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 Health Regulation Committee

BILL:	CS/SB 1050
INTRODUCER:	Criminal Justice Committee and Senators Baker and Siplin
SUBJECT:	Methamphetamine Pharmaceutical Products/Sale
DATE:	March 24, 2010 REVISED: 3/26/10

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Erickson	Cannon	CJ	**Fav/CS**
2.	Stovall	Wilson	HR	**Fav/1 amendment**
3.			JU	
4.			JA	
5.				
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	☐	Statement of Substantial Changes
B. AMENDMENTS.....	☐	Technical amendments were recommended
	☒	Amendments were recommended
	☐	Significant amendments were recommended

I. Summary:

The bill amends the section of law relating to the retail sale of ephedrine and related compounds to do the following:

- Define "ephedrine or related compounds" as ephedrine, pseudoephedrine, phenylpropanolamine, or any of their salts, optical isomers, or salts of optical isomers;
- Revise requirements relating to retail over-the-counter (OTC) sales of any nonprescription compound, mixture or preparation containing ephedrine or related compounds;
- Require a person purchasing, receiving or acquiring any nonprescription compound, mixture or preparation to meet certain requirements;
- Require the Florida Department of Law Enforcement (FDLE) to approve an electronic recordkeeping system for the purpose of recording and monitoring the real time purchase of products containing ephedrine or related compounds and for the purpose of monitoring this information in order to prevent or investigate illegal purchases of these products;
- Require this system to be provided to a pharmacy or retailer at no additional cost or expense;
- Authorize a pharmacy or retailer to request an exemption from the electronic reporting if certain criteria are met;
- Specify what information must be recorded in the system and the capabilities of the system;

- Require a pharmacy or retailer distributing a product containing ephedrine or related compounds to Florida consumers to submit required information to the system (as specified in the bill) before completing the transaction;
- Require data that is submitted to the system to be retained for no less than 2 years from the date of entry;
- Specify entities that are exempt from the requirements of the section;
- Require information that is contained in the system to be disclosed in a manner authorized by state or federal law;
- Provide that a person who sells any product containing ephedrine or related compounds who in good faith complies with the requirements of the section is immune from civil liability for the release of the information;
- Require the FDLE to contract with a private third-party administrator to implement the electronic recordkeeping system; and
- Require the FDLE to adopt rules necessary to implement the section.

This bill substantially amends section 893.1495, of the Florida Statutes.

II. Present Situation:

Use of Chemicals Referenced in the Bill

While some uses of products containing ephedrine, pseudoephedrine, and phenylpropanolamine are legal,[1] these chemicals are also unlawfully used in the production of methamphetamine,[2] a Schedule II controlled substance under state and federal law.[3] Accordingly, sales and purchases of products containing these chemicals are regulated and restricted.

Ephedrine, pseudoephedrine, and phenylpropanolamine are listed precursor chemicals under Florida law.[4] A "listed precursor chemical" is a chemical that may be used in manufacturing a controlled substance in violation of ch. 893, F.S., and is critical to the creation of the controlled substance, and includes any salt, optical isomer, or salt of an optical isomer, whenever the

[1] Asthma treatment (ephedrine): Jennifer Smith, "Nonprescription Asthma Treatment Trends," *US Pharm*. 33(3): 4-7 (2008), http://www.uspharmacist.com/content/t/respiratory_disorders/c/10133/. Section. 499.033, F.S., provides, with some exceptions, that any product that contains any quantity of ephedrine or its salts, optimal isomers, or salts of its optical isomers may be dispensed only upon a prescription of a duly licensed practitioner authorized by the state to prescribe prescription drugs. Decongestant (pseudoephedrine): Linda Bren, "Some Cold Medicines Move Behind Counter," *FDA Consumer* 40(4): 18-19 (July-August 2006). Veterinary use (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." U.S. Drug Enforcement Administration, http://www.deadiversion.usdoj.gov/meth/cma2005.htm.

