

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 691 Retail Sale of Dextromethorphan

SPONSOR(S): Regulatory Affairs Committee; Business & Professions Subcommittee; Broxson and others

TIED BILLS: **IDEN./SIM. BILLS:** CS/SB 938

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Business & Professions Subcommittee	13 Y, 0 N, As CS	Brown-Blake	Anstead
2) Local Government Affairs Subcommittee	10 Y, 0 N	Renner	Miller
3) Regulatory Affairs Committee	17 Y, 0 N, As CS	Brown-Blake	Hamon

SUMMARY ANALYSIS

Dextromethorphan (DXM) is a common active ingredient used by pharmaceutical companies in many over-the-counter (OTC) cough suppressant medications. The ingredient is used most commonly as a cough suppressant and an expectorant, but is also used for the temporary relief of sinus congestions, runny nose, cough, sneezing, itchy nose and throat, and watery eyes caused by allergies, cold, flu, or other upper respiratory infections.

The use of DXM in larger than therapeutic doses causes impaired vision, sweating, fever, rapid breathing, increased blood pressure and heart rate, slurred speech, impaired judgment and mental function, hallucinations and dissociative effects, and in higher doses, coma, or death. Teenagers and young adults have been documented as abusing DXM in larger than therapeutic doses in order to achieve the dissociative effect. The dangers associated with DXM abuse include possible overdose of DXM, overdose of other combined substances, impairment leading to injury or death, and dependence upon the drug.

The bill restricts the sale of a "finished drug product" that contains DXM to persons younger than the age of 18. Specifically, manufacturers, distributors, retail entities, and their employees and representatives are prohibited from knowingly or willfully selling a finished drug product that contains any quantity of DXM to a person younger than 18 years old. Additionally, the bill prohibits a person younger than 18 years of age from purchasing a finished drug product that contains any quantity of DXM. The person making the sale of the finished drug product that contains DXM is required to obtain proof of age from the purchaser prior to completing the sale, unless the person making the sale could reasonably presume from the consumer's outward appearance that the consumer is 25 years old or older.

The bill provides for fines to be paid by manufacturers, distributors, retail entities, or their employees or representatives in violation of this section, as well as persons who possess or receive a finished drug product that contains DXM with the intent to distribute it to a person under the age of 18. The bill provides a way for recipients of the fine to dispute the violation and provides for the local jurisdiction to recover unpaid accrued fines.

The bill preempts any ordinance regulating the sale, distribution, receipt, or possession of DXM which may be enacted by a county, municipality, or other political subdivision of the state. DXM is not subject to further regulation by such political subdivisions.

The bill is expected to have no financial impact on a state or local agency.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

General:

DXM is a common active ingredient used by pharmaceutical companies in many OTC cough suppressant medications. The ingredient is used most commonly as a cough suppressant and an expectorant, but is also used for the temporary relief of sinus congestions, runny nose, cough, sneezing, itchy nose and throat, and watery eyes caused by allergies, cold, flu, or other upper respiratory infections. Approximately 70 products which contain DXM are available to consumers. Additionally, DXM can be purchased in bulk over the internet in a powder form as the pure raw ingredient used by pharmaceutical companies to manufacture the cough medicines. When taken as directed in an OTC medication, DXM has few side effects and has a long history of safety and effectiveness.¹

The use of DXM in larger than therapeutic doses causes impaired vision, sweating, fever, rapid breathing, increased blood pressure and heart rate, slurred speech, impaired judgment and mental function, hallucinations and dissociative effects, and in higher doses, coma.² Teenagers and young adults have been documented as abusing DXM in larger than therapeutic doses in order to achieve the dissociative effect, where the drug distorts how they perceive sight and sound and creates a feeling of detachment from the environment.³ The dangers associated with DXM abuse include possible overdose of DXM, overdose of other combined substances, impairment leading to injury or death, and dependence upon the drug.

Overdoses:

Before 2009, there were five documented fatal overdoses associated with ingestion of DXM.⁴ Very high doses of DXM are shown to shut down the central nervous system, causing death. Additionally, OTC medications that include DXM typically are combined with acetaminophen to relieve pain, or other medications that can be toxic in larger than therapeutic doses, causing liver damage, heart attack, stroke, and death.

Impairment:

DXM causes impaired vision, altered consciousness, and hallucinations, which can lead to irrational or dangerous behavior or otherwise impede the ability of a person to act responsibly. A person who is suffering from these conditions would be a risk to themselves and others if they chose to operate a motor vehicle or otherwise be in a place where their safety was not insured. Individuals have killed and been killed in car related accidents while high on DXM.⁵

¹ Center for Substance Abuse Research, *Dextromethorphan (DXM)*, found at <http://www.cesar.umd.edu/cesar/drugs/dxm.asp> (last visited January 6, 2016).

