

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 Fiscal Policy

BILL: CS/CS/SB 938

INTRODUCER: Commerce and Tourism Committee; Health Policy Committee; and Senator Benacquisto

SUBJECT: Retail Sale of Dextromethorphan

DATE: February 23, 2016 **REVISED:** _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Lloyd</u>	<u>Stovall</u>	<u>HP</u>	Fav/CS
2.	<u>Little</u>	<u>McKay</u>	<u>CM</u>	Fav/CS
3.	<u>Jones</u>	<u>Hrdlicka</u>	<u>FP</u>	Favorable

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 938 regulates dextromethorphan (DXM), a synthetically produced product that is the most commonly used cough suppressant in the United States. The bill prohibits any manufacturer, distributor, or retailer, and their employees and representatives, from knowingly or willfully selling a finished drug 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 finished drug product that contains any quantity of DXM.

The bill also sets forth procedures for local law enforcement officers to enforce the law. An individual who possesses or receives a finished product containing any quantity of DXM in violation of the bill 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 finished drug 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 of up to \$100 per violation. However, a citation issued to a manufacturer, distributor, or retailer may be avoided upon the showing of a "good faith effort" to comply with the bill's requirements.

The bill preempts local regulation of DXM.

The bill has an indeterminate fiscal impact. See Section V. Fiscal Impact Statement.

The bill is effective January 1, 2017.

II. Present Situation:

Dextromethorphan (DXM) is a synthetically produced product that is the most commonly used cough suppressant in the United States.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 120 OTC products contain DXM either alone or in combination with other drugs such as analgesics (for example: acetaminophen), antihistamines, decongestants, and/or expectorants. A total of 10.7 million DXM medications were dispensed in 2013.⁴ DXM can be found in the form of cough syrup, tablets, capsules or powder and is available without a prescription, sold under popular brand names such as Robitussin, Coricidin, and Vicks 44.⁵ 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 HBP. Illicit use of these drugs is also known as “Robo-tripping” or “skittling.”⁹ Cough medicine abuse seems to be most popular among teens and younger children as cough medicine is often cheap, easy to get, and legal.¹⁰

Side effects of DXM intoxication include:

- Over-excitability;
- Lethargy;
- Loss of coordination;
- Slurred speech;
- Sweating;
- Hypertension; and

¹ U.S. Food and Drug Administration, Background information for the DSaRM Advisory Committee, (Aug. 23, 2010), p. 5, available at <http://www.fda.gov/downloads/advisorycommittees/drugs/ucm224446.pdf> (last visited Feb. 20, 2016).

² *Id.* at p. 60.

³ WebMD, *Teen Abuse of Cough and Cold Medicine; Teens and DXM Drug Abuse (June 2012)*, available at <http://www.webmd.com/parenting/teen-abuse-cough-medicine-9/teens-and-dxm-drug-abuse> (last visited Feb. 20, 2016).

⁴ Drug Enforcement Administration, Office of Diversion Control, Drug & Chemical Evaluation Section, *Dextromethorphan (Street Names: DXM, CCC, Triple C, Skittles, Robo, Poor Man’s PCP)*, (March 2014), available at http://www.deadiversion.usdoj.gov/drug_chem_info/dextro_m.pdf (last visited Feb. 20, 2016).

⁵ *Supra* note 3.

⁶ Drug Enforcement Administration, *Drug Fact Sheet Dextromethorphan (DXM)*, available at http://www.dea.gov/druginfo/drug_data_sheets/Detromethorphan.pdf (last visited Feb. 20, 2016).

⁷ *Supra* note 4.

⁸ *Supra* note 1.

⁹ *Supra* note 6.

¹⁰ *Supra* note 3.

- Involuntary spasmodic movement of the eyeballs.¹¹

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 6 deaths related to DXM as of the March 2014 DEA update.¹²

DXM is not a controlled substance regulated by Federal government or the state of Florida.¹³ Legislation has been introduced but never heard in committee.¹⁴ The federal legislation would:

- Restrict sale of DXM to individuals at least 18 years of age, except those with a valid prescription or on active military duty;
- Require a retailer to verify the age of purchasers and to implement an electronic, point of sale verification system;
- Provide affirmative defenses for 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.¹⁵

III. Effect of Proposed Changes:

The bill creates an undesignated section of law to prohibit any manufacturer, distributor, or retailer, or its employees and representatives, from knowingly or willfully selling a finished drug product containing any quantity of DXM to a person younger than 18 years of age.

The bill defines:

- “Finished drug product,” to mean 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 s. 499.003(18), F.S.; and
- “Proof of Age,” to mean 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 a passport, driver license, or a government identification card issued by this state, another state, or any branch of the United States Armed Forces.

An employee or representative of a retailer is required to obtain proof of age from any purchaser prior to sale of a finished drug product containing any quantity of DXM, unless it would be

¹¹ *Supra* note 6.

¹² *Supra* note 4.

¹³ *See* 21 U.S.C. s. 812 and s. 893.03, F.S.

¹⁴ 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. 22, 2016).

¹⁵ *Id.*

reasonable to presume the purchaser is 25 years of age or older. A person younger than 18 years of age may not purchase a finished drug product containing any quantity of 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;
- Apply to medication containing DXM sold by a retail entity pursuant to a valid prescription; and
- Create a criminal violation; any violation is a noncriminal violation.¹⁶

Local law enforcement, and other officials charged with enforcement of state laws are required to enforce the bill 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.