[2] "An estimated 34 different chemicals can be used to produce methamphetamine. Among the most common are ephedrine, pseudoephedrine, phenylpropanolamine, red phosphorous, iodine, hydrochloric acid, ether, hydriodic acid, and anhydrous ammonia. Some of these chemicals are also used to produce other illicit drugs. The United States does not manufacture ephedrine, pseudoephedrine, and phenylpropanolamine; all supplies of these chemicals originate in other countries." Michael S. Scott and Kelly Dedel, *Clandestine Methamphetamine Labs 2nd Edition*, Problem-Oriented Guides for Police Series, Problem-Specific Guide Series No. 16, p. 10 (2006), Office of Community Oriented Policing Services, U.S. Department of Justice.

[3] Section 893.03(2)(c)(4), F.S., and 21 CFR § 1308.12(d)(2). The drug "has limited medical uses for the treatment of narcolepsy, attention deficit disorders, and obesity." U.S. Drug Enforcement Administration, http://www.justice.gov/dea/concern/meth.html (citing by footnote to the National Institute on Drug Abuse, Research Report - Methamphetamine Abuse and Addiction, www.drugabuse.gov/).

[4] Section 893.033(1)(f),(v), and (z), F.S.

existence of such salt, optical isomer, or salt of optical isomer is possible within the specific chemical designation. These chemicals are also listed chemicals. A "listed chemical" is any precursor chemical or essential chemical named or described in s. 893.033, F.S.[5]

Ephedrine, pseudoephedrine, and phenylpropanolamine are also list 1 chemicals under federal law.[6] A list 1 chemical is a chemical specified by regulation of the U.S. Attorney General as a chemical that is used in manufacturing a controlled substance in violation of federal drug abuse prevention and control laws and is important to the manufacture of controlled substances, and includes (until otherwise specified by regulation of, or upon petition to, the U.S. Attorney General) ephedrine, pseudoephedrine, and phenylpropanolamine, and other listed chemicals.[7] These chemicals, including their salts, optical isomers, and salts of optical isomers, are also designated methamphetamine precursor chemicals.[8]

Federal Regulation of Sales and Purchases

Under federal law,[9] sales and purchases of products containing ephedrine, pseudoephedrine, or phenylpropanolamine are regulated and restricted as follows:

Definitions

A "scheduled listed chemical product" is defined as a product that:

- Contains ephedrine, pseudoephedrine, or phenylpropanolamine, and the salts, optical isomers, and salts of optical isomers of these chemicals; and
- May be marketed or distributed lawfully in the United States under the Federal, Food, Drug, and Cosmetic Act as a nonprescription drug.

The term "regulated seller" is defined as a retail distributor (including a pharmacy or a mobile retail vendor), but does not include an employee or agent of that distributor. "Retail distributor" is defined as a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to pseudoephedrine or phenylpropanolamine products are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.

Sales Limits

For regulated sellers and persons required to submit mail order reports under 21 U.S.C. § 830(b)(3), daily sales are limited to 3.6 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base per purchaser, regardless of the number of transactions.

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[5] Section 893.02(13), F.S. The inclusion of a chemical as a listed precursor chemical does not bar, prohibit, or punish legitimate use of the chemical.
[6] 21 U.S.C. § 802(34)(c)(I) and (K). Many of the federal list 1 chemicals are also precursor chemicals under s. 893.033, F.S.
[7] *Id.*
[8] 6 U.S.C. § 220(c).
[9] "The Combat Methamphetamine Epidemic Act of 2005 (Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005, P.L. 109-177) was signed into law March 9, 2006. All changes go into effect on March 9, 2006, (date the legislation was signed) unless a later effective date is specifically stated." Office of Diversion Control, U.S. Drug Enforcement Administration, http://www.deadiversion.usdoj.gov/meth/cma2005.htm. All information pertaining to federal regulation of sales and purchase is from this webpage, which describes the provisions of the Act.

All non-liquid forms (including gel caps) must be in 2-unit blister packs (when a blister pack is not technically feasible, the product may be in unit dosage packets or pouches).

Mail-order sales are limited to 7.5 grams per customer during a 30-day period.

Mobile retail vendor sales are limited to not more than 7.5 grams per customer during a 30-day period, and the vendor must confirm the identity of the purchaser prior to shipping the product.

Unlawful Purchase
It is unlawful for any person to knowingly or intentionally purchase at retail 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 U.S. Postal Service).

Product Placement
A regulated seller must place the product so that customers do not have direct access before the sale is made ("behind the counter" placement) or in a locked cabinet that is located in an area of the facility to which customers do have direct access. A regulated seller must deliver the product directly into the custody of the purchaser. A mobile retail vendor must place the product in a locked cabinet.

