HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 1071 Sale of Ephedrine or Related Compounds
SPONSOR(S): Health Care Regulation Policy Committee and Hays
TIED BILLS: **IDEN./SIM. BILLS:**

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee	13 Y, 0 N, As CS	Holt	Calamas
2)	Criminal & Civil Justice Policy Council			
3)	Full Appropriations Council on Education & Economic Development			
4)	Health & Family Services Policy Council			
5)				

SUMMARY ANALYSIS

The bill limits access to key ingredients (precursors) used in the manufacturing of methamphetamine. The bill defines “ephedrine or related compounds" to include ephedrine, pseudoephedrine, or phenylpropanolamine, or any of their salts, optical isomers, or salts of optical isomers

The bill restricts the quantity of ephedrine or related compounds that may be purchased during specific time periods.

Florida Department of Law Enforcement (FDLE) is required to approve an electronic recordkeeping system (electronic logbook) that will be used to monitor real-time purchase of products containing ephedrine or related compounds to prevent or investigate illegal purchases. The bill requires FDLE to contract with a private third party administrator to implement the electronic logbook. The bill requires retailers and pharmacies to adopt an electronic logbook that will be used to track and report real-time point of sale transactions and block sales that exceed the legal limit of ephedrine and related compounds. However, a pharmacy or retailer may request an exemption from electronic reporting if the entity lacks the technology to access the electronic logbook and sells less than 72 grams of ephedrine or related compounds in a 30-day period. The bill provides immunity from civil liability to individuals who release information concerning the point of sale transaction in good faith.

The bill may have an insignificant fiscal impact to the state and no fiscal impact to local governments (See Fiscal Analysis).

The bill takes effect July 1, 2010 and must be implemented by January 1, 2011.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Drug Schedules

Florida law divides controlled substances[1] into five categories ranging from Schedule I to Schedule V. The scheduling of a controlled substance is relevant to how it can be prescribed and to the severity of the criminal offense for its illicit possession, sale or purchase. A drug in Schedule I has a "high potential for abuse and has no currently accepted medical use in treatment in the United States."[2] Schedule II drugs have a high potential for abuse and a severely restricted medical use.[3] Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use.[4] A drug in Schedule V has a low potential for abuse relative to the substances in Schedule IV and has a currently accepted medical use in treatment in the United States, and abuse of such compound, mixture or preparation may lead to limited physical or psychological dependence relative to the substances in Schedule IV."[5]

Methamphetamine

Methamphetamine is a Schedule II controlled substance.[6] The drug has limited medical uses in the treatment of narcolepsy, attention deficit disorders, and obesity.[7] According to the 2008 National Survey on Drug Use and Health (NSDUH), approximately 12.6 million Americans aged 12 or older reported using methamphetamine at least once during their lifetimes, representing five percent of the population aged 12 or older.[8] Commonly called "speed," "crank," "crystal," or "Poor Man's Cocaine," methamphetamine can be smoked, injected, snorted, or taken orally. It produces an initial "high," lasting between 15 and 30 minutes, that is difficult, if not impossible for the user to repeat, leading the user to ingest more and more of the drug and go on longer binges. Long-term methamphetamine abuse can cause addiction, anxiety, insomnia, mood disturbances, and violent behavior. Additionally, psychotic symptoms such as paranoia, hallucinations, and delusions (such as the sensation of bugs

[1] Controlled substances are classified into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. *See* s. 893.02(4), F.S.
[2] s. 893.03(1), F.S. LSD and heroin are examples of Schedule I controlled substances.
[3] s. 893.03(2), F.S. Codeine and morphine are examples of Schedule I controlled substances.
[4] s. 893.03(3), F.S. Butabarbital and anabolic steroids are examples of Schedule I controlled substances.
[5] s. 893.03(5), F.S.
[6] s. 893.03(2)(c), F.S.
[7] Office of National Drug Control, Methamphetamine Facts & Figures, *available* at: http://www.whitehousedrugpolicy.gov/drugfact/methamphetamine/methamphetamine_ff.html/ last viewed March 3, 2010)
[8] *Id.*

crawling under the user's skin) can occur. The psychotic symptoms can last for months or years after methamphetamine use has ceased.[9]

