# 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 Health Policy							
BILL:	CS/SB 810						
INTRODUCER:	Health Policy Committee and Senator Simmons						
SUBJECT:	Tobacco and Nicotine Products						
DATE:	January 21,	2020	REVISED:				
ANALYST		STAFF	DIRECTOR	REFERENCE		ACTION	
1. Williams		Brown		HP	Fav/CS		
2.	_			IT			
3.	_			RC			

# Please see Section IX. for Additional Information:

**COMMITTEE SUBSTITUTE - Substantial Changes** 

# I. Summary:

# CS/SB 810:

- Increases the minimum age to lawfully purchase and possess tobacco products from 18 years of age to 21 years of age.
- Repeals the exceptions that allow persons in the military and emancipated minors to possess or purchase tobacco products under current law.
- Creates a definition for "vapor-generating electronic device," using the term and definition
  from the Florida Constitution's prohibition against indoor vaping, to provide a consistency of
  terms and to adapt the term to include the cartridges or containers of nicotine or other
  substances used with a vaping device. Modifies the definition of "tobacco products" to
  include vapor-generating electronic devices and products. Provides specific exclusions from
  the definitions.
- Prohibits smoking and vaping by any person under 21 years of age on or near school property, regardless of hours of day.
- By defining vaping products as tobacco products, subjects retail sellers of vaping products to regulation as retail tobacco product dealers, including the requirement for a permit. (This issue is addressed in a separate linked fee bill.)
- Limits the sale of tobacco products through a vending machine if the location prohibits persons under 21 years of age on the premises.
- Requires age verification before a sale or delivery to a person under 30 years of age. (This complies with recently enacted federal law.)
- Incorporates conforming provisions.

The bill will have an indeterminate fiscal impact related to the regulatory responsibilities of the Department of Business and Professional Regulation. In addition, the bill will have an indeterminate fiscal impact on vape product dealers.

The effective date of the bill is October 1, 2020, contingent upon the passage of the linked fee bill.

#### II. Present Situation:

# **Regulation of Tobacco Products**

The Division of Alcoholic Beverage 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 ch. 569, F.S.

Section 569.002, F.S., provides definitions of terms in the context of the regulation of tobacco products under ch. 569, F.S. Subsection (6) 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.

Subsection (7) specifies that the term "any person under the age of 18" does not include any person under age 18 who:

- Has had his or her disability of nonage removed under ch. 743, F.S.;
- Is in the military reserve or on active duty in the Armed Forces of the United States;
- Is otherwise emancipated by a court of competent jurisdiction and released from parental care and responsibility; or
- Is acting in his or her scope of lawful employment 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.

Section 569.003, F.S., relates to retail tobacco products dealer permits, the permit application, qualifications, fees, renewals, and duplicates. Subsection (2) stipulates that permits may only be issued to persons who are 18 years of age or older or to corporations the officers of which are 18 years of age or older. The Division is authorized to refuse to issue a permit to any person, firm, association, or corporation the permit of which has been revoked, to any corporation an officer of which has had his or her permit revoked, or to any person who is or has been an officer of a corporation the permit of which has been revoked.

The fee for an annual permit is established in rule by the Division at an amount to cover the regulatory costs of the program, not to exceed \$50. The proceeds of the fee are deposited into the DBPR Alcoholic Beverage and Tobacco Trust Fund.

# Mail Order, Internet, Other Remote Sales of Tobacco Products, and Tobacco Products Permits

Section 210.095(5), F.S., provides requirements for the delivery of mail order, Internet, and other remote sales of tobacco products, including age verification requirements, all of which is generally referred to as "delivery sales." It also defines 10 relevant terms.

Specific notice and shipping requirements are provided for all delivery sales, whether in-state or out-of-state. Each person who mails, ships, or otherwise delivers tobacco products in connection with an order for a delivery sale is required to:

- Include, as part of the shipping documents, in a clear and conspicuous manner, the following statement: "Tobacco Products: Florida law prohibits shipping to individuals under 18 years of age and requires the payment of all applicable taxes."
- Use a method of mailing, shipping, or delivery which obligates the delivery service to:
  - Require the signature of an adult who resides at the delivery address and obtain proof of the legal minimum purchase age of the individual accepting delivery, if the individual appears to be under 27 years of age.
  - Require proof that the individual accepting delivery is either the addressee or the adult designated by the addressee, in the form of a valid, government-issued identification card bearing a photograph of the individual who signs to accept delivery of the shipping container.
- Provide to the delivery service, if such service is used, evidence of full compliance with requirements for the collection and remittance of all taxes imposed on tobacco products by this state with respect to the delivery sale.<sup>1</sup>

If a person accepts a purchase order for a delivery sale and delivers the tobacco products without using a delivery service, the person must comply with all of the requirements that apply to a delivery service. Before making sales or shipping orders, entities must provide specific notice to the Division as to shipper and receiver, with monthly reporting. There are requirements specific to purchase orders. A

Section 210.095(8), F.S., provides that the penalty for the following violations of the delivery sale requirements is a misdemeanor of the third degree:<sup>5</sup>

- A delivery sale delivers tobacco products, on behalf of a delivery service, to an individual who is under 18 years of age.
- A violation of any provision in s. 210.095, F.S., by an individual who is under 18 years of age.