Logbook Provisions
A seller:

- Must maintain a written or electronic list (logbook) of sales that identifies:
  - Products by name,
  - Quantity sold,
  - Names and addresses of purchasers, and
  - Date and time of the sales;
- May not sell the product unless the prospective purchaser presents a photographic identification card issued by a state or the federal government, or a document considered acceptable for purposes of 8 CFR § 274a.2(b)(1)(v)(A) or (B);
- Must determine that the name entered into the logbook corresponds to the name provided on such identification and that the date and time entered are correct;
- Must enter into the logbook the name of the product and the quantity sold; and
- Must maintain each entry in the logbook for not fewer than 2 years after the date on which the entry is made.

The logbook requirement does not apply to any purchase by an individual of a single sales package that contains not more than 60 mg. of pseudoephedrine.

A purchaser must sign the logbook and enter his or her name, address, and date and time of sale.

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 18 U.S.C. § 1001 and such notice must specify the maximum fine ($250,000) and term of imprisonment (5 years).

The U.S. Attorney General is required to issue regulations establishing restrictions on disclosure of information in logbooks. Disclosure to the U.S. Attorney General and to state and local law enforcement agencies is authorized. 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 regulated seller who in good faith releases logbook information to federal, state, or local law enforcement authorities is immune from civil liability for such release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

Self-Certification and Training

A seller must self-certify to the U.S. Attorney General that each individual who is responsible for delivering such products into the custody of purchasers, or who deals directly with purchasers by obtaining payment for the products, has undergone training provided by the seller to ensure that the individual understands the requirements that apply to the sale of these products. A regulated seller may not sell any scheduled listed chemical product at retail unless the self-certification has been submitted to the U.S. Attorney General.

A seller must maintain a copy of this self-certification and records demonstrating that individuals have undergone such training.

Certification is not effective unless, in addition to provisions regarding the training of individuals, the certification includes a statement that the seller understands the certification applies to the requirements regarding transactional limits, blister-packs, "behind the counter" placement, photo identification, and logbook, and agrees to comply with these requirements.

The U.S. Attorney General is required to:

- Issue regulations to establish the criteria for self-certifications and employee training. Separate certification is required for each place of business at which a regulated seller sells such products at retail;
- Establish a program that:
  - Is carried out through an internet site of the U.S. Department of Justice,
  - Informs regulated sellers that 18 U.S.C. § 1001 applies to these certifications,
  - Makes available to sellers the criteria for certification and training,
  - Permits submission of certifications through the internet site, and
  - Is designed to automatically provide the explanation of the criteria for certification and training and an acknowledgment that the U.S. Department of Justice has received a certification, without requiring direct interaction of regulated sellers with staff of the U.S. Department of Justice; and
- Make copies of certifications available to appropriate state and local officials.

Florida Regulation of Sales

Section 893.1495, F.S., regulates and restricts retail sale of ephedrine, pseudoephedrine, phenylpropanolamine, and any of their salts, optical isomers, or salts of optical isomers. Persons are prohibited from:

- Knowingly delivering in any single retail OTC sale any number of packages of any drug containing a sole active ingredient that contains 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, or more than three packages in any single retail OTC sale, regardless of weight, containing any such sole active ingredient; or

- Knowingly displaying and offering for retail sale packages of any drug having a sole active ingredient of ephedrine, pseudoephedrine, phenylpropanolamine, or any of their salts or optical isomers other than behind a checkout counter where the public is not permitted or other such location that is not otherwise accessible to the general public.

The owner or primary operator of a retail outlet where ephedrine, pseudoephedrine, or phenylpropanolamine products are available for sale is prohibited from knowingly allowing an employee to engage in the retail sale of these products unless the employee has completed an employee training program that includes, at a minimum, basic instruction on state and federal regulations relating to the sale and distribution of such products.

The requirements of this section relating to the marketing, sale, or distribution of ephedrine, pseudoephedrine, or phenylpropanolamine products supersede any local ordinance or regulation passed by a county, municipality, or other local governmental authority.

