer/risk-prevention/tobacco/e-cigarettes-vaping/what-do-we-know-about-e-cigarettes.html (last visited Jan. 23, 2026).
[7] Section 569.004, F.S.
[8] Section 569.33, F.S.
[9] Sections 569.101 and 569.41, F.S., providing the prohibitions against the sale of tobacco products and nicotine products to persons under 21 years of age, respectively.
[10] 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.
[11] Section 775.082, F.S., provides that the penalty for a misdemeanor of the first degree is punishable by a term of imprisonment not exceeding one year. Section 775.083, F.S., provides that the penalty for a misdemeanor of the first degree is punishable by a fine not to exceed $1,000.
[12] 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.

It is a complete defense to a person charged with a violation of s. 569.101, F.S., if the buyer or recipient falsely evidenced that he or she was 21 years of age or older, a prudent person would believe the buyer or recipient to be 21 years of age or older, and the buyer or recipient presented false identification[13] upon which the person relied in good faith.[14]

Persons under the age of 21 years are prohibited from possessing, directly or indirectly, any tobacco products or nicotine products:[15]

- A first violation of this prohibition is a non-criminal violation with a penalty of 16 hours of community service or a $25 fine, and attendance at a school-approved anti-tobacco program, if locally available.
- A second or subsequent violation within 12 weeks of the first violation is punishable with a $25 fine.
- Any second or subsequent violation not within the 12-week time period after the first violation is punishable as a first violation.

The term "any person under the age of 21" does not include any person under age 21 who:[16]

- Is in the military reserve or on active duty in the Armed Forces of the United States;
- Is acting in his or her scope of lawful employment, including with an entity licensed under the provisions of ch. 210, F.S., relating to taxation of cigarettes and other tobacco products, or ch. 569, F.S., relating to tobacco products.

To prevent persons under 21 years of age from purchasing or receiving tobacco products and nicotine devices, the sale or delivery of such products is prohibited, except when those products are under the direct control or line of sight of the dealer or the dealer's agent or employee. If a tobacco product is sold from a vending machine, the vending machine must have: [17]

- An operational lock-out device which is under the control of the dealer or the dealer's agent or employee who directly regulates the sale of items through the machine by triggering the lock-out device to allow the dispensing of one tobacco product;
- A mechanism on the lock-out device to prevent the machine from functioning if the power source for the lock-out device fails or if the lock-out device is disabled; and
- A mechanism to ensure that only one tobacco product is dispensed at a time.

These requirements for the sale of tobacco products do not apply to an establishment that prohibits persons under 21 years of age on the premises.[18]

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[13] *Supra* n. 8. Identification includes carefully checking "a driver license or an identification card issued by this state or another state of the United States, a passport, or a United States armed services identification card presented by the buyer or recipient and acted in good faith and in reliance upon the representation and appearance of the buyer or recipient in the belief that the buyer or recipient was 21 years of age or older." *See* s. 569.101(3)(c), F.S.

[14] *Supra* n. 8.

[15] Sections 569.11(1) and 569.42(1), F.S., providing the prohibitions against the procession of tobacco products and nicotine products by persons under 21 years of age, respectively.

[16] Section 569.002(9) and 569.31(12), F.S., defining the term "any person under the age of 21" in the context of the regulation of tobacco products and nicotine products, respectively.

[17] Sections 569.007 and 569.37, F.S., relating to restrictions on the sale or delivery of tobacco products and nicotine products, respectively.

