

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 224

INTRODUCER: Regulated Industries Committee and Senator Benacquisto

SUBJECT: Nicotine Dispensing Devices

DATE: November 7, 2013

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Oxamendi	Imhof	RI	Fav/CS
2.			CJ	
3.			ACJ	
4.			AP	
5.				
6.				

Please see Section VIII. for Additional Information:

- | | | |
|------------------------------|--|---|
| A. COMMITTEE SUBSTITUTE..... | ☒ | Statement of Substantial Changes |
| B. AMENDMENTS..... | ☐ | Technical amendments were recommended |
| | ☐ | Amendments were recommended |
| | ☐ | Significant amendments were recommended |

I. Summary:

CS/SB 224 extends the current prohibitions related to tobacco products for persons under the age of 18, to prohibit the sale, gifting, possession, or use of nicotine dispensing devices, which include electronic cigarettes (e-cigarettes), to and by persons under the age of 18.

The bill defines the term “nicotine dispensing devices” to mean any product that can be used to deliver nicotine to an individual by inhaling vaporized nicotine from the product, including, but not limited to, an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or other similar device or product and any replacement nicotine cartridge for the device or product.

The bill provides an effective date of July 1, 2014.

This bill substantially amends the following sections of the Florida Statutes: 569.002, 569.0075, 569.101, 569.11, 569.14, and 569.19. The bill reenacts section 322.056, Florida Statutes.

II. Present Situation:

Electronic Cigarettes

Electronic cigarettes, also known as e-cigarettes, are electronic products that permit users to inhale vaporized nicotine, flavor, and other chemicals, without fire, smoke, ash, or carbon dioxide. Electronic cigarettes are manufactured to resemble cigarettes, cigars, or pipes, but some are manufactured to resemble pens and USB memory sticks.¹

Tobacco Regulation in Florida

The Division of Alcoholic Beverage and Tobacco (division) within the Department of Business and Professional Regulation (department) is the state agency responsible for the enforcement of the tobacco product regulation provisions in ch. 569, F.S.

Section 569.002(6), F.S., defines the term “tobacco products” to include:

loose tobacco leaves, and products made from tobacco leaves, in whole or in part, and cigarette wrappers, which can be used for smoking, sniffing, or chewing.

Section 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), or cigars.

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

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.² A second or subsequent violation within one year of the first violation is a first degree misdemeanor.³

Section 569.101(3), provides a complete defense to a person charged with a violation of this section if the buyer or recipient falsely evidenced that he or she was 18 years of age or older, a

¹ What are Electronic Cigarette, Food and Drug Administration, at: <http://www.fda.gov/newsevents/publichealthfocus/ucm172906.htm> (Last visited October 27, 2013), and *Sottera, Inc. v. Food and Drug Administration*, 627 F.3d 891, 893 (D.C. Cir. 2010).

² Section 775.082, F.S., provides that the penalty for misdemeanor of the second degree is punishable by a term of imprisonment not exceeding 60 days. Section 775.083, F.S. provides that the penalty for misdemeanor of the second degree is punishable by a fine not to exceed \$500.

³ Section 775.082, F.S., provides that the penalty for 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 misdemeanor of the first degree is punishable by a fine not to exceed \$1,000.

prudent person would believe the buyer or recipient to be 18 years of age or older, and the buyer or recipient presented false identification⁴ upon which the person relied upon in good faith.

Section 569.11, F.S., prohibits persons under the age of 18 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 violation within 12 weeks of the first violation is punishable with a \$25 fine. A third or subsequent violation within 12 weeks of the first violation requires that the person must be punished with the suspension or revocation of his or her driver's license or driving privilege, as provided in s. 322.056, F.S.

In FY 2012-13, the Department of Highway Safety and Motor Vehicles revoked the driver's license for one person and suspended the driver's license for 561 persons for underage possession of tobacco products, and suspended the driver's license for one underage person for misrepresenting the age to purchase tobacco products.⁵

Section 569.14, F.S., requires that tobacco 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 retail tobacco dealers. Retail tobacco dealers 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.