Precursor Monitoring

Restrictions of purchases of methamphetamine precursors and requirements for point-of-sale documentation of these purchases are circumvented when those involved in methamphetamine production purchase the maximum amount of products containing ephedrine, pseudoephedrine, or phenylpropanolamine from different retail sellers (this activity is referred to as "smurfing").[10]

Several states require active tracking and monitoring of the sale of these products. A 2009 legislative update to a 2008 report on methamphetamine precursor monitoring systems by the National Alliance for Model State Drug Laws (NAMSDL)[11] provides the following information:

- Arkansas, Hawaii, Iowa, Kansas, Kentucky, Louisiana, Oklahoma, and West Virginia are identified by the NAMSDL as states that have passed laws providing for active tracking and monitoring systems that are not pilot programs.[12]
- Illinois, Indiana, Iowa, and Washington are identified by the NAMSDL as passing laws providing for a pilot program.[13]

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[10] According to the FDLE, "Federal law was effective in impacting the production of methamphetamine until meth cooks began using groups of individuals to travel from pharmacy to pharmacy to purchase products containing ephedrine base, pseudoephedrine base, or phenylpropanolamine base to use in the production of methamphetamine which, because of the lack of centrally available sale/purchase data, has made it difficult to identify persons who purchase excessive amounts of precursor ephedrine and/or related compounds." Analysis of SB 1050, dated March 10, 2010, Florida Department of Law Enforcement. This analysis will be cited in further references as the "FDLE analysis."

[11] *Electronic Tracking Systems for Methamphetamine Precursors/Legislative and Policy Update to 2008 Report* (October 2009), National Alliance for Model State Drug Laws, http://www.namsdl.org/documents/2009CongressionalReportFinal.pdf. This report will be cited in further references as the "NAMSDL report."

[12] NAMSDL report at pp. 11-13, 16-21, 33, 35-36, 41-45, and 47. Statutes or legislation: Ark. Code Ann. §§ 5-64-1104-1112 (West 2009); Haw. Rev. Stat. § 329-75 (2009); S.B. 33, 83rd Leg., Reg. Sess. (Ks. 2009); Ky. Rev. Stat. Ann § 218A.1446 (West 2009) ; La. Rev. Stat. Ann. §§ 40: 1049, 1 through 1049.11 (2009); Okla. Stat. Ann., Title 63, §§ 2-210 and 309A-H (West 2009) and Title 63, § 2-309C (West 2009); and W. Va. Code Ann. §§ 60A-9-4 and 60A-10-8 (West 2009).

[13] NAMSDL report at pp. 14-17, 33, 37-40, and 46. Statutes: 720 Ill. Comp. Stat. Ann. § 648/36-40 (West 2009); Ind. Code Ann. §§ 5-2-6-20 (West 2009) and 35-48-414.7 (West 2009); and Wash. Rev. Code Ann. § 69.43.170 (West 2009).

- Tennessee, through the Tennessee Methamphetamine Intelligence System (TMIS), which was created in 2005, allows the Tennessee Methamphetamine Task Force (Task Force) to receive, manage, and monitor substantial criminal justice information data, which includes data on methamphetamine precursor purchases. The NAMSDL does not identify any Tennessee laws that specifically address this system but indicates that the yearly operating budget allows for operation of this system. The NAMSDL also indicates that the TMIS has a statewide scope, and that the Task Force provides the TMIS software, free of charge, to officials in Arizona, Illinois, Indiana, and New Mexico. Alaska, California, Hawaii, Nevada, Oregon, and Washington also have access to the TMIS through the Western States Information Network, and the Task Force is expanding the exchange to include Georgia, Mississippi, North Carolina, and South Carolina.[14]

Precursor monitoring may be provided "in-house" without a private contractor (e.g., Tennessee), provided through the TMIS (e.g., California, which modified the TMIS software), with contractor involvement (e.g., Arkansas contracts with LeadsOnlabs), or by a memorandum of understanding (MOU) that allows access to the NPLEx (National Precursor Log Exchange), a "real-time electronic logging system used by pharmacies and law enforcement to track sales of over-the-counter (OTC) cold and allergy medications containing precursors to the illegal drug, methamphetamine."