[18] *Id.*

Retail tobacco products dealers and retail nicotine product dealers (retailers) must post a clear and conspicuous sign that the sale of tobacco products is prohibited to persons under the age of 21 and that proof of age is required for purchase. The division is required to make the signs available to retailers. Retailers must also have instructional material in the form of a calendar or similar format to assist in determining the age of the person attempting to purchase a tobacco product.[19]

Section 386.212, F.S., in the Florida Clean Indoor Air Act,[20] prohibits any person under the age of 21 from smoking tobacco within 1,000 feet of a public or private elementary, middle, or secondary school between the hours of 6:00 a.m. and midnight.[21] A violation of this prohibition is punishable by a maximum noncriminal civil penalty not to exceed $25, or 50 hours of community service or, where available, successful completion of a school-approved anti-tobacco "alternative to suspension" program.[22]

Administrative Penalties

A retail tobacco dealer permit-holder can be disciplined under the division's penalty guidelines. For a violation of the prohibition in s. 569.06, F.S., against the sale of tobacco products to persons under 21 years of age, the guidelines provide:

- 1st occurrence -- $500 fine.
- 2nd occurrence -- $1,000 fine.
- 3rd occurrence -- $2,000 fine and a 20-day suspension of the dealer permit.
- 4th occurrence -- revocation of the dealer permit.

These penalties are based on a single violation in which the permit-holder committed or knew about the violation; or a pattern of at least three violations on different dates within a 12-week period by employees, independent contractors, agents, or patrons on the licensed premises or in the scope of employment in which the permit-holder did not participate; or violations which were occurring in an open and notorious manner on the licensed premises.[23]

Section 569.008, F.S., provides a process for a retail tobacco products dealer to mitigate penalties imposed against a dealer because of an employee's illegal sale of a tobacco product to a person under 21 years of age.[24] The process encourages retail tobacco products dealers to comply with responsible practices. The division may mitigate penalties if:

- The dealer is qualified as a responsible dealer having established and implemented specified practices designed to ensure that the dealer's employees comply with ch. 569, F.S., such as employee training;
- The dealer had no knowledge of that employee's violation at the time of the violation and did not direct, approve, or participate in the violation; and

[19] Sections 569.14 and 569.43, F.S., providing requirements for the posting of notices by retail tobacco products dealers and retail nicotine product dealers, respectively.
[20] Part II of ch. 386, F.S.
[21] Section 386.212(1), F.S.
[22] Section 386.212(3), F.S.
[23] Fla. Admin. Code R. 61A-2.022(1) (2019).
[24] The Florida Responsible Vendor Act in ss. 561.701 - 561.706, F.S., provides a comparable process for mitigation of penalties against vendors of alcoholic beverages.

- If the sale was made through a vending machine, it was equipped with an operational lock-out device.[25]

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:[26]

- 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 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.[27]

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.[28]

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 products containing nicotine from any source, including synthetic nicotine.[29]

Federal law preempts states from providing additional or different requirements for tobacco products in regard 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,

[25] Section 569.008(3), F.S.
[26] Section 569.19, F.S.
[27] Section 569.44, F.S.
[28] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 351 *et seq*; 15 U.S.C. s. 1333, s. 1335; 21 U.S.C. s. 387g, s. 387f.
[29] U.S. Food and Drug Administration, "*Regulation and Enforcement of Non-Tobacco Nicotine (NTN) Products."* "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*, www.fda.gov/tobacco-products/products-ingredients-components/regulation-and-enforcement-non-tobacco-nicotine-ntn-products (last visited Jan. 20, 2026).

exposure to, access to, advertising and promotion of tobacco products which are more stringent than federal requirements.[30]

Registration by Manufacturers

Under federal law, tobacco product manufacturers[31] are required initially and annually thereafter to register with the FDA the name,[32] places of business, and all such establishments of that manufacturer in any state.[33] 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.[34]

FDA Premarket Review Application Process for Tobacco Products

21 U.S.C. § 387j requires the manufacturer of a new tobacco product[35] to submit a marketing application to the FDA and receive authorization[36] before it can be distributed into interstate commerce. 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).[37]

The FDA may issue a marketing granted order, temporarily suspend a marketing order, withdraw a marketing granted order, or issue a marketing denial order.[38] If exempt, the FDA would issue a "found exempt order."[39]

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, could voluntarily apply to the FDA by May 14, 2022,[40] to receive a determination that the product is a pre-existing tobacco product. A

