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 938
INTRODUCER:	Health Policy Committee and Senator Benacquisto
SUBJECT:	Retail Sale of Dextromethorphan
DATE:	January 19, 2016 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Fav/CS**
2.			CM	
3.			FP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 938 prohibits a retail entity from knowingly and willingly selling a finished drug product containing dextromethorphan (DXM) to an individual less than 18 years of age. DXM is most commonly used to relieve coughs due to colds or influenza. The bill requires proof of age from any individual presumed to be less than 25 years of age prior to purchasing a finished drug product with any quantity of DXM. The requirement does not apply to medication sold by a retail entity pursuant to a valid prescription.

CS/SB 938 provides for a written first warning, then a civil citation of no more than $100 for each subsequent violation for retailers, wholesalers, and distributers for selling DXM to a person 18 years of age or younger in violation of this act. However, a manufacturer, distributor, or retailer may avoid the fine for the employee's or representative's sale upon a showing of a good faith effort to comply with the requirements. An employee or representative who sells DXM in violation of this act is subject to a written warning.

The bill establishes requirements for the delivery of civil citations to the manager on duty by local law enforcement and for the specific content of the citations. Civil citation recipients will also be notified of a dispute process with hearings held in the local jurisdiction. Enforcement of this act shall remain with local law enforcement and with the officials charged with the enforcement of the laws of this state.

The act does not impose restrictions on the placement of products in a retail store, direct access by consumers to products, or the maintenance of transaction records. This act preempts any local ordinance regulating the sale, distribution, receipt, or possession of DXM, and it is not subject to further regulation by such political subdivisions.

The bill has an indeterminate fiscal impact and is effective January 1, 2017.

II. Present Situation:

Dextromethorphan (DXM) is an antitussive medicine most commonly used to relieve coughs due to colds or influenza.[1] It is available without a prescription and sold under popular brand names such as Robitussin, Pediacare, Coricidin, and Vicks 44. The federal Drug Enforcement Agency (DEA) reports that the most commonly abused products are Robitussin and Coricidin.[2] Illicit use of these drugs is also known as "Robo-tripping" or "skittling."[3] DXM can be found in the form of cough syrup, tablets, capsules or powder.

DXM is in almost half of all over-the-counter (OTC) drugs sold in the United States.[4] 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.[5] DXM was first approved by the Food and Drug Administration (FDA) in 1958 as a safe and effective cough suppressant. In response to growing reports of teenagers dying from the use of raw DXM, the FDA issued a warning about its dangers in 2005.[6] A total of 10.7 million DXM medications were dispensed in 2013.[7]

On its own, DXM is very safe; however, when taken in large doses, it may cause hallucinations, a heightened sense of awareness, and altered time perception.[8] Cough medicine abuse seems to be most popular among teens and younger children as cough medicine is often cheap, easy to get, and legal. A powdered version of DXM is sold over the internet.

At high doses, DXM can cause:
- Impaired vision;
- Sweating and fever;
- Rapid breathing;
- Increased and irregular heart rate and blood pressure;
- Nausea, vomiting, and diarrhea;

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[1] Mayo Clinic, *Dextromethorphan,* http://www.mayoclinic.org/drugs-supplements/dextromethorphan-oral-route/description/drg-20068661 (last visited Jan. 13, 2016).
[2] Drug Enforcement Administration, *Dextromethorphan* (March 2014), http://www.deadiversion.usdoj.gov/drug_chem_info/dextro_m.pdf (Last visited Jan. 13, 2016).
[3] Id.
[4] 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 Jan. 13, 2016).
[5] *Supra* note 2.
[6] U.S. Food and Drug Administration, *Dextromethorphan Talk Paper* (May 20, 2005), http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm151133.htm (last visited Jan. 13, 2016).
[7] *Supra* note 4.
[8] Id.

- Slurred speech;
- Impaired judgment and mental function;
- Memory loss;
- Rapid eye movements;
- Hallucinations and dissociative effects; and
- Coma.[9]

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.[10]

DXM is not currently a controlled substance nor a regulated chemical under the Controlled Substances Act (CSA).[11] The CSA is a federal statute 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.[12]

For example, a Schedule I substance has a high potential for abuse, no currently accepted medical use, and a lack of accepted safety for its use as opposed to a Schedule V drug that has a low potential for abuse relative to a Schedule IV drug, has a currently accepted medical use for treatment in the United States, and abuse of the drug or other substance may lead to limited physical or psychological dependence relative to the drugs or substances in Schedule IV.[13]

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

- Restrict its sale to individuals under 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 $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

[9] Id.
[10] *Supra* note 2.
[11] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. 18583, 91st Cong. (1970).
[12] 21 U.S.C. §812(b) (2014).
[13] Id.

- 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:

CS/SB 938 creates an undesignated section of law to establish restrictions on the sale of dextromethorpham (DXM) to individuals younger than 18. 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.

The bill prohibits the sale of any finished drug product containing any quantity of DXM by any retail entity knowingly or willfully to any individual under the age of 18 without a valid prescription. A person 18 years of age or younger may not purchase a finished drug product containing any quantity of DXM, without a prescription.

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 unless it would be reasonable to presume the purchaser is 25 years of age or older.

Each sales location of a manufacturer, distributor, or retailer whose employees or representatives sells DXM in violation of this act is subject to a written warning for the first warning 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 fine may be waived if the manufacturer, distributor, or retailer demonstrated a good faith effort to comply with the requirements.

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

If a person possesses or receives DXM with the intent to distribute, a civil citation of not more than $100 for each violation shall be assessed by the local jurisdiction. A civil citation must also provide information on how to dispute the citation and clearly state that the citation is not a criminal violation. No consequences are imposed on a person who purchases DXM if no intention to distribute exists.

CS/SB 938 requires a civil citation that is directed towards a manufacturer, distributor, or retailer be delivered to the manager on duty at the time the citation is issued. If 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 provides specific components for the civil citation, including:

- The date and approximate time of the sale in the 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;[14]and
- How to dispute the notice and what to expect in the dispute process.

CS/SB 938 requires uniform application of the program with enforcement through local law enforcement and other officials charged with enforcement of state laws.

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 act also does not apply to medication containing DXM sold by a retail entity pursuant to a valid prescription.

CS/SB 938 does not create a criminal violation; a person who violates this act commits a non-criminal violation as defined in s. 775.08(3), F.S.[15]

CS/SB 938 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.

The bill is effective January 1, 2017.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

[14] In Florida law, the term "non-criminal violation" or "non-criminal offenses" refers to offenses that are punishable by no other penalty other than a fine, forfeiture, or other civil penalty. A non-criminal violation is one that 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 non-criminal offenses include some traffic-related offenses, parking violations or citations for loud-noises.
[15] Id.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

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

Unlawful sales subjects the retailers, manufacturers, and distributers to a $100 fine after a written warning in most cases. However, if a manufacturer, distributor, or retailer makes a "good faith effort" to comply with this law, it will not incur the $100 fine 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 distributers 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:

The bill prohibits the purchase of a finished drug product containing any quantity of DXM by a person 18 years old and younger. This age description includes an 18 year old who is considered an adult under the law and is different from the age range to describe to whom sale of DXM may not be made. The sale may not be made to "persons younger than 18 years of age." This description does not include an 18 year old individual.

An exception is made for products sold pursuant to a valid prescription. The bill does not address situations where a person younger than 18 years of age may be an emancipated minor or on active military duty, an exception made in the proposed federal legislation.

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.

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