According to officials with Appriss, the technology vendor for the NPLEx, Kentucky has been using MethCheck, an Appriss product, and now the NPLEx, since June of 2008. Louisiana and Illinois both passed legislation and signed the NPLEx agreements last year, and the NPLEx is currently being implemented in those states. Missouri recently awarded their RFP to the NPLEx and an MOU will soon be made final. Kansas also recently selected the NPLEx and is drafting an MOU. Iowa is finalizing their regulations and MOU to join the NPLEx. Alabama and Washington (state) have passed NPLEx legislation, which awaits Governors' signatures. In addition to Florida, electronic tracking legislation is pending in California, Georgia, New Jersey, Pennsylvania, South Carolina, and Virginia.

The FDLE has indicated that it contracted with Appriss to use their web-accessed database to conduct a 23-county pilot project.

The NAMSDL indicates that two states have adopted alternatives to precursor monitoring systems. Oregon requires a prescription for products containing ephedrine, pseudoephedrine, or phenylpropanolamine.[15] Alabama law prohibits the sale of any product containing ephedrine or pseudoephedrine unless it is manufactured in such a manner that these chemicals cannot be extracted so as to be used in the production of methamphetamine.[16] The NAMSDL states that it is unaware of any product that has been "chemically engineered to prevent its conversion into a methamphetamine precursor[.]"[17]

[14] NAMSDL report at pp. 22-32 and 48-54.
[15] NAMSDL report at p. 56. Or. Rev. Stat. Ann. § 475.973 (West 2009) and Or. Admin. R. 855-080-0023 (2009).
[16] Ala. Code § 20-2-190 (2009).
[17] NAMSDL report at p. 57.

III. Effect of Proposed Changes:

The bill amends s. 893.1495, F.S., as follows:

Definition
The bill defines the term "ephedrine or related compounds" as ephedrine, pseudoephedrine, phenylpropanolamine, or any of their salts, optical isomers, or salts of optical isomers.

Regulating Sales and Purchases
Currently, s. 893.1495(1), F.S., provides that no person shall knowingly deliver in any single retail OTC sale any number of packages of any drug containing a sole active ingredient that contains 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, or more than three packages in any single retail OTC sale, regardless of weight, containing any such sole active ingredient.

The bill amends this subsection to provide 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 OTC sale, three packages, regardless of weight, containing ephedrine or related compounds; or
- In any 30-day period, in any number of retail OTC sales, a total of 9 grams or more of ephedrine or related compounds.

The bill revises language in current s. 893.1495(2), F.S. (requiring retail sales behind the counter or inaccessible to the general public), current s. 893.1495(3), F.S (requiring employee training), and current s. 893.1495(4), F.S. (providing section requirements supersede local ordinances or regulations), to conform to the definition of "ephedrine or related compounds" and language used in the amendment of current s. 893.1495(1), F.S. The bill also makes a subsection referencing change in current s. 893.1495(5), F.S. (penalties), to conform the reference to changes in the numbering of subsections.

The bill provides that any person purchasing, receiving, or otherwise acquiring any nonprescription compound, mixture, or preparation containing any detectable quantity of ephedrine or related compounds must:

- Be at least 18 years of age;
- Produce a government-issued photo identification showing his or her name, date of birth, address, and photo identification number; and
- Sign his or her name on a record of the purchase, either on paper or on an electronic signature capture device.

Electronic Recordkeeping System

The bill requires the FDLE to approve an electronic recordkeeping system ("system") for the purpose of recording and monitoring the real time purchase of products containing ephedrine or related compounds and for the purpose of monitoring this information in order to prevent or investigate illegal purchases of these products. The approved system must be provided to a pharmacy or retailer without any additional cost or expense.

A pharmacy or retailer may request an exemption from electronic reporting from the FDLE if the pharmacy or retailer lacks the technology to access the system and maintains a sales volume of less than 72 grams of ephedrine or related compounds in a 30-day period.

The system must record the following:

- Date and time of the transaction;
- Name, date of birth, address, and photo identification number of the purchaser, as well as the type of identification and the government of issuance;
- The number of packages purchased, total grams per package, and name of the compound, mixture, or preparation containing ephedrine or related compounds; and
- The signature of the purchaser, or a unique number relating the transaction to a paper signature maintained at the retail premises.

The system must provide for:

- Real-time tracking of nonprescription OTC sales under s. 893.1495, F.S., and
- Blocking of nonprescription OTC sales in excess of those allowed by the laws of this state or federal law.

