

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 487 Dextromethorphan

SPONSOR(S): Criminal Justice Subcommittee; Gonzalez and others

TIED BILLS: None **IDEN./SIM. BILLS:** SB 1156

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Criminal Justice Subcommittee	14 Y, 0 N, As CS	Williams	Cunningham
2) Health & Human Services Access Subcommittee			
3) Business & Consumer Affairs Subcommittee			
4) Judiciary Committee			

SUMMARY ANALYSIS

Section 893.1495, F.S., regulates the retail sale of ephedrine and related compounds. The statute:

- Prohibits a person from knowingly obtaining or delivering to an individual in any retail over-the-counter sale any nonprescription compound, mixture, or preparation containing ephedrine or related compounds in excess of specified amounts:
- Prohibits a person from knowingly displaying and offering for retail sale packages of any drug having a sole active ingredient of ephedrine or related compounds other than behind a checkout counter where the public is not permitted.
- Requires owners or primary operators of retail stores to ensure that all employees who engage in the retail sale of ephedrine or related compounds attend an employee training program that includes basic instruction on state and federal regulations relating to the sale and distribution of such compounds.

Any person who violates the above described provisions commits a 2nd degree misdemeanor for a first offense, a 1st degree misdemeanor for a second offense, and a 3rd degree felony for a third or subsequent offense.

Section 893.1495, F.S., also requires purchasers of ephedrine or related compounds to:

- Be at least 18 years of age; and
- Present a government issued photo identification showing their name, date of birth, address, and photo identification number.

Dextromethorphan (DXM), a cough suppressant, is found in cold medications, either alone or in combination with other drugs. When ingested at recommended dosage levels, DXM is generally safe and effective. However, within the past few years, reports of illicit use and abuse of DXM have risen. The United States Drug Enforcement Administration reports that illicit use may be related to the ease of purchasing nonprescription cough medicines from a variety of drug stores and internet companies. Currently, s. 893.1495, F.S., does not regulate the retail sale or delivery of any nonprescription compound, mixture, or preparation containing DXM.

CS/HB 487 amends s. 893.1495, F.S., to define the term "ephedrine, dextromethorphan, or related compounds" as "ephedrine, pseudoephedrine, phenylpropanolamine, dextromethorphan, or any of their salts, optical isomers, or salts of optical isomers, and to make terminology changes to various provisions of s. 893.1495, F.S. As a result, all of the above-described prohibitions and requirements that relate to sale of ephedrine will apply to the sale of DXM.

On March 2, 2011, the Criminal Justice Impact Conference determined that this bill will have an insignificant prison bed impact on the Department of Corrections. Since the bill creates new misdemeanor offenses, there may also be a fiscal impact on county jails.

The bill provides an effective date of July 1, 2011.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

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FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Dextromethorphan:

In 1958, the Food and Drug Administration (FDA) approved dextromethorphan (DXM) after research supported its legitimacy and effectiveness as a cough suppressant.¹ Since that time, DMX has been found in more than 120 over-the-counter (OCT) cold medications, either alone or in combination with other drugs such as analgesics, antihistamines, decongestants and expectorants.² When ingested at recommended dosage levels, DXM generally is a safe and effective cough suppressant.³ The typical adult dose for a cough is 15 or 30 mg taken three to four times daily, with the cough-suppressing effects of DXM persisting five to six hours after taken.⁴

Substance Abuse:

DXM is a dissociative anesthetic that, at high doses, can create powerful psychedelic effects.⁵ These effects include confusion, agitation, paranoia, and hallucinations.⁶ Anecdotal reports and limited clinical research suggest that extensive and prolonged abuse of DXM may cause learning and memory impairment.⁷

In recent years, reports of illicit use and abuse of DXM have risen.⁸ The United States Drug Enforcement Administration (DEA) reports that illicit use of DXM may be related to the ease of purchasing nonprescription cough medicines from drug stores and internet companies.⁹ The most frequently abused products containing DXM are Coricidin HBP Cough & Cold and Robitussin DM.¹⁰

The Consumer Healthcare Products Association (CHPA) reports that DXM is not addictive and that the ingredient is most dangerous when it is in its raw (or unfinished) form.¹¹ DXM contained in OTC products is not in raw form. CHPA supports federal initiatives that prohibit the sale of cough medicines containing DXM to persons under the age of 18 and also supports a prohibition of the sale of the raw, unfinished form of DXM to ensure only entities registered with the FDA have access to such form of the ingredient.¹²

OTC products that contain DXM often contain other ingredients such as acetaminophen,¹³ chlorpheniramine,¹⁴ and guaifenesin¹⁵ that have their own effects if used in large dosages, such as liver damage, increased heart rate, lack of coordination, seizures, vomiting and coma.¹⁶

¹ Dextromethorphan (DXM), CESAR: Center for Substance Abuse Research, University of Maryland. May 2005.