Florida law does not provide a criminal penalty classification for a misdemeanor of the third degree. However, the prohibitions and penalties in s. 569.101, F.S., (prohibiting the sale,

<sup>&</sup>lt;sup>1</sup> Section 210.095(5), F.S.

 $<sup>^{2}</sup>$  Id.

<sup>&</sup>lt;sup>3</sup> Section 210.095(6), F.S.

<sup>&</sup>lt;sup>4</sup> Section 210.095(7), F.S.

<sup>&</sup>lt;sup>5</sup> Section 775.082, F.S., provides that the penalty for 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 the penalty for a misdemeanor of the second degree is punishable by a fine not to exceed \$500.

delivery, bartering, furnishing, or giving, directly or indirectly, to any person who is under 18 years of age, any tobacco product, and s. 569.11, F.S., prohibiting persons under 18 years of age from possessing, directly or indirectly, any tobacco product) apply to s. 210.095, F.S., relating to the delivery of tobacco products to persons under the age of 18.

Section 210.15, F.S., relates to permits for the sale of specific tobacco products. Among the requirements for the issuance of such a permit is the provision found in paragraph (b) of subsection (2) to require that permits may be issued only to persons of good moral character, who are not less than 18 years of age. In addition, permits to corporations may be issued only to corporations whose officers are of good moral character and not less than 18 years of age.

# **Tobacco Products and Minors**

To prevent persons under 18 years of age from purchasing or receiving tobacco products, the sale or delivery of tobacco 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:

- 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.<sup>6</sup>

These requirements for the sale of tobacco products do not apply to an establishment that prohibits persons under 18 years of age on premises and do not apply to the sale or delivery of cigars and pipe tobacco.<sup>7</sup>

Section 569.0075, F.S., prohibits the giving of sample tobacco products to persons under the age of 18.

Section 569.008, F.S., provides a process for a retail tobacco product dealer to mitigate penalties imposed against a dealer because of an employee's illegal sale of a tobacco product to a person under 18 years of age. The process encourages retail tobacco product 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.

<sup>&</sup>lt;sup>6</sup> Section 569.007(1), F.S.

<sup>&</sup>lt;sup>7</sup> Section 569.007(2) and (3), F.S.

<sup>&</sup>lt;sup>8</sup> 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.

• The sale was made through a vending machine equipped with an operational lock-out device.<sup>9</sup>

Section 569.101, F.S., prohibits the sale, delivery, bartering, furnishing or giving of tobacco products to persons under the age of 18. A violation of this prohibition is a second degree misdemeanor. A second or subsequent violation within one year of the first violation is a first degree misdemeanor.

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 18 years of age or older, a prudent person would believe the buyer or recipient to be 18 years of age or older, and the buyer or recipient presented false identification<sup>12</sup> upon which the person relied in good faith.<sup>13</sup>

Section 569.11, F.S., prohibits persons under the age of 18 years from possessing, directly or indirectly, any tobacco products:

- 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 provided for a first violation.<sup>14</sup>

Eighty percent of all civil penalties received by a county court under s. 569.11, F.S., must be remitted to the Department of Revenue for transfer to the Department of Education for teacher training and for research and evaluation to reduce and prevent the use of tobacco products, nicotine products, or nicotine dispensing devices by children. The remaining 20 percent of civil penalties received by a county court must remain with the clerk of the county court to cover administrative costs.<sup>15</sup>

Section 569.12, F.S., provides enforcement authority to full-time, part-time, and auxiliary law enforcement officers for the provisions of ch. 569, F.S. The section also authorizes a county or municipality to designate certain of its employees or agents as tobacco product enforcement officers within specified guidelines. Such enforcement officers are authorized to issue a citation to a person under 18 years of age based on a reasonable cause to believe that a civil infraction

<sup>&</sup>lt;sup>9</sup> Section 569.008(3), F.S.

<sup>&</sup>lt;sup>10</sup> Supra note 5.