The bill prohibits the OTC sale of a nonprescription compound, mixture, or preparation containing any quantity of ephedrine or related compounds unless reported to the system approved by the FDLE. It also provides that, prior to completing a transaction, a pharmacy or retailer distributing products containing ephedrine or related compounds to consumers in Florida must submit all required data into the system approved by the FDLE either at the point of sale or through an interface with the system, unless granted an exemption by the FDLE.

Data submitted to the system must be retained within the system for no less than 2 years from the date of entry. Information contained within the system must be disclosed in a manner authorized by state or federal law. A person who sells any product containing ephedrine or related compounds who in good faith complies with the requirements of s. 893.1495, F.S., is immune from civil liability for the release of the information.

The FDLE is required to contract or enter into a MOU with a private third-party administrator to implement the system.

The FDLE is also required to promulgate rules necessary to implement s. 893.1495, F.S.

Exceptions to Application
The bill provides that s. 893.1495, F.S., does not apply to:

- Licensed manufacturers manufacturing and lawfully distributing products in the channels of commerce;
- Wholesalers lawfully distributing products in the channels of commerce;
- Health care facilities licensed under ch. 395, F.S. (hospitals, ambulatory surgical centers, and mobile surgical facilities);
- Licensed long-term care facilities;
- Government-operated health departments;
- Physicians' offices;
- Publicly operated prisons, jails, or juvenile correctional facilities or private adult or juvenile correctional facilities under contract with the state;
- Public or private educational institutions maintaining health care programs; and
- Government-operated or industry-operated medical facilities serving employees of the government or industry operating them.

Effective and Implementation Dates
The effective date of the bill is July 1, 2010. The date for implementation of the bill is January 1, 2011.

Other Potential Implications:

The FDLE states:

- "SB 1050 follows the federal 2005 Combat Methamphetamine Act which establishes most of the key provisions within this bill that relate to the restricted sale of any product containing an ephedrine base, pseudoephedrine base, or phenylpropanolamine base and the required use of a purchaser logbook. Law enforcement already has access to the logbooks and purchaser information."
- "In addition, the federal Methamphetamine Production Prevention Act of 2008 recognized the use of electronic logbooks in lieu of written logbooks. Real time electronic record keeping systems that capture and/or block point of sale transactions of products containing ephedrine based or related compounds have been in existence in other states for a couple of years. Thus far, the courts have found no constitutional violation with these systems."[18]

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The bill provides that information contained within the electronic recordkeeping system must be disclosed in a manner authorized by state or federal law.

[18] FDLE analysis.

Federal law provides that the disclosure of information in logbooks is restricted as follows:

- The information shall be disclosed as appropriate to the DEA and to state and local law enforcement agencies, and
- The information in the logbooks shall not be accessed, used, or shared for any purpose other than to ensure compliance with Title 21 of the Code of Federal Regulations or to facilitate a product recall to protect public health and safety.[19]

Additionally, if this private information is maintained by a criminal justice agency or accessed from a private source and retained by a criminal justice agency to monitor possible criminal activity, the information would probably constitute criminal intelligence information, which is exempt from public records inspection as long as the information is active.[20]

Additionally, disclosure limitations mirroring federal law are typically a condition of a contract or MOU between a private third-party administrator of an electronic recordkeeping system that contains logbooks information and a state agency that will access that information.

Florida law does not limit private entities (third-party administrators and retailers and sellers who have this logbook information) from disclosing logbook information. Records pertinent to Florida's public records law are records made or received pursuant to law or ordinance or in connection with the transaction of official business by a public agency. However, many private records (e.g., bank account information, credit card information, and personal medical records) are not disclosed to the public because of federal law and/or the private entities' commitment or contractual obligation to the consumer not to disclose the records to the public.

There is case law that indicates that private records are public records when accessed electronically by public agents for "a public purpose." However, the records discussed in those cases did not appear to be restricted from public disclosure by federal law. In *National Collegiate Athletic Ass'n v. Associated Press*, 18 So.3d 1201 (Fla. 1st DCA 2009), the court held that NCAA documents were public records because they were examined by lawyers for a public agency, Florida State University, and used in the course of the agency's official business. Similarly, in *Times Publishing Co. v. City of St. Petersburg*, 558 So.2d 487 (Fla. 2d DCA 1990), the court held that documents of negotiations between the Chicago White Sox and the City of St. Petersburg for the use of the Suncoast Dome were public records. These documents were prepared and maintained by the White Sox, but were examined by agents for the City under a confidentiality agreement and used in the course of its business.