Civil Citations: Manufacturers, Distributors, Retailers

Each sales location of a manufacturer, distributor, or retailer may be subject to a civil citation if an employee or representative sells finished drug products containing any quantity of DXM to a person younger than 18 during the course of the his or her employment or association with the manufacturer, distributor, or retailer. The sales location 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, a manufacturer, distributor, or retailer who demonstrates a good faith effort to comply with the bill is not subject to a citation.

A civil citation issued to a manufacturer, distributor, or retailer must be provided to the manager on duty when the citation is issued. If a manager is not available, the local law enforcement must attempt to contact the manager to issue the citation. If the law enforcement officer is unsuccessful in contacting the manager, he or she 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 law enforcement officer may also return at a later time to issue the citation.

The civil citation issued to a manufacturer, distributor, or retailer must include:

- The date and approximate time of the sale;
- 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 noncriminal violation.

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.

Civil Citations: Employees or Representatives of a Manufacturer, Distributor or Retailer

An employee or representative of a manufacturer, distributor, or retailer who during the course of his or her employment or association with the manufacturer, distributor, or retailer sells a finished drug product containing any quantity of DXM to a person younger than 18 is subject to a written warning.

Civil Citations: Others

A person who possesses or receives a finished drug product containing any quantity of DXM in violation of the bill with the intent to distribute is subject to a civil citation of up to \$100 for each violation. Civil citations may accrue and be recovered in a civil action brought by the local jurisdiction. The civil citation must include information on how to dispute the citation and state that the violation is a noncriminal violation.

The bill does not impose consequences on a person who purchases a finished drug product containing any quantity of DXM in violation of the act if no intention to distribute exists.

Disputing a Civil Citation

The bill requires the recipient of a citation to provide notice of any dispute of the citation 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.

The bill is effective January 1, 2017.

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

Article VII, section 18(b) of the Florida Constitution states that “[e]xcept upon approval of each house of the legislature by two-thirds of the membership, the legislature may not enact, amend or repeal any general law if the anticipated effect of doing so would be to reduce the authority that the municipalities or counties have to raise revenues in the aggregate, as such authority exists on February 1, 1989.” Article VII, section 18(d) of the Florida Constitution provides an exemption from the mandates provision for laws having an insignificant fiscal impact, which for Fiscal Year 2016-2017, is \$2 million or less.^{17, 18}

¹⁷ An insignificant fiscal impact is the amount not greater than the average statewide population for the applicable fiscal year times \$0.10. See Florida Senate Committee on Community Affairs, Interim Report 2012-115: Insignificant Impact, (September 2011), available at <http://www.flsenate.gov/PublishedContent/Session/2012/InterimReports/2012-115ca.pdf> (last visited Feb. 22, 2016).

¹⁸ Based on the Demographic Estimating Conference’s population adopted on December 1, 2015. The conference packet is available at <http://edr.state.fl.us/Content/conferences/population/ConferenceResults.pdf> (last visited Feb. 22, 2016).

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 finished drug products containing any quantity of DXM who appear to be less than 25 years of age.

Unlawful sales under the act subject retailers, manufacturers, and distributors to a civil citation and fine of up to \$100 for any violation of the act that occurs after an initial violation. 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 finished drug products containing any quantity of DXM with the intention to distribute the finished drug product, are subject to civil citation and a fine up to \$100.

C. Government Sector Impact:

The Department of Health regulates pharmacies and 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. However, there is no fiscal impact to the department to implement the bill.

Local law enforcement agencies will be required to monitor the activities of retailers, manufacturers, and distributors for unlawful sales of finished drug products containing DXM. County courts may incur costs related to holding hearings and disposing these civil citations. The local jurisdiction where the civil citation is issued will have to bring a civil action to recover the civil fines associated with the civil citation. The bill also preempts all local regulation of DXM.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill 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 finished drug products containing DXM without a valid prescription.

The bill requires an employee or representative to “obtain proof of age” of the purchaser. This may unintentionally require the employee or representative to take the “proof of age” document.

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 under the bill which is eventually designated.

The bill requires that enforcement of its 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, an entity with statewide jurisdiction would need to be given the authority to enforce the bill’s requirements.

Lines 58-60 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. “Good faith effort” is not defined.

The bill does not address how or if an employee or representative of a manufacturer, distributor, or retailer can dispute a written warning. The bill also do not specify what needs to be included in the written warning.

The bill makes a person who possesses or receives a finished drug product containing any quantity of DXM with the intent to distribute subject to a civil citation of up to \$100 for each violation. This language does not contemplate a parent purchasing a finished drug product containing any quantity of DXM to give to a sick child under the age of 18. As drafted this could subject a parent to a civil citation of up to \$100.

The bill specifies what must be included on a civil citation for a manufacturer, distributor, or retailer but does not specify such for a civil citation given to a person who possesses or receives a finished drug product containing any quantity of DXM.

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.”

The bill allows for a copy of a civil citation to be mailed to the owner's business address as filed with the Department of State. This does not account for franchises or if an owner's name is not on the filings with the Department of State.

VIII. Statutes Affected:

This bill creates an undesignated section of Florida law.

IX. Additional Information:

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

CS/CS by Commerce and Tourism on February 16, 2016:

The committee substitute makes technical changes to clarify the bill prohibits the sale of a finished drug product containing any quantity of DXM to an individual younger than the age of 18 years old, without a valid prescription.

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.