<sup>&</sup>lt;sup>11</sup> 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.

<sup>&</sup>lt;sup>12</sup> 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 18 years of age or older." *See* s. 569.101(3)(c), F.S.

<sup>&</sup>lt;sup>13</sup> Section 569.101(3), F.S.

<sup>&</sup>lt;sup>14</sup> Section 569.11(1), F.S.

<sup>&</sup>lt;sup>15</sup> Section 569.11(6), F.S.

has been committed. Similar authority is provided for correctional probation officers. Details are provided as to the required elements of the citation.

Retail tobacco product dealers (retailers) must post a clear and conspicuous sign that the sale of tobacco products is prohibited to persons under the age of 18 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.<sup>16</sup>

Section 569.19, F.S., requires the Division to annually provide to the Legislature and the Governor by December 31, a progress report on its enforcement actions specific to: number and results of compliance visits, number of violations for failure of a retailer to hold a valid license, number of violations of selling tobacco products to persons under age 18, and the results of administrative hearings on these issues, and the number of persons under age 18 cited for violations of underage purchases and sanctions imposed as a result of a citation.

Section 386.212, F.S., in the Florida Clean Indoor Air Act, prohibits any person under the age of 18 from smoking tobacco within 1,000 feet of a public or private elementary, middle, or secondary school between the hours of 6 a.m. and midnight.<sup>17</sup> 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.<sup>18</sup>

#### **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 18 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.<sup>19</sup>

# **Nicotine Dispensing Devices**

Section 877.112, F.S., provides requirements for the sale of nicotine dispensing devices and nicotine products to minors, such as electronic cigarettes (e-cigarettes). This statute extends the

<sup>&</sup>lt;sup>16</sup> Section 569.14, F.S.

<sup>&</sup>lt;sup>17</sup> Section 386.212(1), F.S.

<sup>&</sup>lt;sup>18</sup> Section 386.212(3), F.S.

<sup>&</sup>lt;sup>19</sup> Fla. Admin. Code R. 61A-2.022(1) (2019).

current prohibitions related to tobacco products to the sale, gifting, possession, or use of nicotine dispensing devices and nicotine products to and by persons under 18 years of age.

# A "nicotine dispensing device" is:

any product that employs an electronic, chemical, or mechanical means to produce vapor 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.<sup>20</sup>

# A "nicotine product" is:

any product that contains nicotine, including liquid nicotine intended for human consumption, whether inhaled, chewed, absorbed, dissolved or ingested by any means. The definition does not include a tobacco product under Florida law, a drug or device under federal law, or a product that contains incidental nicotine.<sup>21</sup>

The sale or giving of nicotine products or nicotine dispensing devices to any person under 18 years of age is prohibited and punishable as a second degree misdemeanor.<sup>22</sup> It is a complete defense to a violation if an underage person falsely misrepresented his or her age, the underage person had the appearance to a prudent person to 18 years of age or older, and the person carefully checked, and relied on, the driver license or identification card of the recipient.<sup>23</sup>

Persons under 18 years of age possessing, purchasing, or misrepresenting their age or military service to obtain nicotine products or nicotine dispensing devices commit a noncriminal violation. The penalty is 16 hours of community service or a \$25 fine for a first violation, and attendance at a school-approved anti-tobacco and nicotine program, if available. A second or subsequent violation within 12 weeks of the first violation requires a \$25 fine. Any second or subsequent violation not within the 12-week time period after the first violation is punishable as provided for a first violation.<sup>24</sup>

If a person under 18 years of age is found by the court to have committed such a noncriminal violation and that person has failed to complete community service, pay the required fine, or attend a school-approved anti-tobacco and nicotine program, if locally available, the court may direct the Department of Highway Safety and Motor Vehicles to withhold issuance of or suspend the driver license or driving privilege of that person for 30 or 45 consecutive days, depending on the infraction.<sup>25</sup>

<sup>&</sup>lt;sup>20</sup> Section 877.112(1)(a), F.S.

<sup>&</sup>lt;sup>21</sup> Section 877.112(1)(b), F.S.

<sup>&</sup>lt;sup>22</sup> Supra note 5.

<sup>&</sup>lt;sup>23</sup> Section 877.112(5), F.S.

<sup>&</sup>lt;sup>24</sup> Sections 877.112(6) and (7), F.S.

<sup>&</sup>lt;sup>25</sup> Section 877.112(8), F.S.