Methamphetamine Production and Precursors

The ease with which methamphetamine can be manufactured is a major contributing factor to the increase in its use. Rural areas are popular sites for production because strong odors are produced during manufacturing. It is easily "cooked" up by anyone in a makeshift lab hidden in mobile homes, warehouses, motel rooms, or cars.[10] Methamphetamine hydrochloride is produced using ephedrine, hydroiodic acid (both controlled substances), or over-the-counter pseudoephedrine or phenylpropanolamine found in cold medication.[11] Hydroiodic acid is a necessary ingredient in one of the major manufacturing processes. Recently, phenylpropanolamine has been used as a precursor chemical to produce amphetamine. Precursors are substances that, in nature, might be inactive. However, when combined with another chemical the result is a new product.[12]

There are literally thousands of recipes and information about making methamphetamine on the Internet.[13] An investment of a few hundred dollars in over-the-counter medications and chemicals can produce thousands of dollars worth of methamphetamine.[14]

State and federal chemical restrictions of precursors, combined with sustained law enforcement pressure, have reduced domestic methamphetamine production over the past several years.[15] Reported methamphetamine laboratory seizures have decreased sharply each year since 2004; the year that states began implementing strong, retail-level sales restrictions of ephedrine and pseudoephedrine products.[16] Moreover, in September 2006 the federal Combat Methamphetamine Epidemic Act of 2005[17] became effective nationwide, setting restrictions on the retail sale of pseudoephedrine, phenylpropanolamine and ephedrine products.[18] However, purchasing legal quantities of pseudoephedrine at various locations (called “smurfing”) circumventing purchasing limitations is common practice among methamphetamine producers.[19]

To address the issue of smurfing, a some states have mandated the use of a real-time electronic pseudoephedrine tracking system. Eleven states[20] have adopted laws requiring pseudoephedrine tracking systems.[21] A tracking system usually includes a “stop sale” or “lead generating” program. In a stop sale program, the seller transmits information about an attempted purchase.[22] The system then notifies the seller that the purchase would be in violation of federal or state over-the-counter sales restrictions.[23] The sale is not completed unless specific exceptions are satisfied. In a lead generating program, all sales are completed and the system analyzes the collected purchase information to identify apparent violations of law.[24]

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[9] *Id.*
[10] KCI, The Anti-Meth site, Manufacturing of Methamphetamine, *available* at: http://www.kci.org/meth_info/making_meth.htm (last viewed March 7, 2010).
[11] *Id.*
[12] KCI, The Anti-Meth site, FAQ About Methamphetamine, *available* at: http://www.kci.org/meth_info/faq_meth.htm (last viewed March 7, 2010).
[13] *Id.*
[14] *Id.*
[15] *Id.*
[16] *Id.*
[17] Public Law 109-177.
[18] KCI, The Anti-Meth site, FAQ About Methamphetamine, *available* at: http://www.kci.org/meth_info/faq_meth.htm (last viewed March 7, 2010).
[19] Florida Department of Law Enforcement, Methamphetamine Briefing, December 7, 2009.
[20] Arkansas, Hawaii, Illinois, Indiana, Kansas, Kentucky, Oklahoma, Washington, Iowa, Louisiana, and West Virginia. See National Alliance for Model State Drug Laws (NAMSDL), Electronic Tracking Systems for Methamphetamine Precursors, Legislative & Policy Update to 2008 Report (October 2009); National Alliance for Model State Drug Laws (NAMSDL), Controlling Methamphetamine Precursor Chemicals: Factors and Considerations for Developing and Operating Effective Electronic Pseudoephedrine Tracking Systems, A Report to the Senate Appropriations Committee, Final Report (2008).
[21] National Alliance for Model State Drug Laws (NAMSDL), Electronic Tracking Systems for Methamphetamine Precursors, Legislative & Policy Update to 2008 Report (October 2009).
[22] *Id.*
[23] *Id.*
[24] *Id.*