(<http://www.cesar.umd.edu/cesar/drugs/dxm.asp>) (last accessed March 30, 2011).

² "Drugs and Chemicals of Concern," U.S. Dept. of Justice Drug Enforcement Administration, Office of Diversion Control, August 2010. (http://www.deadiversion.usdoj.gov/drugs_concern/dextro_m/dextro_m.htm) (last accessed on March 30, 2011).

³ "Intelligence Bulletin: DXM (Dextromethorphan)" National Drug Intelligence Center. Doc. Id. # 2004-L0424-029. October 2004. (<http://www.justice.gov/ndic/pubs11/11563/11563p.pdf>) (last accessed March 30, 2011).

⁴ *Get Smart About Drugs: A Resource for Parents from the DEA*. Drug Fact Sheet. November 17, 2010.

(http://www.justice.gov/dea/pubs/abuse/drug_data_sheets/dextromethorphan_dxm_DrugDataSheet.pdf) (last accessed March 30, 2011).

⁵ See *supra* note 1.

⁶ *Get Smart About Drugs: A Resource for Parents from the DEA*. Drug Fact Sheet. November 17, 2010.

(http://www.justice.gov/dea/pubs/abuse/drug_data_sheets/dextromethorphan_dxm_DrugDataSheet.pdf) (last accessed March 30, 2011).

⁷ See *supra* note 3.

⁸ See *supra* note 1.

⁹ *Id.*

¹⁰ Coricidin HBP Cough & Cold contains 30 mg of DXM per tablet and Robitussin DM contains 2 mg of DXM per milliliter. See *supra* note 3.

¹¹ OTC Cough Medicine Abuse and Dextromethorphan. Consumer Healthcare Products Association. 2010. (http://www.chpa-info.org/governmentalaffairs/Medicine_Abuse_DXM.aspx) (last accessed March 30, 2011).

¹² *Id.*

¹³ "Acetaminophen," also called APAP, is a drug that relieves pain and fever and can be found in both prescription and OCT products. *FDA limits acetaminophen in prescription combination products; requires liver toxicity warnings*. U.S. Food and Drug

Federal Actions:

DXM is neither a controlled substance nor a regulated chemical under the Federal Controlled Substances Act.¹⁷ However, in August 2010, the DEA listed this substance as a drug of concern, and is reviewing it for possible control scheduling.¹⁸

Florida law:

Currently, Florida does not regulate the retail sale or delivery of any nonprescription compound, mixture, or preparation containing DXM. However, s. 893.1495, F.S., does regulate the retail sale of ephedrine, a similar OCT substance, and related compounds.¹⁹

Section 893.1495(4), F.S., defines the term “ephedrine or related compounds” as “ephedrine, pseudoephedrine, phenylpropanolamine, or any of their salts, optical isomers, or salts of optical isomers”. The statute provides that a person may not knowingly obtain or deliver to an individual in any retail OTC sale any nonprescription compound, mixture, or preparation containing ephedrine or related compounds in excess of the following amounts:

- In any single day, any number of packages that contain a total of 3.6 grams of ephedrine or related compounds;
- In any single retail, over-the-counter sale, three packages, regardless of weight, containing ephedrine or related compounds; or
- In any 30-day period, in any number of retail, over-the-counter sales, a total of 9 grams or more of ephedrine or related compounds.²⁰

Additionally, the statute prohibits a person from knowingly displaying and offering for retail sale packages of any drug having a sole active ingredient of ephedrine or related compounds other than behind a checkout counter where the public is not permitted.²¹ Owners or primary operators of retail stores must ensure that all employees who engage in the retail sale of ephedrine or related compounds attend an employee training program that includes basic instruction on state and federal regulations relating to the sale and distribution of such compounds.²²

Any person who violates the above-described provisions of s. 893.1495, F.S., commits a misdemeanor of the second degree²³ for a first offense, a misdemeanor of the first degree²⁴ for a second offense, and a felony of the third degree²⁵ for a third or subsequent offense.²⁶

Administration, January 13, 2011. (<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm239894.htm>) (last accessed March 30, 2011).

¹⁴ “Chlorpheniramine” is an antihistamine that helps control the symptoms of cold or allergies. Chlorpheniramine. MedlinePlus Drug Information. U.S. National Library of Medicine. August 2010. (<http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682543.html>) (last accessed March 30, 2011).

¹⁵ “Guaifenesin” is a expectorant used to relieve chest congestion. Guaifenesin. MedlinePlus Drug Information. U.S. National Library of Medicine. August 2010. (<http://www.nlm.nih.gov/medlineplus/druginfo/meds/a682494.html>) (last accessed March 30, 2011).

¹⁶ See *supra* note 2.

¹⁷ 21 U.S.C. Chapter 13, entitled, “Drug Abuse Prevention and Control.”