Eighty percent of civil penalties specific to possession of nicotine products or nicotine dispensing devices by minors and misrepresenting age in making such purchases are remitted to the Department of Revenue for transfer to the Department of Education for teacher training and for research and evaluation to reduce and prevent the use of tobacco products, nicotine products, or nicotine dispensing devices by children. The remaining 20 percent of civil penalties received by a county court are retained by the clerk of the county court to cover administrative costs. <sup>26</sup>

Subsection 877.112(10), F.S., requires a retail dealer of nicotine products and nicotine dispensing devices to post signs that the sale of nicotine products and nicotine dispensing devices to persons under 18 years of age is prohibited.

Nicotine products or nicotine dispensing devices may not be sold or delivered by self-service merchandising, except when such products are under the direct control of, or in the line of sight where effective control may be reasonably maintained by, the retailer or their agent or employee.<sup>27</sup>

To prevent persons under 18 years of age from purchasing or receiving nicotine products or nicotine dispensing devices, s. 877.112(12), F.S., requires retailers to comply with restrictions identical to the restrictions on the sale of tobacco products in s. 569.007(1), F.S., such as requiring the products to be sold or delivered only when under the direct control or line of sight of the retailer and requiring a lock-out device if the products are sold or delivered from a vending machine.

# **Regulation of Vaping**

During the 2019 session, CS/SB 7012<sup>28</sup> was enacted to implement Amendment 9 to the Florida Constitution, which was approved by the voters of Florida on November 6, 2018, to ban the use of vapor-generating electronic devices, such as electronic cigarettes (e-cigarettes), in enclosed indoor workplaces, as part of the Florida Clean Indoor Air Act. The use of e-cigarettes is commonly referred to as vaping.

The use of vapor-generating electronic devices is permitted in the enclosed indoor workplace of a "vapor-generating device retailer" or "retail vape shop," which is defined as "any enclosed indoor workplace dedicated to or predominantly for the retail sale of vapor-generating electronic devices and components, parts, and accessories for such products, in which the sale of other products or services is merely incidental." Vaping is permitted at the same locations authorized to permit tobacco smoking, i.e., private residences whenever not being used for certain commercial purposes, stand-alone bars, designated rooms in hotels and other public lodging establishments, retail tobacco shops, facilities owned or leased by a membership association, smoking cessation program locations, medical or scientific research locations, and customs smoking rooms in airport in-transit lounges.

Local governments may adopt more restrictive local ordinances on the use of vapor-generating electronic devices.

<sup>&</sup>lt;sup>26</sup> Section 877.112(9), F.S.

<sup>&</sup>lt;sup>27</sup> Section 877.112(11), F.S.

<sup>&</sup>lt;sup>28</sup> See ch. 2019-14, L.O.F.

The above provisions were approved by the Governor and took effect July 1, 2019.

Unlike the retail sale of tobacco products, which is subject to regulation under ch. 569, F.S., the sale of vape products is only regulated under the provisions of s. 877.112, F.S. While tobacco products in Florida are subject to specific taxation under ch. 210, F.S., vaping products are only subject to sales taxes.

# **Rates of Youth Vaping**

According to recent data from the federal Centers for Disease Control and Prevention (CDC), more than one in four high school students is an e-cigarette user. <sup>29</sup> That represents an increase from approximately one in five last year. At the same time, around 10 percent of middle school students reported using e-cigarettes in the month prior to being surveyed, up from around 5 percent last year. Nearly 70 percent of e-cigarette users reported using a flavored product, and the availability of flavors such as mint and chocolate was a reason that many students cited for trying e-cigarettes. The findings come a year after the U.S. Surgeon General declared the surge in youth vaping an epidemic. <sup>30</sup>

### **Health Issues Relating to Vaping**

The findings noted above regarding the increases in youth vaping come at the same time that the CDC is conducting an ongoing national investigation of vaping-related lung injuries. The CDC, the federal Food and Drug Administration (FDA), state and local health departments, and public health and clinical stakeholders have spent the past several months investigating and monitoring the nationwide illness outbreak. The condition has been labelled as **E**-cigarette, or **V**aping, product use-**A**ssociated **L**ung **I**njury, or EVALI. The latest count from the CDC finds that 2,409 people have been hospitalized and 52 people have died across 25 states and Washington, D.C., as of December 10, 2019.<sup>31</sup> Two of the deaths have occurred in Florida, and 103 cases of vaping-related illness hospitalizations have been documented in Florida as of December 3, 2019.<sup>32</sup>

#### National Minimum Age of Sale of Tobacco Products

As part of the federal budget revisions adopted in December 2019, and signed into law on December 20, 2019, the minimum age for the sale of tobacco products is now 21 years of age.<sup>33</sup>

<sup>&</sup>lt;sup>29</sup> See "Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019" Centers for Disease Control and Prevention- Morbidity and Mortality Weekly Report (MMWR), (December 6, 2019), *available at* <a href="https://www.cdc.gov/mmwr/volumes/68/ss/ss6812a1.htm">https://www.cdc.gov/mmwr/volumes/68/ss/ss6812a1.htm</a> (last visited Jan. 16, 2020).