² WebMD, *Teen Drug Abuse of Cough Medicine*, found at <http://www.webmd.com/parenting/teen-abuse-cough-medicine-9/teens-and-dxm-drug-abuse?page=3> (last visited January 6, 2016).

³ What is DXM, *About DXM*, found at <http://www.whatisdxm.com/about-dxm.html>, (last visited January 6, 2016).

⁴ Journal of Analytical Toxicology, Vol. 33, March 2009, *Five Deaths Resulting from Abuse of Dextromethorphan Sold Over the Internet*, found at https://www.researchgate.net/publication/24037337_Five_Deaths_Resulting_from_Abuse_of_Dextromethorphan_Sold_Over_the_Internet, (last visited on January 6, 2016).

⁵ The Morning Call, *Moore teen who drove high on 'poor man's PCP,' killing 2, pleads guilty,* found at <http://www.mcall.com/news/breaking/mc-moore-township-teen-killed-two-while-driving-high-cough-syrup-20151023-story.html>, (last visited on January 6, 2016).

Dependence:

The level and likelihood of experiencing addiction to DXM depends upon the dose and frequency of the use by an individual. High dose chronic use of DXM can lead to toxic psychosis, a mental condition which is characterized by loss of contact with reality and confusion, as well as other physiological and behavioral problems.⁶

Regulation:

The sale of DXM directly to consumers is not regulated by the state of Florida or the Federal government. It is not considered a controlled substance that would require a prescription. The Federal Drug Administration approved DXM in 1958 as an OTC cough suppressant. During the 1960s and 70s, DXM was available OTC in tablet form by the brand name of Romilar. In 1975, the extensive abuse of Romilar was recognized, and the medication was removed from the OTC market. However, DXM was specifically excluded from the 1970 Controlled Substances Act (CSA), which required the regulation of manufacture, importation, possession, use, and distribution of certain medications. Because DXM was excluded from the CSA, it remained legal to produce and sell in OTC medications, thus it was still readily available for abuse. Shortly after the removal of Romilar from the market, other pharmaceutical companies introduced other medications, including various cough syrups, which included DXM.⁷ These new medications were allegedly designed to limit recreation use by creating an unpleasant taste if consumed in large quantities. However, shortly after their introduction, many of the companies introduced more tolerable flavors in order to increase sales of their products.⁸

Currently, larger retailers such as Target, Walgreens, and CVS already prohibit their employees from selling DXM-related products to persons under the age of 18. Therefore, the possible violations of this provision are likely to be related to the sale of DXM-related products from smaller retailers or retailers that do not specialize in the sale of OTC medications and do not currently require age verification prior to sale.

Effect of the Bill

The bill restricts the sale of a “finished drug product” that contains DXM to persons younger than the age of 18. The term “finished drug product” is defined to mean a drug legally marketed under the Federal Food, Drug, and Cosmetic Act that is in finished dosage form. The term “drug” is defined pursuant to s. 499.003(18), F.S.

The bill specifies that a manufacturer, distributor, retail entity, or its employee or representative is prohibited from knowingly or willfully selling a finished drug product that contains any quantity of DXM to a person younger than 18 years old. Additionally, the bill prohibits a person younger than 18 years of age from purchasing a finished drug product that contains any quantity of DXM.

The employee or representative making the sale of the finished drug product that contains DXM is required to obtain proof of age from the purchaser prior to completing the sale, unless the person making the sale could reasonably presume from the consumer’s outward appearance that the consumer is 25 years old or older. “Proof of age” is defined 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, but is not limited to, a passport, United States Armed Services identification card, driver license, or an identification card issued by this state or another state of the United States.

⁶ Jaffe, J.H. (ed). (1995). Encyclopedia of Drugs and Alcohol, Vol. 1. Simon & Schuster MacMillan: New York. (Id. Footnote 1).

⁷ Id. at 1.

⁸ Id. at 1.

The bill provides for the following fines to be paid by entities or individuals in violation of these requirements:

- A manufacturer, distributor, or retailer whose employee sells to a consumer under the age of 18 during the course of employment or in association with the manufacturer, distributor, or retailer, is subject to:
 - A warning for the initial violation at each sales location;
 - A \$100 fine for any subsequent violations at each sales location.

Note: The manufacturer, distributor, or retailer may avoid the fine if it can demonstrate a good faith effort to comply with the requirements.

