

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 Commerce and Tourism

BILL: CS/SB 938

INTRODUCER: Health Policy Committee and Senator Benacquisto

SUBJECT: Retail Sale of Dextromethorphan

DATE: February 15, 2016

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Lloyd</u>	<u>Stovall</u>	<u>HP</u>	<u>Fav/CS</u>
2.	<u>Little</u>	<u>McKay</u>	<u>CM</u>	<u>Pre-meeting</u>
3.	_____	_____	<u>FP</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

Dextromethorphan (DXM) is an antitussive medicine, most commonly used as a cough suppressant. CS/SB 938 prohibits any manufacturer, distributor, or retailer, and their employees and representatives, from knowingly or willfully selling a product that contains DXM to an individual under the age of 18 without a valid prescription. The bill requires individuals presumed to be less than 25 years of age to provide proof of age prior to purchasing a product that contains any quantity of DXM.

The bill also sets forth uniform procedures for local law enforcement officers and other officials responsible for enforcing the law. An individual who possesses or receives DXM in violation of the act with the intent to distribute is subject to a civil citation of up to \$100 for each violation. An employee or representative who sells a product containing DXM in violation of the act is subject to a written warning. A manufacturer, distributor, or retailer found to be in violation of the act may be subject to a civil citation, and a fine of up to \$100 per violation. However, a citation may be avoided upon the showing of a good faith effort to comply with the bill's requirements.

The bill has an indeterminate fiscal impact and provides an effective date of January 1, 2017.

II. Present Situation:

Dextromethorphan (DXM) is an antitussive medicine, most commonly used as a cough suppressant.¹ DXM was first approved by the Food and Drug Administration (FDA) in 1958 as a safe and effective ingredient found in many over-the-counter (OTC) cough and cold remedies.² Today, DXM is in almost half of all OTC drugs sold in the United States.³

More than 125 OTC products contain DXM either alone or in combination with other drugs such as analgesics (for example: acetaminophen), antihistamines, decongestants, and/or expectorants.⁴ A total of 10.7 million DXM medications were dispensed in 2013.⁵ DXM can be found in the form of cough syrup, tablets, capsules or powder. It is available without a prescription and sold under popular brand names such as Robitussin, Pediacare, Coricidin, and Vicks 44. When taken as directed, side-effects from DXM are rarely observed.⁶ However, when taken in large doses in combination with alcohol or other drugs, it may cause serious adverse health effects, including death.⁷

In response to growing reports of teenagers dying from the illicit use of DXM, the FDA issued a warning about its dangers in 2005.⁸ The federal Drug Enforcement Agency (DEA) reports that the most commonly abused products containing DXM are Robitussin and Coricidin.⁹ Illicit use of these drugs is also known as “Robo-tripping” or “skittling.”¹⁰ Cough medicine abuse seems to be most popular among teens and younger children as cough medicine is often cheap, easy to get, and legal.

Side effects of DXM intoxication include:

- Over-excitability;
- Lethargy;
- Loss of coordination;
- Slurred speech;
- Sweating;
- Hypertension; and
- Involuntary spasmodic movement of the eyeballs.¹¹

¹ U.S. Food and Drug Administration, *Dextromethorphan Talk Paper* (May 20, 2005), <http://www.fda.gov/downloads/advisorycommittees/drugs/ucm224446.pdf> (last visited Feb. 8, 2016).

² *Id.*

³ WebMD, *Teen Abuse of Cough and Cold Medicine*, <http://www.webmd.com/parenting/teen-abuse-cough-medicine-9/teens-and-dxm-drug-abuse> (last visited Feb. 8, 2016).

⁴ Drug Enforcement Administration, *Dextromethorphan* (March 2014), http://www.deadiversion.usdoj.gov/drug_chem_info/dextro_m.pdf (last visited Feb. 8, 2016).

⁵ *Id.*

⁶ Drug Enforcement Administration, *Drug Fact Sheet Dextromethorphan*, http://www.dea.gov/druginfo/drug_data_sheets/Detromethorphan.pdf (last visited Feb. 10, 2016).

⁷ *Supra*, note 4.

⁸ *Supra*, note 1.

⁹ *Supra*, note 4.

¹⁰ *Id.*

¹¹ *Supra*, note 6.

The side effects of DXM can be worsened if combined with alcohol or other drugs. The American Association of Poison Control Centers reported 45,748 case mentions, 33,811 single exposures, and six deaths related to DXM as of the March 2014 DEA update.¹²

DXM is not a controlled substance nor a regulated chemical under the Controlled Substances Act (CSA). The CSA is a federal statute¹³ that prescribes and regulates the United States' drug policy which includes the manufacture, importations, possession, use, and distribution of certain substances. Federal law provides five schedules of controlled substances, known as Schedules I, II, III, IV, and V. The placement of a substance under a specific schedule is made based on a number of criteria for the drug or substance:

- Potential for abuse;
- Accepted medical use in treatment in the United States;
- Safety for use of the drug or substance; and
- Abuse of the drug or substance which leads to psychological or physical dependence.¹⁴

In Congress, the DXM Abuse Prevention Act of 2015 (H.R. 3250) was introduced in July 2015 to specifically address DXM issues.¹⁵ The legislation would:

- Restrict its sale to individuals at least 18 years of age, except those with a valid prescription or on active military duty;
- Require retailers to verify individuals are at least 18 years of age and to implement an electronic, point of sale verification system;
- Provide affirmative defenses to retailers who check identifications and reasonably conclude the identification is valid and the individual is 18 years of age;
- Create penalties for violations ranging from a warning for a first violation to up to a fine of up to \$5,000 for a fourth or subsequent violation;
- Prohibit possession or receipt of unfinished DXM by any person not registered, licensed, or approved under federal or state law to practice pharmacy, engage in pharmaceutical production, or manufacture or distribute drug ingredients;
- Prohibit the distribution of unfinished DXM to unregistered or unlicensed persons; and
- Establish a civil penalty of up to \$100,000 for the unfinished DXM possession, receipt, and distribution violations.

The legislation has not been heard in committee.

III. Effect of Proposed Changes:

The bill creates an undesignated section of law to prohibit the sale of OTC products containing DXM to individuals who are under the age of 18. Specifically, the bill prohibits any manufacturer, distributor, or retailer, from knowingly or willfully selling a finished drug product containing DXM to an individual younger than 18 years of age without a valid prescription.

¹² *Id.*

¹³ Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. 18583, 91st Cong. (1970).

¹⁴ 21 U.S.C. § 812 (2014).

¹⁵ DXM Abuse Prevention Act of 2015, HB 3250, 114th Cong. (2016) available at <https://www.congress.gov/bill/114th-congress/house-bill/3250> (last visited Feb. 9, 2016).

The bill provides definitions for:

- “Finished drug product,” which means a drug legally marketed under the Federal Food, Drug, and Cosmetic Act that is in finished dosage form. The term “drug” has the same meaning as provided in s. 499.003(18), F.S.
- “Proof of Age,” which means any document issued by a governmental agency that contains the date of birth and a description or photograph of the person purchasing the finished drug product. The term includes, but is not limited to, a passport, driver license, or a government identification card issued by this state, another state, or any branch of the United States Armed Forces.

Under the bill, an employee or representative of a retailer of a finished drug product containing any quantity of DXM is required to obtain proof of age from any purchaser prior to sale of the product, unless it would be reasonable to presume the purchaser is 25 years of age or older. A person 18 years of age or younger may not purchase a finished drug product containing DXM.

The bill does not impose any restrictions on the placement of products in retail stores, direct access of customers to finished drug products, or the maintenance of transaction records. The bill also does not apply to medication containing DXM sold by a retail entity pursuant to a valid prescription.

Local law enforcement, and other officials charged with enforcement of state laws, are required to enforce the act uniformly throughout the state. The bill preempts any local ordinances regulating the sale, distribution, receipt, or possession of DXM, and DXM is not subject to any further regulation by county, municipality, or other political subdivisions of the state.

Penalties

An employee or representative of a manufacturer, distributor, or retailer, who sells DXM during the course of his or her employment in violation of the act is subject to a written warning.

The bill also establishes civil penalties for violations of the act. The bill does not create a criminal violation; a person who violates this act commits a noncriminal violation as defined in s. 775.08(3), F.S.¹⁶

Each sales location of a manufacturer, distributor, or retailer whose employees or representatives sell DXM in violation of this act is subject to a written warning for the initial violation and a civil citation of not more than \$100 for each subsequent violation. Civil citations may accrue and be recovered in a civil action by the local jurisdiction. However, the citation may be waived if the manufacturer, distributor, or retailer demonstrates a good faith effort to comply with the bill’s requirements.

¹⁶ Section 775.08(3), F.S., defines “noncriminal violation” as an offense that is punishable by only a fine, forfeiture, or other civil penalty. A noncriminal violation does not constitute a crime, and a conviction for one these offenses would not give rise to any legal disability based on a criminal offense. Examples of noncriminal offenses include some traffic-related offenses, parking violations or citations for loud-noises.

A person who possesses or receives DXM in violation of the act with the intent to distribute is subject to a civil citation of up to \$100 for each violation. The amount of the fine imposed is assessed by the local jurisdiction. The bill does not impose consequences on a person who purchases DXM if no intention to distribute exists.

Civil Citations

The bill requires the following information to be included in any civil citation issued for a violation of the act:

- The date and approximate time of the sale in violation;
- The location of the sale, including the address;
- The name of the employee or representative that completed the sale;
- Information on how to dispute the citation;
- Notice that the citation is a non-criminal violation; and
- How to dispute the notice and what to expect in the dispute process.

The bill also requires a civil citation directed towards a manufacturer, distributor, or retailer, to be delivered to the manager on duty at the time the citation is issued. If a manager is not available, the local law enforcement officer is required to attempt to contact the manager; or, if unsuccessful, the local law enforcement officer may leave a copy with an employee who is 18 years of age or older and mail a copy of the citation by certified mail to the business owner's address, as listed on the Department of State's records.