<sup>&</sup>lt;sup>30</sup> See "Surgeon General Warns Youth Vaping Is Now An 'Epidemic" (December 18, 2018), *available at* <a href="https://www.npr.org/sections/health-shots/2018/12/18/677755266/surgeon-general-warns-youth-vaping-is-now-an-epidemic">https://www.npr.org/sections/health-shots/2018/12/18/677755266/surgeon-general-warns-youth-vaping-is-now-an-epidemic (last visited Dec. 12, 2019).</a>

<sup>&</sup>lt;sup>31</sup> Mikosz CA, Danielson M, Anderson KN, et al. Characteristics of Patients Experiencing Rehospitalization or Death After Hospital Discharge in a Nationwide Outbreak of E-cigarette, or Vaping, Product Use–Associated Lung Injury — United States, 2019. CDC, *Morbidity & Mortality Weekly Report 2020;68:1183-1188*. (December 20, 2019), *available at* http://dx.doi.org/10.15585/mmwr.mm685152e1external icon (last visited January 8, 2020).

<sup>&</sup>lt;sup>32</sup> See "Florida reports second vaping death" (December 11, 2019), *available at* <a href="http://www.orlandosentinel.com/news/os-ne-florida-reports-second-vaping-death-20191211-dvz3tehxevbpvkcavhe2jdiepe-story.html">http://www.orlandosentinel.com/news/os-ne-florida-reports-second-vaping-death-20191211-dvz3tehxevbpvkcavhe2jdiepe-story.html</a> (last visited Dec. 12, 2019).

<sup>&</sup>lt;sup>33</sup> See the "Further Consolidated Appropriations Act, 2020," Rules Committee print 116-44, Text of the House Amendment to the Senate Amendment to H.R. 1865, December 16, 2019, beginning at page 1492 of 1773, *available at* 

The specific tobacco provisions in the budget document amended section 906(d) of the Federal Food, Drug, and Cosmetic Act to increase the federal minimum age to purchase tobacco products from 18 to 21, and to add a provision that it is unlawful for any retailer to sell a tobacco product to any person younger than age 21. The provisions also require the FDA to update its applicable tobacco regulations within specified timelines.

As part of this rule update process, the FDA is to update the relevant age verification requirements to require age verification for individuals under age 30 (as opposed to the current age verification threshold for individuals under age 27). This topic had been under consideration for some time, and adoption of the changes were the result of the recent increased vaping rates among youth as highlighted above, the recent EVALI cases as highlighted above, and the adoption of age 21 as the minimum age for purchase of tobacco products in multiple states as highlighted in the **Related Issues** portion of this analysis.

# Federal Food and Drug Administration Enforcement Priorities for Electronic Nicotine Delivery Systems and Other Deemed Products on the Market without Premarket Authorization (FDA Guidance Document)

On January 2, 2020, the FDA released "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market without Premarket Authorization" (FDA Guidance Document) as a Guidance for Industry document.<sup>34</sup> (For all intents and purposes, the reference to ENDS products is a reference to vaping products.) The Guidance Document's introduction describes how the FDA intends to prioritize its enforcement resources with regard to the marketing of certain deemed tobacco products that do not have premarket authorization.

The introduction further indicates that, as with FDA's prior compliance policies on deemed new tobacco products that do not have premarket authorization, this guidance document does not apply to any deemed product that was not on the market on August 8, 2016.<sup>35</sup> For ENDS

https://rules.house.gov/sites/democrats.rules.house.gov/files/BILLS-116HR1865SA-RCP116-44.PDF (last visited Jan. 8, 2020).