It is not clear whether the tobacco prohibitions for minors in current law include e-cigarettes as tobacco products. In an attempt to restrict minors' access to e-cigarettes, the division's Internet site advises tobacco retailers that e-cigarettes containing nicotine from tobacco leaves are tobacco products regulated in the state, and that it is unlawful to sell tobacco products, including electronic cigarettes, to a person under 18 years of age.⁶ According to the division, this statement reflects the consensus among tobacco retailers that e-cigarettes should not be sold to persons under the age of 18. The division further states that the law should be amended to clarify the legal status of e-cigarettes.

Currently, the division's sworn law enforcement officers, as well as the non-sworn inspectors, routinely inspect retail tobacco permit holders for compliance with the ch. 569, F.S. The division's sworn law enforcement officers also perform what is termed "surveys," which are undercover operations with underage operatives, as a means of enforcing the prohibitions on the sale of tobacco products to persons less than 18 years of age; and the prohibition on possession of tobacco products by persons less than 18 years of age.⁷

⁴ Identification includes carefully checking "driver's 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(2)(c), F.S.).

⁵ 2014 Agency Legislative Bill Analysis for SB 224, Department of Highway Safety and Motor Vehicles, October 30, 2013.

⁶ See <http://www.myfloridalicense.com/dbpr/abt/index.html> (Last visited October 31, 2013).

⁷ 2014 Agency Legislative Bill Analysis for SB 224, Department of Business and Professional Regulation, October 30, 2013.

According to the department, for the period of January 1, 2012 through December 28, 2012, the division performed 2,805 visits of retail tobacco dealers to determine compliance with ch. 569, F.S. These inspections resulted in 270 arrests for selling, delivering, furnishing, or giving tobacco products to persons under the age of 18. These visits also found three violations for failure to hold a valid retail tobacco permit.

According to the division, 29 administrative cases were initiated against licensees for selling tobacco products to underage persons and 28 civil penalties were collected. Section 569.008(5), F.S., requires a pattern of three or more violations by the employees of the tobacco dealer permit before a permit holder can be sanctioned for sales made by his or her employee. During this same period, the division also cited 136 persons under the age of 18 for possession of tobacco products.

Federal Regulation of E-Cigarettes

The federal U.S. Food and Drug Administration (FDA) is a federal agency within the Department of Health and Human Services. The FDA's organization consists of the Office of the Commissioner and four directorates overseeing the core functions of the agency: Medical Products and Tobacco, Foods, Global Regulatory Operations and Policy, and Operations.⁸ The Office of Medical Products and Tobacco provides advice and regulatory oversight to the FDA Commissioner through the centers for drug, biologics, medical devices, and tobacco products. The office also oversees the agency's special medical programs.⁹

Electronic cigarettes that are marketed for therapeutic purposes are regulated by the FDA Center for Drug Evaluation and Research (CDER).¹⁰ The FDA Center for Tobacco Products regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco.

The authority of the FDA to regulate e-cigarettes is based on the Family Smoking Prevention and Tobacco Control Act of 2009 (Tobacco Control Act).¹¹ Enacted on June 22, 2009, this act amended the Federal Food, Drug, and Cosmetic Act (FDCA) to authorize the FDA to regulate "tobacco products." The Tobacco Control Act defines the term "tobacco product," in part, as any product "made or derived from tobacco" that is not a "drug," "device," or combination product under the FDCA.

The Food and Drug Administration initially determined that certain e-cigarettes were both a drug and a device under the FDCA.¹² Products that fall under the authority of the FDCA as drugs or devices must go through a preapproval process before they can be marketed or sold to the consumer. Tobacco products do not have to go through a pre-approval process.

⁸ See <http://www.fda.gov/AboutFDA/CentersOffices/default.htm>. (Last visited November 4, 2013).

⁹ See <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/default.htm>. (Last visited November 4, 2013).

¹⁰ See <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm172906.htm>. (Last visited November 4, 2013).

¹¹ Federal Food, Drug, and Cosmetic Act, 21 USC s. 351 et seq.

¹² See Department of Health & Human Service, Food and Drug Administration, Letter to Matt Salmon, President of Electronic Cigarette Association, dated September 8, 2010, available at: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM225263.pdf> (Last visited October 10, 2013).