In contrast, Oregon[25] requires a prescription for all drugs containing methamphetamine precursors, and Alabama[26], outlawed the sale of drugs containing ephedrine, pseudoephedrine, and phenylpropanolamine unless they are formulated so as to prevent their use in methamphetamine synthesis.[27] However, pharmaceutical companies thus far have not formulated "non-convertible" forms of ephedrine, pseudoephedrine, and phenylpropanolamine, but alternatives to these drugs are now available for some indications.[28]

Federal Combat Methamphetamine Epidemic Act of 2005

Effective September 30, 2006, federal law requires sellers of nonprescription (over-the-counter) ephedrine, pseudoephedrine, or phenylpropanolamine to place items containing these ingredients where customers do not have direct access before the sale is made ("behind the counter" placement) or in a locked cabinet located in an area of the facility to which customers do not have direct access. The seller must deliver the product directly into the custody of the purchaser.

The seller is required to maintain a logbook (paper or electronic) that identifies: a products name; quantity sold; name and address of purchaser; and the date and time of the sale. The purchaser must present a photographic identification card issued by a state or the federal government (i.e. driver's license) and sign a logbook. The logbook must contain a notice to purchasers that entering false statements or misrepresentations in the logbook may subject the purchaser to criminal penalties under Title 18 U.S.C. § 1001 and such notice must specify the maximum fine ($250,000.00) and term of imprisonment (5 years). The federal Combat Methamphetamine Epidemic Act of 2005 ("Act") authorizes disclosure of information contained in the logbook to the Attorney General and to State and local law enforcement agencies. The Act prohibits accessing, using, or sharing the logbook information for any purpose other than to comply with the Controlled Substances Act or to facilitate a product recall to protect public health and safety is prohibited. A seller who in good faith releases logbook information to Federal, State or local law enforcement authorities, is immune from civil liability for releasing the information unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

The Act sets daily sales limit of ephedrine base, pseudoephedrine base, or phenylpropanolamine base at 3.6 grams per purchaser, regardless of the number of transactions.[29] In addition, the act makes it unlawful for any person to knowingly or intentionally purchase at retail store more than 9 grams during a 30 day period (of which no more than 7.5 grams can be imported by private or commercial carrier or the Postal Service).[30]

Table 1. Daily sales limit of ephedrine base, pseudoephedrine base, or phenylpropanolamine base is 3.6 grams per purchaser, regardless of number of transactions.

Ingredient	Number of Tablets [as base]
25 mg Ephedrine HCl	175
25 mg Ephedrine Sulfate	186
30 mg Pseudoephedrine HCl	146
60 mg Pseudoephedrine HCl	73
120 mg Pseudoephedrine HCl	36
30 mg Pseudoephedrine Sulfate	155
60 mg Pseudoephedrine Sulfate	77

[25] OR. REV. STAT. s.475.973 (2009).
[26] ALA.CODE s. 20-2-190 (2008).
[27] National Alliance for Model State Drug Laws (NAMSDL), Controlling Methamphetamine Precursor Chemicals: Factors and Considerations for Developing and Operating Effective Electronic Pseudoephedrine Tracking Systems, a Report to the Senate Appropriations Committee, Final Report (2008).
[28] National Alliance for Model State Drug Laws (NAMSDL), Electronic Tracking Systems for Methamphetamine Precursors, Legislative & Policy Update to 2008 Report (October 2009).
[29] 21 U.S.C. § 830.
[30] 21 U.S.C. § 844(a)

120 mg Pseudoephedrine Sulfate	38
Phenylpropanolamine	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.

US Department of Justice, Drug Enforcement Agency, Office of Drug Diversion

Table 2. Effective April 8, 2006, for mail-order sellers, sales are limited to 7.5 grams per customer during a 30-day period.

Ingredient	Number of tablets [as base]
25 mg Ephedrine HCl	366
25 mg Ephedrine Sulfate	389
30 mg Pseudoephedrine HCl	305
60 mg Pseudoephedrine HCl	152
120 mg Pseudoephedrine HCl	76
30 mg Pseudoephedrine Sulfate	324
60 mg Pseudoephedrine Sulfate	162
120 mg Pseudoephedrine Sulfate	81
Phenylpropanolamine	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.