<sup>&</sup>lt;sup>34</sup> See "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market without Premarket Authorization: Guidance for Industry, released by the U.S. Department of Health and Human Services, Food and Drug Administration, Center for Tobacco Products, (January 2, 2020), available at https://www.fda.gov/media/133880/download (last visited Jan. 8, 2020). The document as released is a follow-up to a draft document that was released by the FDA in March 2019. Appendix A of the document, consisting of pages 32-52 of the 52 page document, reflects FDA's response to comments received on the March 2019 draft document. <sup>35</sup> A brief explanation of "deeming" is helpful in this context. The Family Smoking Prevention and Tobacco Control Act (2009) (the ACT) gave the FDA the authority to regulate tobacco products. The Act broadly defined "tobacco products" as any product that is "made or derived from tobacco" that is "intended for human consumption." However, the Act, when passed, only immediately applied to a few specific products, namely cigarettes, cigarette tobacco, smokeless tobacco, and roll-your-own tobacco. To regulate any other tobacco products, the Act requires the FDA to assert jurisdiction through regulation. In other words, for the FDA to start regulating cigars, e-cigarettes, hookah, and other products currently unregulated by the federal government, the FDA must create a rule through its formal notice-and-comment rulemaking process. A rule, or regulation, that extends the FDA's jurisdiction to all tobacco products is often referred to as a Deeming Regulation because the language of the Tobacco Control Act states that the FDA can regulate additional tobacco products that it "deems to be subject" to the Act. While this process exists and has been used, its use is infrequent. From A Deeming Regulation: What is Possible Under the Law, Tobacco Control Legal Consortium, available at

products marketed without the FDA's authorization, the FDA intends to prioritize enforcement against:

- Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);
- All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
- Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors.

The Guidance Document provides background details of the FDA's statutory and regulatory history of tobacco related products, evidence of increasing youth use of vaping products, applicable definitions, enforcement priorities, strategies for avoiding use of "black market" products, and the FDA's logic regarding enforcement and pre-market review for other deemed new tobacco products.

# III. Effect of Proposed Changes:

# Smoking and Vaping Prohibited Near School Property; Penalties

**Section 2** amends s. 386.212, F.S., relating to smoking and vaping on or near school property and related penalties, to prohibit smoking and vaping by anyone under the age of 21 during any hours of day, on public or private school property or within 1,000 feet of such property. Under current law, that prohibition applies only to persons under 18 years of age between the hours of 6 a.m. and midnight. Current law and the bill provide an exception to this prohibition for any person occupying a moving vehicle or within a private residence.

#### **Definitions of Primary Terms**

**Section 3** amends s. 569.002, F.S., which provides definitions specific to the regulation of tobacco products, to:

- Redefine the term "tobacco products" in subsection (6) as including:
  - Any product containing, made of, or derived from tobacco or nicotine that is intended for human consumption or is likely to be consumed, whether inhaled, absorbed, or ingested by any other means, including, but not limited to, a cigarette, a cigar, pipe tobacco, chewing tobacco, snuff, or snus;
  - Any vapor-generating electronic device and any substances that may be aerosolized or vaporized by such device, whether or not any of the substance contains nicotine; or
  - Any component, part, or accessory of a product described in (a) or (b), whether or not any of these contain tobacco or nicotine, including but not limited to, filters, rolling papers, blunt or hemp wraps, and pipes.

The term does not include drugs, devices, or combination products authorized for sale by the United States Food and Drug Administration, as those terms are defined in the Federal Food, Drug, and Cosmetic Act.

https://www.publichealthlawcenter.org/sites/default/files/resources/tclc-fs-deeming-reg-what-is-possible-2014.pdf (last visited January 8, 2020).

• Define the term "vapor-generating electronic device" in subsection (7) as "any product that employs an electronic, chemical, or mechanical means capable of producing vapor or aerosol from a nicotine product or any other substance, 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 substance form intended to be used with or within an electronic cigarette, an electronic cigar, an electronic cigarillo, an electronic pipe, a vape pen, an electronic hookah, or other similar device or product. The term includes any component, part, or accessory of the device and also includes any substance intended to be aerosolized or vaporized during the use of the device, whether or not the substance contains nicotine." The term does not include drugs, devices, or combination products authorized for sale by the United States Food and Drug Administration, as those terms are defined in the Federal Food, Drug, and Cosmetic Act.

• Delete the definition of the term "any person under the age of 18."

#### **Sales Restrictions**

**Section 1** amends s. 210.15 (1)(b), F.S., relating to permits for the sale of tobacco products, to increase the minimum age for the issuance of such permits from 18 years of age to 21 years of age.

**Section 5** amends s. 569.007(1) and (2), F.S., to modify the general restrictions on the sale or delivery of tobacco products. The bill reflects the increase in the age for the purchase of tobacco products to at least 21 years of age from 18 years of age. Sales of tobacco products from a vending machine are only permissible from a machine that is located in an establishment that prohibits persons under age 21 on the licensed premises at all times.

**Section 6** amends s. 569.101, F.S., relating to the probation and penalties for any person who sells, delivers, barters, furnishes, or gives tobacco products to an under-age person, to increase in the age for the purchase of tobacco products to at least 21 years of age from 18 years of age.