The regulatory classification of e-cigarettes as tobacco products was resolved by the United States Court of Appeals for the District of Columbia Circuit, in *Sottera, Inc. v. Food & Drug Administration*.¹³ The court determined whether the FDA has the authority to regulate e-cigarettes as “tobacco products” under the Family Smoking and Tobacco Control Act of 2009¹⁴ or whether they could be regulated by the FDA as drugs/devices under the FDCA.

The case involved Sottera, Inc., an importer and distributor of e-cigarettes, whose shipment of e-cigarettes had been denied entry by the FDA because, the FDA asserted, they appeared to be adulterated, misbranded, or unapproved drug-device combinations under the FDCA. The company sought an injunction to bar the FDA from denying their e-cigarettes entry into the United States and from regulating e-cigarettes under the drug-device combinations under the FDCA. The United States District Court for the District of Columbia granted the injunction and agreed that e-cigarettes were subject to regulation as tobacco products and were not subject to regulation as drugs/devices under FDCA.¹⁵

On appeal, the United States Court of Appeals for the District of Columbia Circuit held that e-cigarettes and other products made or derived from tobacco should be regulated as “tobacco products,” and not regulated as drugs/devices unless they are marketed for therapeutic purposes.

The FDA did not appeal this decision. The FDA has stated its intent to issue a proposed rule that would extend FDA’s tobacco product regulatory authority to products that meet the statutory definition of “tobacco product.”¹⁶

The National Association of Attorneys General (NAAG) issued a letter to the commissioner of the FDA urging the FDA to immediately regulate the sale and advertising of e-cigarettes as “tobacco products.” The letter was signed by 42 attorneys general, including Florida Attorney General Pam Bondi. The letter noted that, according to the U.S. Centers for Disease Control and Prevention, 1.8 million middle and high school students have said that they had tried e-cigarettes in 2012, which is double the amount for the previous year. The letter noted that e-cigarettes with fruit and candy flavors that appeal to youth and advertising have led consumers to believe that e-cigarettes are a safe alternative to cigarettes. The letter asserted that e-cigarettes are addictive, and regulatory oversight was needed to ensure the safety of e-cigarette ingredients.¹⁷

Some e-cigarettes specifically note in their marketing that e-cigarettes have not been evaluated by the Food and Drug Administration, are not intended to help people to stop smoking, and are

¹³ *Sottera, Inc. v. Food & Drug Administration*, 627 F.3d 891 (D.C. Cir. 2010).

¹⁴ The Family Smoking and Tobacco Control Act of 2009, Pub.L. 111-31, 123 Stat. 1776.

¹⁵ Another importer of e-cigarettes, Smoking Everywhere, Inc., had sought an injunction to bar the FDA from denying their e-cigarettes entry into the United States and from regulating e-cigarettes under the drug-device combinations under the FDCA. Sottera, Inc., then joined as an intervenor-plaintiff and also sought an injunction. Smoking Everywhere, Inc., dismissed its complaint against the FDA while the appeal was pending.

¹⁶ See: Unified Agenda entry describing this rulemaking, Office of Information and Regulatory Affairs, Office of Management and Budget: <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201210&RIN=0910-AG38> (Last visited October 31, 2013).

¹⁷ Letter from the National Association of Attorneys General to Margaret Hamburg, Commissioner of the U.S. Food and Drug Administration, October 23, 2013. A copy of the letter is available at: <http://www.naag.org/assets/files/pdf/signons/E%20Cigarette%20Final%20Letter%20w%20Florida.pdf> (Last visited November 1, 2013).

not intended to treat, prevent or cure any disease or condition. Some retailers also assert that they voluntarily restrict sales to persons who are 18 years of age or older.

As noted above, the Centers for Disease Control and Prevention reported that the number of middle school and high school students in the United States who used electronic cigarettes doubled in 2012 compared to the previous year. According to the report, nearly 1.78 million students tried e-cigarettes in 2012 nationwide.¹⁸ In Florida, 4.3 percent of middle school students and 12.1 percent of high school students have tried e-cigarettes in 2013. The number of Florida high school students who have tried e-cigarettes has increased from 6 percent in 2011 to 12.1 percent in 2013.¹⁹

III. Effect of Proposed Changes:

The bill extends the current prohibitions related to tobacco products for persons under the age of 18, to prohibit the sale, gifting, possession, or use of nicotine dispensing devices, which include electronic cigarettes (e-cigarettes), to and by persons under the age of 18.