US Department of Justice, Drug Enforcement Agency, Office of Drug Diversion

Florida Law

Section 893.1495, F.S., provides that no person shall knowingly deliver in any single over-the-counter retail sale:

- any number of packages of any drug containing a sole active ingredient that he or she knows to contain a combined total of more than 9 base grams of ephedrine, pseudoephedrine, phenylpropanolamine, or any of their salts, optical, isomers, or salts of optical isomers;[31] or

- more than 3 packages, regardless of weight containing any such sole active ingredient.[32]

Additionally, no person shall knowingly display and offer for retail sale packages of any drug having a sole active ingredient of ephedrine, pseudoephedrine, phenylpropanolamine, or any of their salts, optical, isomers, or salts of optical isomers other than behind a checkout counter where the public is not permitted.[33]

Any person who violates these provisions commits a second degree misdemeanor[34] for a first offense, a first degree misdemeanor[35] for a second offense and a third degree felony[36] for a third or subsequent offense.

Moreover, current law prohibits a owner or primary operator of a retail outlet where ephedrine, pseudoephedrine or phenylpropanolamine products are available for sale shall knowingly allow an employee to engage in the retail sale of such products unless the employee has completed an

[31] s. 893.1495(1), F.S.
[32] *Id.*
[33] s. 893.1495(2), F.S.
[34] Second degree misdemeanors are punishable by up to 60 days in prison and/or up to $500 fine. ss. 775.082, 775.083, F.S.
[35] First degree misdemeanors are punishable by up to 1 year in prison and/or up to $1,000 fine. ss. 775.082, 775.083, F.S.
[36] Third degree felonies are punishable by up to 5 years in prison and/or up to a $5,000 fine. ss. 775.082, 775.083, F.S.

employee training program that must include, at a minimum, basic instruction on state and federal regulations relating to the sale and distribution of such products.[37]

The provisions in s. 893.1495, F.S., supersede any municipal ordinance or regulation passed on or after July 1, 2005, to the extent that such ordinance or regulation is more restrictive than the provisions of the section.[38]

The Effects of the Bill

The bill provides the definition of "ephedrine or related compounds" as ephedrine, pseudoephedrine, or phenylpropanolamine, or any of their salts, optical isomers, or salts of optical isomers and conforms the change in terminology throughout the bill.

The bill specifically provides that a person may not knowingly obtain or delivery in any retail over-the counter sale, in a single day, a nonprescription compound, mixture, or preparation that contains ephedrine or related compounds that:

- Contains a total of 3.6 grams per of ephedrine or related compounds.
- Consists of more than three packages (regardless of weight) that contain ephedrine or related compounds.

Additionally, the bill makes it unlawful for any person to knowingly or intentionally purchase at a retail store more than 9 grams of ephedrine or related compounds within a 30-day period.

The bill 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
- sign a log book (paper or electronic).

Florida Department of Law Enforcement (FDLE) is required to approve an electronic recordkeeping system (electronic logbook) that will be used to monitor real-time purchase of products containing ephedrine or related compounds to prevent or investigate illegal purchases. The bill requires FDLE to contract with a private third party administrator to implement the electronic logbook. The bill requires retailers and pharmacies to adopt an electronic logbook that will be used to track real-time point of sale transactions and block sales that exceed the legal limit of ephedrine and related compounds. Pharmacies and retailers are also required to report purchases at the point of sale or through an interface with the electronic logbook. However, a pharmacy or retailer may request an exemption from electronic reporting if the entity lacks the technology to access the electronic logbook and sells less than 72 grams of ephedrine or related compounds in a 30-day period.

The bill specifies that the electronic logbook must record:

- the date and time of the transaction;
- name, date of birth, address, type of photo identification presented and the identification number;
- number of packages purchased, total grams per package, and the name of the compound, mixture or preparation purchased;
- signature of the purchaser or a unique number that is associated with a paper signature that is maintained on the premises.

