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:	SB 938
INTRODUCER:	Senator Benacquisto
SUBJECT:	Retail Sale of Dextromethorphan
DATE:	January 14, 2016
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Lloyd	Stovall	HP	**Pre-meeting**
2.			CM	
3.			FP	

I. Summary:

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.

SB 938 provides for fines for retailers, wholesalers, distributers and their employees and associates for selling DXM to a person younger than 18 in violation of this act. However, a manufacturer, distributor, or retailer may avoid the fine for the employee's or associate's sale upon a showing of a good faith effort to comply with the requirements. A fine may also be imposed on the minor purchaser.

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 no 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

[1] Mayo Clinic, *Dextromethorphan*, http://www.mayoclinic.org/drugs-supplements/dextromethorphan-oral-route/description/drg-20068661 (last visited Jan. 13, 2016).

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;
- 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]

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[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.
[9] Id.
[10] *Supra* note 2.

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
- 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:

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.

[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.

- "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, government identification card, or driver license.

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 younger than age 18 may not purchase a finished drug product containing any quantity of DXM, without a prescription.

Under the bill, 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.

Fines may be assessed for the sale, purchase, or possession of DXM in violation of the act. The amount of the fine is based on who failed to comply with the act. The fine may also be waived if the individual demonstrated a good faith effort to comply with the requirements.

Assessments for Violations			
Actor	**Entity Fined**	**Amount of Fine**	**Good Faith Compliance; Waiver of Fine?**
Employee\Representative during course of employment	Manufacturer, Distributor or Retailer	$100	Yes
Employee	Employee	$25	No
Purchaser	Purchaser	$25	No
Purchaser with intent to distribute	Purchaser	$25	No

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.

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.

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. 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. The employee or associate who made the sale is subject to a $25 fine and the minor is subject to a $25 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.

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:

The bill did not identify which agency is responsible for the monitoring for compliance, determination of a good faith effort, and ultimately the assessment of any fine.

VII. Related Issues:

The bill prohibits the purchase of a finished drug product containing any quantity of DXM by a person younger than 18 years old and subjects that person to a $25 if he or she purchases such a product. 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 Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.