The bill creates s. 569.002(8), F.S., to define the term “nicotine dispensing devices” to mean any product that can be used to deliver nicotine to an individual by inhaling vaporized nicotine from the product, including, but not limited to, an electronic cigarette, electronic cigar, electronic cigarillo, electronic pipe, or other similar device or product and any replacement nicotine cartridge for the device or product.

The bill amends s. 569.0075, F.S., to include nicotine dispensing devices in the prohibition against giving a sample of tobacco products to persons under the age of 18.

The bill amends s. 569.101, F.S., to include nicotine dispensing devices in the prohibition against the sale, delivery, bartering, furnishing or giving of tobacco products to persons under the age of 18.

The bill amends s. 569.11, F.S., to include nicotine dispensing devices in the prohibition against persons under the age of 18 from possessing, directly or indirectly, any tobacco products. It also adds a nicotine component to the anti-tobacco program that a first offender must attend.

The bill amends s. 569.19, F.S., to require the department to include the number of violations for selling nicotine dispensing devices to person under age 18 in its annual report.

The bill amends s. 569.14, F.S., to include nicotine dispensing devices in the signage requirements.

The bill reenacts s. 322.056, F.S., to incorporate the amendments in the bill to s. 569.11, F.S.

The bill provides an effective date of July 1, 2014.

¹⁸ See <http://www.cdc.gov/media/releases/2013/p0905-ecigarettes-use.html>. (Last visited November 4, 2013).

¹⁹ See <http://newsroom.doh.state.fl.us/wp-content/uploads/newsroom/2013/05/090613-E-Cigarette-Use-Among-Teens-Doubles.pdf> (Last visited November 5, 2013).

IV. Constitutional Issues:**A. Municipality/County Mandates Restrictions:**

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

Tobacco permit holders would be required to replace their point of sale calendars that indicate the date that a person is of legal age to purchase tobacco products to new calendars that reference nicotine dispensing devices, unless the permit holders are using readers, scanners, or other electronic or automated systems. They would also be required to replace signage that gives notice that the sale of tobacco products to persons under the age of 18 is prohibited with signage that also references nicotine dispensing devices. The cost for this requirement is indeterminate.

C. Government Sector Impact:

The Department of Business and Professional Regulation has indicated that if additional surveys are required for electronic cigarettes, then funds for an additional survey team would be required. The department estimates that a new survey team, which consists of two law enforcement officers and one underage operative, can complete an average of 3 tobacco surveys in a 4-hour time period or the equivalent of 1,191.75 surveys per year. The total cost would be \$273,559.00 for FY 2014-2015 and \$176,415.00 for subsequent years.

VI. Technical Deficiencies:

None.

VII. Related Issues:

According to the National Conference of State Legislatures there are 27 states that have banned the sale of electronic cigarettes to minors.²⁰

VIII. 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 Committee on March 7, 2013:

The committee substitute (CS) amends s. 569.002(8), F.S., to define the term “nicotine dispensing devices.” The CS also replaces the term “alternative nicotine products” with the term “nicotine dispensing devices” in ss. 569.0075, 569.101, 569.11, and 569.14, F.S.

The CS does not create s. 569.002(1)(a), F.S., to define the term “alternative nicotine product,” and to provide an exemption from the meaning of that term for tobacco products; a product that is a drug, as defined in 21 U.S.C. s. 37321(g)(1), a product that is a device as defined in 21 U.S.C. s. 39321(h); and a combination product that is a device regulated under 21 U.S.C. s. 353(g).

The CS also does not create s. 569.002(1)(c), F.S., to define the term “electronic cigarette.”

The CS amends s. 569.19, F.S., to require the department to include the number of violations for selling nicotine dispensing devices to person under age 18 in its annual report.

B. Amendments:

None.

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

²⁰ Those states are: AK (products containing nicotine other than cigs), AL (age 19), AZ, AR, CA, CO, HI, ID, IL (signed August 2013) IN, KS, MD, MN, MS, NV (definition includes “or derived from tobacco”), NH, NJ (age 19), NY, NC, OR (All sales banned, ordered by DOJ), SC, TN, UT (age 19), VT, WA, WI, WY.