The data submitted into an electronic logbook must be retained for at least two years after the date of entry. Individuals who sell a product containing ephedrine or related compounds are immune from civil liability for releasing information concerning the sale if they comply in good faith.

[37] s. 893.1495(3), F.S.
[38] s. 893.1495(4), F.S.

Current law[39] requires owners or primary operator of retail stores to ensure that all employees that engage in the retail sale of ephedrine or related compounds must attend an employee training program that includes basic instruction on state and federal regulations. The bill provides, via a cross reference, that failure to provide this training to employees is a second degree misdemeanor (first offense); first degree misdemeanor (second offense) and a third degree felony (third offense).

The bill exempts the following entities from these provisions:

- licensed manufacturers who lawfully manufacture and distribute products;
- wholesalers who lawfully distribute products;
- hospitals 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/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.

The bill provides FDLE the authority to adopt rules to implement the provisions in the bill.

The bill takes effect July 1, 2010 and must be implemented by January 1, 2011.

B. SECTION DIRECTORY:

Section 1. Amends s. 893.1495, F.S., relating to retail sale of ephedrine and related compounds.
Section 2. Provides an effective date of July 1, 2010 and implementation date of January 1, 2011.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Many large retail and pharmacy chains already use an electronic logbook in an effort to comply with federal law. Retailers and pharmacies that do not already have computers equipped with card readers capable of scanning and capturing information from the magnetic strip on the back of driver's licenses may decide to purchase this equipment or have someone manually enter the required information into an electronic logbook or interface with the electronic logbook.

[39] s. 893.1495(5), F.S.

However, the fiscal impact to pharmacies or retailers may be mitigated since the bill provides an exemption from electronic reporting if the entity lacks the technology to access the electronic logbook and sells less than 72 grams of ephedrine or related compounds in a 30-day period.

D. FISCAL COMMENTS:

According to FDLE, there will be a workload impact to one full-time equivalent employee who will coordinate with law enforcement agencies and the third party administrator to provide access to the electronic logbook to law enforcement officers. FDLE will manage this increase in workload within existing resources. The provisions of the bill will require FDLE to approve and use an electronic recordkeeping system. Currently there are electronic recordkeeping systems available at no cost to users (i.e. state law enforcement agencies, retailers, or pharmacies). One such, electronic recordkeeping system is being offered by Apriss/MethCheck. This system is part of the National Precursor Log Exchange (NPLex). The Apriss/MethCheck electronic recordkeeping system is being paid for by manufacturers of ephedrine products and is managed by the National Association of Drug Diversion Investigators.[40]

On February 23, 2010, the Criminal Justice Impact Conference met and concluded that the bill will have an insignificant impact on prison beds.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to: require the counties or cities to spend funds or take an action requiring the expenditure of funds; reduce the authority that cities or counties have to raise revenues in the aggregate; or reduce the percentage of a state tax shared with cities or counties.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides FDLE sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

On March 16, 2010, the Health Care Regulation Policy Committee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The strike-all:

- Requires FDLE to approve an electronic logbook for use by pharmacies and retailers at no cost to them.
- Requires retailers and pharmacies to report to an electronic recordkeeping system.
- Deletes use of "reasonable showing of imposition of additional cost" and states that retailers or pharmacies may apply for exemption from the electronic reporting requirement if they lack technology to access the system or maintain sales of less than 72 grams within 30 days.
- Requires data be kept in the electronic recordkeeping system for at least two years from the date of entry.
- States that information in the electronic recordkeeping system may only be disclosed in accordance with federal or state law.
- Clarifies that the "amount" of compound, mixture, or preparation required to be reported actually means number of packages, and total of grams per package.

[40] Email correspondence with Florida Department of Law Enforcement on file with Health Care Regulation Policy Committee staff (March 13, 2010).

- Provides immunity from civil liability for individuals who properly disclose information.
- Requires FDLE to contract with a private third party administrator to implement an electronic logbook.
- Provides FDLE authority to promulgate rules.
- Provides an implementation date.

This analysis is drafted to the committee substitute.