The bill requires the recipient of the citation to provide notice of any dispute to the clerk of the county court in the jurisdiction where the violation occurred within 15 days of receiving the citation. The local jurisdiction must hold a hearing regarding the citation when:

- a citation for the violation of the bill is issued;
- the violation is disputed; and
- the recipient is issued the citation by a local law enforcement officer employed by or acting on behalf of the jurisdiction.

Effective Date

The bill provides an effective date of January 1, 2017.

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:

Retailers, manufacturers, and distributors would be required to train employees and associates to check the identification of any individuals purchasing products containing any quantity of DXM who appear to be less than 25 years of age.

Unlawful sales subjects retailers, manufacturers, and distributors of DXM to a civil citation and fine of up to \$100 for any violation of the act that occurs after an initial violation is found. However, if a manufacturer, distributor, or retailer makes a “good faith effort” to comply with this law, it will not incur a citation for the unlawful sale by an employee or associate.

Persons who possess or receive DXM in violation of this bill, with the intention to distribute the DXM, are subject to a \$100 fine.

C. Government Sector Impact:

The Department of Health has indicated that there would be no fiscal impact to implement the provisions of this act. As the regulator of pharmacies, the department is assumed to have the responsibility of monitoring the manufacturers, retailers, and distributors in their compliance efforts as well as the good faith efforts of their employees and associates.

Local law enforcement agencies will be required to monitor the activities of retailers, manufacturers, and distributors for the unlawful sales of DXM. Written warnings are required for first time offenders and citations for repeat offenders. In those instances when individuals elect to dispute their citations and fines, courts in the county where the citation was issued may incur costs related to holding hearings and disposing of the matter.

Counties, municipalities, and other political subdivisions of the state are preempted from any local regulation over the sale, distribution, possession, or receipt of DXM.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Line 39 of the bill contains the phrase “a person younger than 18 years of age” while line 40 of the bill contains the phrase “a person 18 years of age or younger” when referring to individuals who cannot purchase products containing DXM without a valid prescription. The language appears to be conflicting and may cause confusion as to whether or not a person that is 18 years old is able to be sold and purchase a product containing DXM without a valid prescription.

The bill also does not address situations in which an individual younger than 18 years of age may be considered an adult for other purposes. Under the bill emancipated minors and individuals under 18 years of age in active military duty cannot purchase products containing DXM without a valid prescription.

The bill does not define the terms manufacturer, retailer, or distributor. Because the bill creates an undesignated a section of law, the definition of these terms may be defined by the section of law the bill is designated under.

The bill regulates the sale of “a finished drug product containing any quantity of dextromethorphan” on lines 38 and 44. However, lines 53, 64, and 66 refer to the sale and possession of “dextromethorphan in violation of this section,” rather than a finished drug product. It is unclear whether the civil citation applies to the sale of finished drug products containing DXM, DXM by itself, or both.

The bill requires that enforcement of the bill’s provisions must be applied uniformly throughout the state by local law enforcement and officials. In order for the laws to be applied uniformly throughout the state, a state agency would need to be given the authority to enforce the bill’s requirements.

Lines 57-59 of the bill provide that manufacturers, retailers, or distributors may avoid a citation upon the showing of good faith effort to comply with the bill’s requirements. It is unclear by the language of the bill whether the good faith effort to comply should be shown at the time the citation is issued, or at a hearing regarding a disputed citation.

The bill requires a local jurisdiction to hold a hearing in the court of competent jurisdiction, “when a citation for a violation of this section is issued, when the violation is disputed, and when the recipient is issued the citation by a local law enforcement officer employed by or acting on behalf of the jurisdiction.” This language could be simplified by providing that a hearing in the court of competent jurisdiction should be held “when a citation is issued by a local law enforcement officer employed by or acting on behalf of the jurisdiction and the recipient of the citation has provided notice of dispute of the citation.”

Lines 109-112 of the bill provide that the bill does not impose any restriction on the placement of products in a retail store, direct access of customers to finished drug products, or the maintenance of transaction records. However, the bill does impose restrictions that prohibit individuals under the age of 18 from purchasing finished drug products containing DXM, and the bill also requires individuals presumed to be younger than 25 years of age to show proof of age.

VIII. Statutes Affected:

This bill creates an undesignated section of law in the Florida Statutes.

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 19, 2016:**

The committee substitute:

- Modifies the definitions for “finished drug product” and “proof of age”;
- Subjects each sales location of a manufacturer, distributor, and retailer whose employee or representative sells dextromethorphan (DXM) to someone under age 18 to a violation of this act and provides for a written first warning followed by a civil citation with no more than a \$100 fine for each subsequent violation;
- Provides that fines assessed under this act may accrue and may be recovered in a civil action brought by the local jurisdiction;
- Subjects an employee or representative of a manufacturer, distributor, or retailer who sells DXM in violation of this act to a written warning;
- Subjects a person who possesses or receives DXM with the intent to distribute to a civil citation and fine for each violation which may be recovered in a civil action;
- Describes the contents of a civil citation;
- Provides a process for notification of a written warning or civil citation to the manager on duty;
- Requires uniformity in application across the state, but enforcement remains with local law enforcement departments and officials charged with enforcement of state laws; and
- Clarifies that the bill does not create a criminal violation.

B. Amendments:

None.