**Section 7** repeals s. 877.112, F.S., to eliminate the general restrictions on the sale or delivery of tobacco products, nicotine dispensing devises, and nicotine products to persons under the age of 18. Many of these provisions are incorporated into the provisions of ch. 569, F.S., by other portions of the bill, and comparable provisions of ch. 569, F.S., are made applicable to vaping devices and products via revised definitions.

**Section 8** amends s. 210.095(5)(a) and (b), F.S., relating to mail order, Internet, and remote sales of tobacco products, and age verification related to such sales. The specifications for the warning label on shipped tobacco products is modified to indicate that Florida law prohibits the shipping to individuals under 21 years of age, rather than 18 years of age. Proof of legal minimum purchase age of the individual accepting delivery is required only if the individual appears to be under 30 years of age, rather than the current 27 years of age. (This latter provision is modified to ensure conformity with recent federal law provisions.<sup>36</sup>)

<sup>&</sup>lt;sup>36</sup> Supra note 33.

**Section 11** amends s. 569.11, F.S., relating to prohibitions on the possession of tobacco products by persons under the minimum age of purchase, to reflect the increase in the minimum age for the purchase or sale of tobacco products in these provisions from 18 years of age to 21 years of age. The section is also amended to delete reference to military service in the context of age of purchase, since the bill separately removes an exception to age limits for tobacco purchase or possession by members of the active duty or reserve military.

# **Conforming Provisions**

Sections 4, 9, 10, 12, 13, and 14 amend ss. 569.003(2)(a), 569.0075, 569.008, 569.12(2)(b) and (3), 569.14 and 569.19(3) and (4), F.S., respectively, to incorporate conforming provisions to reflect the increase in the minimum age for the purchase or sale of tobacco and nicotine products from 18 years of age to 21 years of age.

#### **Effective Date**

**Section 15** provides for an effective date of October 1, 2020, contingent upon the passage of the linked fee bill (yet to be specified) being adopted in the same legislative session or an extension thereof and becoming law.

#### 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:

Retail dealers of vapor-generating electronic devices, such as electronic cigarettes, will be required to obtain a retail tobacco product dealer permit. There is a linked bill that will apply that annual fee of \$50.

# C. Government Sector Impact:

The Department of Business and Professional Regulation (DBPR) may incur indeterminate expenses related to personnel costs or modification of operational priorities needed to accommodate the additional licensure of dealers of vapor-generating electronic devices, which may be offset by a regulatory fee, to be applied via a linked bill.

The DBPR indicates that the bill will require modifications to the department's regulatory data system and related devices used by inspection staff. The department indicates that these modifications can be implemented using existing resources.<sup>37</sup>

### VI. Technical Deficiencies:

None.

#### VII. Related Issues:

#### **Taxation of Tobacco Products**

As previously indicated, Section 3 amends s. 569.002(6), F.S., to modify the definition of "tobacco products." Existing language in s. 210.25(11), F.S., relating to the tax on tobacco products other than cigarettes or cigars, defines the term "tobacco products" to mean:

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), F.S., or cigars.

By not revising the definition of "tobacco products" in ch. 210, F.S., which governs the excise tax and surcharge imposed and collected on cigarettes and other tobacco products, the bill does not affect:

- The collection of excise taxes and surcharge taxes on tobacco products; and
- The licensure, reporting, and recordkeeping of manufacturers and distributors of the additional nicotine delivery products.

<sup>&</sup>lt;sup>37</sup> Department of Business and Professional Regulation, *Senate Bill 810 Analysis* (December 9, 2019) (on file with the Senate Committee on Health Policy).

# **Types of Vaping Devices Subject to Federal Enforcement Priorities**

It should be noted that the vaping devices that will be subject to enhanced enforcement by the federal FDA under its January 2, 2020, guidance document are those vaping devices that are cartridge-based.<sup>38</sup> This means that tank-based vaping devices will not be subject to enhanced federal FDA enforcement. Given this bifurcated approach at the federal level, it is not completely clear if the state's efforts in regulation of *all* vaping devices could face added scrutiny.

# **Exemptions from the Definition of Underage**

Section 4 amends s. 569.002(7), F.S. This subsection presently provides specific exclusions from the meaning of "any person under the age of 18." The bill does not provide comparable exclusions for persons under 21 years of age, other than those related to employment and compliance check participation. The elimination of these exceptions to the minimum age to purchase tobacco products, coupled with the increase of the minimum age to 21 years of age, may, for instance, require active duty or reserve military personnel to be 21 years of age to purchase or possess tobacco products, including electronic smoking devices.