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[30] 21 U.S.C. § 387p.
[31] 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 U.S.C. § 387e(a)(1).
[32] 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 U.S.C. § 387e(a)(2).
[33] 21 U.S.C. § 387e(b)(c).
[34] 21 U.S.C. § 387e(d).
[35] "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).
[36] 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 Jan. 20, 2026).
[37] *Id.*
[38] 21 U.S.C. § 387j.
[39] *See* U.S. Food and Drug Administration, *Searchable Tobacco Products Database Additional Information, Database Terminology*, defining EXREQ – Found Exempt Order, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/searchable-tobacco-products-database-additional-information#rfr (last visited Jan. 20, 2026).
[40] 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 Jan. 20, 2026).

tobacco manufacturer may challenge the FDA's determination.[41] 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.[42]

An applicant may submit a PMTA to demonstrate that a new tobacco product meets the requirements to receive a marketing granted order.[43] The PMTA must contain information[44] for the FDA to ascertain whether there are any applicable grounds for a marketing denial order. To receive a "marketing granted" 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.[45]

A Substantially Equivalent 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.[46] 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.[47]

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.[48]

By January 14,, 2025, the FDA made determinations on more than 26 million PMTA applications, including 99.5 percent of the higher-market share e-cigarette products. It issued marketing denial orders for more than 65,000 non-tobacco flavored e-cigarette product applications.[49]

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[41] *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 Jan. 20, 2026).
[42] U.S. Food and Drug Administration, *Premarket Tobacco Product Applications* at: https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/premarket-tobacco-product-applications (last visited Jan. 20, 2026).
[43] 21 CFR 1114.5.
[44] 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).
[45] *Supra* n. 35.
[46] *See* 21 CFR 1107.16 and 21 CFR 1107.18.
[47] 21 CFR 1107.18.
[48] 21 CFR 1107.1.
[49] U.S. Food and Drug Administration, *A Year in Review: FDA's Progress on Tobacco Product Regulation in 2024*, https://www.fda.gov/tobacco-products/ctp-newsroom/year-review-fdas-progress-tobacco-product-regulation-2024 (last visited Jan. 20, 2026); and U.S. Food and Drug Administration, *Premarket Tobacco Product Marketing Granted Orders,*"

In 2024, the FDA issued several marketing orders for non-tobacco flavored e-cigarette products.[50]

The FDA provides a searchable database on its website for tobacco products, including e-cigarettes that may be legally marketed.[51] The FDA also maintains a printable, one-page flyer of authorized e-cigarettes indicating that only 17 e-cigarette products from three manufacturers have been authorized for sale.[52]

Legal Challenges to the FDA's PMTA Process

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 for flavored e-cigarettes.[53] 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."[54] The FDA subsequently appealed the Fifth Circuit decision to the United State Supreme Court, which heard oral arguments on December 2, 2024.[55]

Regarding the PMTA process, the FDA's was also successfully challenged by a group of retailers based in Texas and Mississippi and a North Carolina-based company whose PMTA was denied by the FDA for a menthol-flavored e-cigarette product and the FDA appealed to the Fifth Circuit Court of Appeals, which is based in Louisiana. The Fifth Circuit rejected the FDA motion to move the case to the D.C. Circuit in Washington D.C.[56] The FDA subsequently appealed to the United States Supreme Court, which held oral arguments in January 2025 on the jurisdictional issue of "whether a manufacturer may file a petition for review in a circuit (other than the U.S. Court of Appeals for the District of Columbia Circuit) where it neither resides nor has its principal place of business, if the petition is joined by a seller of the manufacturer's products that is located within that circuit."[57]

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updated as of Mar. 28, 2024, www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders (last visited Jan. 20, 2026).

[50] *Id.*

[51] U.S. Food and Drug Administration, *Searchable Tobacco Products Database*, https://www.accessdata.fda.gov/scripts/searchtobacco/ (last visited Jan. 20, 2026).

[52] U.S. Food and Drug Administration, *FDA Authorized E-Cigarette Products*, https://digitalmedia.hhs.gov/tobacco/print_materials/CTP-250?locale=en (last visited Jan. 20, 2026).

[53] *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.

[54] *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 the 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).