¹⁸ See *supra* note 2.

¹⁹ The provisions of s. 893.1495, F.S., do not apply to any of the following: licensed manufacturers who lawfully manufacture and distribute products; wholesalers who lawfully distribute products; healthcare facilities licensed under ch. 395, F.S.; licensed long-term care facilities; government-operated health departments; physician offices; publicly operated prisons, jails, juvenile correctional facilities, or private adult or juvenile correctional facilities under contract with the state; public or private educational institutions that maintain health care programs; and government operated or industry operated medical facilities serving employees of the government or industry operating them. s. 893.1495(10), F.S.

²⁰ Section 893.1495(2), F.S.

²¹ Section 893.1495(3), F.S.

²² Section 893.1495(4), F.S.

²³ A second degree misdemeanor is punishable by up to 60 days in jail and a \$500 fine. See ss. 775.082 and 775.083, F.S.

²⁴ A first degree misdemeanor is punishable by up to one year in county jail and a maximum \$1,000 fine. See ss. 775.082 and 775.083, F.S.

²⁵ A third degree felony is punishable by up to five years in prison and a \$5,000 fine. See ss. 775.082, and 775.083, F.S.

²⁶ Section 893.1495(11), F.S.

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Section 893.1495, F.S., also requires purchasers of ephedrine or related compounds to:

- Be at least 18 years of age;
- Present a government issued photo identification showing their name, date of birth, address, and photo identification number; and
- Provide a signature on paper or on an electronic signature capture device for recordkeeping.²⁷

A person who sells any product containing ephedrine or related compounds in good faith, is immune from civil liability for the release of the above information to federal, state, or local law enforcement officers, or any person acting on their behalf, unless the release constitutes gross negligence or intentional, wanton or willful misconduct.²⁸

Currently, s. 893.1495, F.S., does not regulate the retail sale or delivery of any nonprescription compound, mixture, or preparation containing DXM.

Effect of bill:

CS/HB 487 amends s. 893.1495, F.S., to define the term “ephedrine, dextromethorphan, or related compounds” as “ephedrine, pseudoephedrine, phenylpropanolamine, dextromethorphan, or any of their salts, optical isomers, or salts of optical isomers.” The bill makes this change in terminology in various provisions of s. 893.1495, F.S.

As a result, the following prohibitions and requirements that relate to the sale of ephedrine will also relate to the sale of DXM:

- A prohibition on knowingly obtaining or delivering to an individual in any retail over-the-counter sale any nonprescription compound, mixture, or preparation containing DXM in excess of amounts described above.
- A prohibition on knowingly displaying and offering for retail sale packages of any drug having a sole active ingredient of DXM other than behind a checkout counter where the public is not permitted.
- A requirement that owners or primary operators of retail stores ensure that all employees who engage in the retail sale of ephedrine or related compounds attend an employee training program that includes basic instruction on state and federal regulations relating to the sale and distribution of DXM.

Persons who violate the above-described provisions commit a misdemeanor of the second degree for a first offense, a misdemeanor of the first degree for a second offense, and a felony of the third degree for a third or subsequent offense.

The bill also requires anyone purchasing DXM to:

- Be at least 18 years of age; and
- Present a government issued photo identification showing their name, date of birth, address, and photo identification number.

A person who sells any product containing DXM in good faith, is immune from civil liability for the release of information to federal, state, or local law enforcement officers, or any person acting on their behalf, unless the release constitutes gross negligence or intentional, wanton or willful misconduct.

The bill does not include DXM in any provisions of current law relating to the Florida Department of Law Enforcement’s (FDLE) electronic recordkeeping system for products containing ephedrine or related compounds.

²⁷ Section 893.1495(5)(a), F.S.

²⁸ Section 893.1495(13), F.S.

B. SECTION DIRECTORY:

Section 1. Amends s. 893.1495, F.S., related to retail sale of ephedrine and related compounds.

Section 2. Provides an effective date of July 1, 2011.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

On March 2, 2011, the Criminal Justice Impact Conference determined that this bill will have an insignificant prison bed impact on the Department of Corrections.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

The bill provides that a person who violates certain provisions of s. 893.1495, F.S., commits a misdemeanor of the second degree for a first offense, and a misdemeanor of the first degree for a second offense. As a result, the bill could impact county jails.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill could cause an indeterminate increase in the cost of doing business for retailers who sell products containing DXM due to the requirements in the bill related to product sales, product display, and employee training.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill appears to be exempt from the requirements of Article VII, Section 18 of the Florida Constitution because it is a criminal law.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On April 6, 2011, the Criminal Justice Subcommittee adopted one amendment to the bill and reported the bill favorably as a Committee Substitute. The amendment clarifies definitions relating to DXM and ephedrine.

This analysis is drafted to the Committee Substitute.