# Age of Tobacco Purchase in Other States

As of September 18, 2019, 18 states have raised the tobacco purchase age to 21 years of age, along with Washington, DC, and over 500 localities.<sup>39</sup> Some of the localities are in states that subsequently enacted statewide laws. Collectively, these laws now cover over half of the U.S. population. The strength of state and local laws, such as their enforcement and penalties, varies substantially.

Those states and the effective date of their adoption of the restrictive provisions are as follow:

State and Effective Date	State and Effective Date		
Hawaii (effective 1/1/16)	Arkansas (effective 9/1/19)		
California (effective 6/9/16)	Texas (effective 9/1/19)		
New Jersey (effective 11/1/17)	Vermont (effective 9/1/19)		
Oregon (effective 1/1/18)	Connecticut (effective 10/1/19)		
Maine (effective 7/1/18)	Maryland (effective 10/1/19)		
Massachusetts (effective 12/31/18)	Ohio (effective 10/17/19)		
Illinois (effective 7/1/19)	New York (effective 11/13/19)		
Virginia (effective 7/1/19)	Washington (effective 1/1/20)		
Delaware (effective 7/16/19)	Utah (effective 7/1/21)		

The following are among the localities that have raised their age for sale of tobacco products to the minimum to 21 years of age: New York City, Chicago, San Francisco, San Antonio, Boston, Cincinnati, Cleveland, Columbus, and Kansas City (in Kansas and Missouri), plus Washington,

<sup>&</sup>lt;sup>38</sup> Supra note 34.

<sup>&</sup>lt;sup>39</sup> See Campaign for Tobacco-Free Kids, States and Localities that have Raised the Minimum Legal Sale Age for Tobacco Products to 21, available at

https://www.tobaccofreekids.org/assets/content/what\_we\_do/state\_local\_issues/sales\_21/states\_localities\_MLSA\_21.pdf (Last visited Nov. 26, 2019).

D.C. In Florida, Alachua County and the city of Fort Lauderdale have raised their minimum age for purchase of tobacco products to 21 years of age.

# Age Restrictions on Youth Access to Electronic Cigarettes in Other States

As of September 15, 2019, all states and the District of Columbia (with the exception of Pennsylvania) have laws that restrict youth access to electronic cigarettes, or e-cigarettes. In this context, *e-cigarette* broadly refers to any product, and its component parts and accessories, that contains nicotine and/or other substances intended for use in the form of an aerosol, often referred to as vapor. In 18 states, the restriction is set at age 21. In four states, the restriction is set at age 19. In 28 states, the restriction is set at age 18. At least one state (Utah) is on a path to increase the age restriction one year at a time to age 21 over a few years. There are certain exceptions and exemptions that are applicable within any given state.<sup>40</sup>

#### VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 210.095, 210.15, 386.212, 569.002, 569.003, 569.007, 569.0075, 569.008, 569.101, 569.11, 569.12, 569.14, and 569.19.

This bill repeals the following section of the Florida Statutes: 877.112.

This bill creates one non-statutory section of the Laws of Florida.

# 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 Health Policy on January 21, 2020:

The CS revises the bill to:

- Use the term and definition for "vapor-generating electronic device" from the Florida Constitution's prohibition against indoor vaping to provide a consistency of terms and to adapt the term to include the cartridges or containers of nicotine or other substances used with a vaping device.
- Apply the prohibition against smoking and vaping within 1,000 feet of school property to persons under 21 years of age during all hours of day (instead of to persons under 18 years of age between the hours of 6 a.m. and midnight.)
- Require age verification before a sale or delivery to a person under 30 years of age. This complies with new federal law.

<sup>&</sup>lt;sup>40</sup> See "Youth Access to E-Cigarettes, States with Laws Restricting Youth Access to E-Cigarettes, Enacted as of September 15, 2019," Public Health Law Center at Mitchell Hamline School of Law, available at <a href="https://www.publichealthlawcenter.org/sites/default/files/States-with-Laws-Restricting-Youth-Access-to-ECigarettes-September152019.pdf">https://www.publichealthlawcenter.org/sites/default/files/States-with-Laws-Restricting-Youth-Access-to-ECigarettes-September152019.pdf</a> (last visited Jan. 8, 2019).

The CS removes from the bill provisions that:

• Exempt retailers who only sell vaping devices and products from the fee (\$50) required for a retail tobacco dealer permit.

- Decriminalize, and revise the applicable penalties, for the prohibition against the sale, delivery, barter, or furnishing of tobacco products to a person under the age of 21.
- Repeal the current prohibitions against the possession of tobacco and vaping products by persons under the minimum age of lawful possession.
- Require the DBPR to conduct enhanced compliance checks of retail establishments.
- Prohibit deliveries of tobacco products to consumers.

#### B. Amendments:

None.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.