[55] *Wages & White Lion Investments, L.L.C. v. Food & Drug Admin*., 144 S.Ct. 2714 (2024), *cert. granted.*

[56] *Food and Drug Administration, v. R.J. Reynolds Vapor Co.*, 2024 WL 1945307 (5th Cir. 2024).

[57] *Food and Drug Administration, v. R.J. Reynolds Vapor Co.*, 145 S.Ct. 116 (2024), *cert. granted*; and Petition for Writ of Certiorari in *Food and Drug Administration, v. R.J. Reynolds Vapor Co.*, No. 23-1187, May 5, 2024, WL 1995213.

Federal Enforcement Efforts

In October 2024, FDA and U.S. Customs and Border Protection (CBP), seized $76 million in unauthorized e-cigarettes, including popular, youth-appealing, foreign-owned brands. In April 2024, the U.S. Marshals Service seized unauthorized e-cigarettes valued at more than $700,000 at a warehouse in California.

In addition, the FDA made compliance and enforcement actions against unauthorized tobacco products in 2024, especially those most appealing to youth, including issuing warning letters to more than 50 manufacturers and distributors and more than 430 retailers for selling unauthorized tobacco products. In 2024, the CBP also filed civil money penalty complaints for unauthorized products consisting of 44 complaints against manufacturers and more than 100 complaints against retailers.[58]

Florida Directory of Nicotine Products that are Attractive to Children

Enacted during the 2024 Regular Session, s. 569.311, F.S.,[59] authorizes the Florida Attorney General to adopt rules to create a directory of nicotine dispensing devices that the Attorney General has determined to be "attractive to minors," thereby removing those products from the market. Under the section, the term "nicotine dispensing devices" includes e-cigarettes, vapes, and other similar products. Each individual stock keeping unit is considered a separate nicotine dispensing device. Open systems in which a consumer fills a vial or other containers with a nicotine solution are exempted from the provisions of s. 569.311, F.S.

To determine that a product is "attractive to minors," the Attorney General must consider several factors, including:[60]

- Surveys or other data sources indicating that a nicotine dispensing device is being used by minors at a higher rate than other nicotine dispensing devices.
- Complaints, reports, or other information related to the use of a nicotine dispensing device by minors from other minors, from parents, teachers, school employees, school boards, and law enforcement officers, retailers, and other industry officials as compared to other nicotine dispensing devices.
- The extent to which the product is designed and marketed to be attractive to minors (e.g., use of bright colors or cartoon characters, ease of use for minors, resemblance to a food product, and uniquely marketed to minors).
- Use of actual intellectual property that resemble consumer food products that are popular with minors.
- Any reports of physical harm to minors from using the nicotine dispensing device or evidence that the nicotine dispensing device presents unique risks to minors.
- Whether the manufacturer of the nicotine dispensing device submitted a timely filed premarket tobacco product application for the nicotine dispensing device pursuant to 21 U.S.C. s. 387j.

[58] *Supra* note 49.
[59] Chapter 2024-127, Laws of Fla.
[60] Section 569.311(3), F.S.

- Decisions by the U.S. Food and Drug Administration (FDA) regarding the product, including the extent to which the FDA's decision was predicated, in whole or part, on the risks to minors outweighing other benefits of the nicotine dispensing device.

The Department of Legal Affairs must also develop and maintain a directory listing all of the nicotine product manufacturers that sell nicotine dispensing devices in Florida, which the Attorney General has deemed attractive to minors. The department must make the directory available January 1, 2025, for public inspection on its website.[61]

The Attorney General's decision to include a product in the directory is subject to review under the Florida Administrative Procedure Act under ch. 120, F.S.[62] After a product is included in the directory, retailers and wholesale dealers have 60 days from the date the directory is made public to sell or otherwise discard the products.[63]