- A person who possesses or receives a finished drug product that contains DXM with the intent to distribute it to a person under the age of 18 is subject to a fine of \$100.
- An employee or representative of a manufacturer, distributor, or retailer who sells to a person under the age of 18 during the course of employment is subject to a warning.

The civil penalties issued shall accrue and may be recovered in a civil action brought by the local jurisdiction. The civil penalty issued to the person in possession with the intent to distribute must include information regarding how to dispute the penalty, and shall clearly state that the violation is a noncriminal violation. The civil penalty issued to the manufacturer, distributor, or retailer must include:

- The date and approximate time of the sale in violation of this section;
- The location of the sale, including the address;
- The name of the employee or representative that completed the sale;
- Information regarding how to dispute the penalty; and
- Notice that the violation is a noncriminal violation.

The civil penalty issued to the manufacturer, distributor, or retailer must be provided to the manager on duty. If no manager on duty is available, the law enforcement officer may attempt to contact the manager. If the attempt to contact fails, a copy of the penalty may be given to an employee 18 years of age or older and a copy mailed by certified mail to the owner's business address as filed with the Department of State or the law enforcement officer may return for service to the manager at a later time.

The civil penalty may be disputed by the recipient of the penalty. In order to dispute, the recipient must provide notice of a dispute to the clerk of the county court in the jurisdiction in which the violation occurred within 15 days of receipt of the penalty. The local jurisdiction then must hold a hearing in a court of competent jurisdiction. If the court finds in favor of the jurisdiction, the jurisdiction can then recover the fine.

The requirements of the bill do not:

- Restrict on the placement of finished drug products that contain DXM in a retail store, restrict direct access of consumers to the finished drug product, or require the maintenance of transaction records;
- Create a criminal violation; or
- Apply to a medication that contains DXM that is sold pursuant to a prescription.

The bill preempts any ordinance regulating the sale, distribution, receipt, or possession of DXM which may be enacted by a county, municipality, or other political subdivision of the state. DXM is not subject to further regulation by such political subdivisions.

B. SECTION DIRECTORY:

Section 1 restricts the sale of a “finished drug product” that contains dextromethorphan to persons over the age of 18.

Section 2 provides an effective date of January 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

The bill provides for local jurisdictions to recover the fines after the issuance of penalties by local law enforcement officers to persons who violate this provision. Therefore, there may be a minimal increase in revenues for local governments that receive payment for the fines, though the amount is difficult to determine and would likely be minimal due to the anticipated low number of citations issued.

2. Expenditures:

Local law enforcement offices would be required to issue citations for the violations. Because the possible violations of this provision are likely to be related to the sale of DXM related products from smaller retailers, and the officers would need to be present or run a sting in order to catch a violation, the number of violations is likely to be low. Local law enforcement agencies likely will be able to meet these requirements with existing resources. Any projected expenditures by local governments should be insignificant.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Private entities would be required to train their employees to check the identifications of individuals purchasing certain medications. If there is a cost to this additional training, it should be minimal.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable. This bill does not appear to affect county or municipal governments

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill neither authorizes nor requires implementation by administrative rulemaking.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 12, 2016, the Business & Professions Subcommittee adopted a strike-all amendment and an amendment to the strike-all and reported the bill favorably as a committee substitute. The amendments:

- Create s. 501.975, F.S., placing the language in the Consumer Protection chapter of the Florida Statutes.
- Clarify the definition of “drug”.
- Update the term “proof of age” to mirror the identification requirements for the sale of tobacco.
- Extend the prohibition to sell to include manufacturers, distributors, retailers and their employees and representatives.
- Clarify that the violation is non-criminal.
- Clarify that failure to pay the required fine issued for a violation will subject the person to civil recovery by the local jurisdiction.
- Provide due process for individuals or entities to dispute the violation in county court.
- Provide enforcement by local law enforcement.
- Remove penalties for underage purchasers or employees in violation of this section.
- Provide a warning for any violations by employees and for first violations by distributors, manufacturers, and retailers.
- Provide a \$100 fine for any subsequent violation by distributors, manufacturers, and retailers.

On February 4, 2016, the Regulatory Affairs Committee adopted an amendment and reported the bill favorably as a committee substitute. The amendment:

- Raises the fine from \$25 to \$100 for a person in possession of dextromethorphan with the intent to distribute to persons under the age of 18.
- Requires the law enforcement officers to provide the notice to an employee 18 years or older if he or she is unable to contact a manager.
- Requires law enforcement officers to mail the notice certified mail if he or she is unable to contact a manager.

This analysis is drafted to the committee substitute as passed by the Regulatory Affairs Committee.