Section 569.312(1), F.S., provides that a nicotine product manufacturer, a retail nicotine products dealer, a wholesaler, or a distributor may not sell, ship, or otherwise distribute a nicotine dispensing device in this state for eventual retail sale to a consumer in this state that is listed on the directory. A person who knowingly sells, ships, or receives for retail sale a prohibited nicotine dispensing device commits a misdemeanor of the first degree.[64] A violation is also deemed to be a deceptive trade practice and may be enforced by the Attorney General. The DBPR may impose a civil penalty of up to $1,000 per prohibited device sold.[65]

Products that are listed in the directory are contraband and are subject to seizure under the Florida Contraband Forfeiture Act.[66] A court having jurisdiction must order contraband nicotine dispensing devices forfeited upon a showing that, by a preponderance of the evidence, the devices were sold, delivered, possessed, or distributed contrary to any provision of ch. 569, F.S., relating to tobacco and nicotine products. Once any administrative proceedings under ch. 120, F.S., related to such devices have been completed, the court must order seized nicotine dispensing devices to be destroyed, except as provided by applicable court orders. The department is required to keep specified records of all nicotine dispensing devices seized under the act.[67]

As of March 6, 2025, the Attorney General's Nicotine Dispensing Devises Directory lists approximately 640 nicotine dispensing devices, which are identified by the product's stock keeping unit (SKU), as attractive to minors.[68]

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[61] Section 569.311(9), F.S.
[62] Section 569.311(5), F.S.
[63] Section 569.311(10), F.S.
[64] 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.
[65] Section 569.312, F.S.
[66] *See* ss. 932.701-932.7062, F.S.
[67] Section 569.345, F.S.
[68] *See* Florida Attorney General, *Nicotine Dispensing Devices*, https://www.myfloridalegal.com/NDD (last visited Jan. 20, 2026).

III. Effect of Proposed Changes:

Section 1 of the bill provides that the act may be cited as the "Florida Age Gate Act."

Definition

The bill amends s. 569.31, F.S., to define the term "non-FDA-authorized nicotine dispensing device" to mean any nicotine dispensing device, including any single use device, nonrefillable closed system cartridge device, or disposable device, which has not received a marketing authorization under 21 U.S.C. s. 387j from the United States Food and Drug Administration.[69]

Consent to Inspection and Search without a Warrant

The bill amends s. 569.33, F.S., to provide that an applicant for a retail nicotine products dealer permit, by accepting the permit, also agrees that the place or premises covered by the permit is subject to inspection and search without a search warrant by the FDLE to determine compliance with part II of ch. 569, F.S., relating to the unlawful sale, advertising, promotion, or display for sale of non-FDA-authorized nicotine dispensing devices.

Under the bill, the division must conduct regular inspections of the licensed premises of dealers who sell non-FDA-authorized nicotine dispensing devices to ensure compliance with part II of ch. 569, F.S.

Criminal and Administrative Penalties

The bill amends s. 569.35, F.S., to authorize the division to assess administrative penalties for each violation involving the unlawful advertising, promotion, or display for sale of non-FDA-authorized nicotine dispensing devices as provided in s. 569.37(3), F.S.

The bill authorizes the division to impose the following penalties:

- For a first violation, an administrative fine not to exceed $1,000 but not less than $500, a 7-day permit suspension, and an order requiring corrective action within 15 days;
- For a second violation within 36 months of a first violation, an administrative fine not to exceed $5,000 but not less than $2,500, a 14-day permit suspension, and an order requiring corrective action within 3 days; and
- For a third violation within 36 months of a first violation, an administrative fine not to exceed $20,000 but not less than $5,000, and revocation of the permit.

The provides that a dealer, or a dealer's agent or employee, who commits a third or subsequent violation within 12 weeks after the first violation commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083, F.S.[70]

[69] The bill references the Food and Drug Administration instead of the agency's full title of the United States Food and Drug Administration.

[70] 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.

Under the bill, fines collected by the division for violations of the requirements in s. 569.37(3), F.S., relating to restrictions on the sale, advertising, or promotion of non-FDA-authorized nicotine dispensing devices, must be deposited into the Division of Alcoholic Beverages and Tobacco Trust to be used by the division and the FDLE to:

- Increase enforcement personnel;
- Fund compliance inspections and investigations; and
- Develop and implement public awareness campaigns to reduce nicotine use by persons under the age of 21.

Advertisement, Promotion, or Display for Sale of Nonapproved Disposable Devices

The bill creates s. 569.37(3)(a), F.S., to prohibit a dealer who allows persons younger than 21 years of age on the licensed premises, and who sells non-FDA-authorized nicotine dispensing devices from advertising, promoting, or displaying such devices in any location that is visible to:

- Any person outside of the dealer's licensed premises; and
- Any person younger than 21 years of age, including any open display unit.

Under s. 569.37(3)(b), F.S., a dealer who prohibits persons younger than 21 years of age on the licensed premises, and who sells a nicotine dispensing device that has received a marketing authorization order under 21 U.S.C. s. 387j, may advertise, promote, or display for sale such devices in areas visible inside or outside the licensed premises.

Section 569.37(3)(c), F.S., provides that the restrictions in paragraph (a) do not apply to non-FDA-authorized nicotine dispensing devices that have received an FDA marketing authorization order issued under 21 U.S.C. s. 387j sold exclusively in compliance with restrictions in s. 559.37, F.S., including:

- Each stock-keeping unit marketed by the manufacturer within the same brand family as the authorized product; and
- A closed-system, replaceable-cartridge devices designed exclusively for use with a proprietary, reusable, rechargeable device for which a marketing authorization order has been granted.

There may be nicotine dispensing devices that are not required to receive a marketing order under 21 U.S.C. s. 387j, such as a pre-existing tobacco product, which is any tobacco product (including those products in test markets) that was commercially marketed in the United States on, or as of, February 15, 2007, or was a modification of a tobacco product that was commercially marketed in the U.S. before Feb. 15, 2007. A manufacturer of such a product may voluntarily apply to the FDA for a marketing order but is not required to apply. Such devices would be subject to the advertising and display restrictions provided in the bill.

Rulemaking

The bill amends s. 569.39, F.S., to require the division to adopt by rule guidelines for compliance audits and enforcement actions pertaining to the sale, advertising, promotion, and display for sale of non-FDA-authorized nicotine dispensing devices. Such rules must expressly authorize establishments that prohibit persons younger than 21 years of age on the licensed premises to sell

single-use nicotine dispensing devices that have not received a marketing authorization order issued under 21 U.S.C. s. 387j, consistent with s. 569.37(5), F.S.

DBPR Annual Report

The bill amends s. 569.44, F.S., to require that the annual report of the DBPR list the number of dealers cited for violations for any of the restrictions in the bill on the advertising, promotion, or display of non-FDA-authorized nicotine dispensing devices, and the penalties imposed.

Effective Date

The bill takes effect July 1, 2026.

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:

All nicotine products dealer permit holders will subject to the restriction in the bill for the sale, advertising, promotion, and display for sale of non-FDA-authorized nicotine dispensing devices.

C. Government Sector Impact:

The DBPR has not provided a fiscal analysis for this bill.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 569.31, 569.33, 569.35, 569.37, 569.39, and 569.44.

IX. Additional Information:

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

CS by Regulated Industries on January 27, 2026:
The committee substitute:

- Revises the term "Food and Drug Administration" to "United States Food and Drug Administration;"
- Limits the current $1,000 cap on the amount of a fine to violations of ch. 569, F.S., other than those provisions created in the bill.
- Revises the penalties in s. 569.35(2), F.S.
- Requires funds collected by the division from fines related to violations of the restrictions in the bill to be deposited into the Division of Alcoholic Beverages and Tobacco Trust.
- Deletes the duplicative provision in s. 569.37(3)(c), F.S., of the bill.
- Revises s. 569.37(3)(c), F.S., to provide that the restrictions in the bill on the requirements in the bill for the sale, advertising, or promotion of non-FDA-authorized nicotine dispensing devices do not apply to a nicotine dispensing device manufactured by a company with at least one FDA marketing authorization order issued under 21 U.S.C. s. 387j, and sold in compliance with the restrictions in the bill.

B. Amendments:

None.