[19] 21 CFR § 1314.45(c).

[20] Sections 119.011(3)(a) and (d), and (4) and 119.071(2), F.S. It is uncertain if the limited exemption for data processing software would also be applicable. Sections 119.011(6) and 119.071(1)(f), F.S.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Depending on the third-party administrator chosen, there may or may not be costs for technology purchases (software, hardware, etc.), system administration, training, etc.

C. Government Sector Impact:

The bill requires the FDLE to contract with a private third-party administrator to implement the electronic recordkeeping system required by the bill.

There appears to be at least three private third-party administrators providing "real-time" tracking/monitoring: NPLEx, MethShield,[21]and LeadsOnlabs.[22] System requirements and costs vary depending on the private vendor or administrator.

The NPLEx's website states that "NPLEx is provided free of charge on a permanent basis to state governments that pass appropriate legislation and regulations."[23] "[M]anufacturers of the medicines are the sponsors for NPLEx, and pay for the entire cost of the service."[24] MethShield's website indicates some involvement in county pilot projects in Kansas and Missouri but does not indicate any current contract with a state agency. The NAMSDL reports that start-up costs for Arkansas' system (Arkansas contracts with LeadsOnlabs) were $350,000 for the first 2 years, and annual operating costs/FTE's are $300,000/1 FTE.[25] It is unknown how much of start-up costs and annual operating costs are costs for contractual services.

At the present time, it appears that the NPLEx is the only private third-party administrator able to meet the electronic recordkeeping system capability requirements of the bill and provide the system to a pharmacy or retailer without any additional cost or expense (as represented by Appriss).

[21] MethShield, https://www.methshield.com/.
[22] LeadsOnlabs, http://www.leadsonlabs.com/main/.
[23] NPLEx, http://www.nplexservice.com/faq.html.
[24] *Id.* Appriss officials verbally communicated to Senate professional staff of the Committee on Criminal Justice that Appriss' financial benefit comes from increased volume (per contract with the drug manufacturers funding NPLEx).
[25] NASMSDL report at p. 12.

VI. Technical Deficiencies:

Subsection (6), beginning on line 113 of the committee substitute, prohibits the over the counter sale of these substances unless reported to an electronic recordkeeping system. Although an exemption process is authorized on lines 90 – 95 in paragraph (5)(b), subsection (6) does not reference that exemption. Either subsection (6) could be deleted from the committee substitute since it may not be necessary given the requirement in subsection (7), or line 117 could be deleted and insert Enforcement, unless granted an exemption by the Department of Law Enforcement pursuant to paragraph (5)(b).

The traveling amendment refers to "logbook" information, which is the federal term. However, that term is not used in the existing state law or in the committee substitute. A substitute amendment (with title amendment) could be offered that deletes line 163 and inserts: by state or federal law. Any retailer or entity that collects information on behalf of a retailer as required by the Combat Methamphetamine Epidemic Act of 2005 and this section may not access or use that information, except for law enforcement purposes pursuant to state or federal law or to facilitate a product recall for public health and safety.

VII. Related Issues:

None.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Criminal Justice on March 18, 2010:

- Defines "ephedrine or related compounds" as ephedrine, pseudoephedrine, phenylpropanolamine, or any of their salts, optical isomers, or salts of optical isomers.
- Revises requirements in s. 893.1495, F.S., relating to retail OTC sales of any nonprescription compound, mixture or preparation containing ephedrine or related compounds.
- Requires a person purchasing, receiving or acquiring any nonprescription compound, mixture or preparation to meet certain requirements.
- Requires the FDLE to approve an electronic recordkeeping system for the purpose of recording and monitoring the real time purchase of products containing ephedrine or related compounds and for the purpose of monitoring this information in order to prevent or investigate illegal purchases of these products.
- Requires that this system be provided to a pharmacy or retailer at no additional cost or expense.
- Provides that a pharmacy or retailer may request an exemption from the electronic reporting if certain criteria are met.
- Specifies what information must be recorded in the system and the capabilities of the system.

- Requires a pharmacy or retailer distributing a product containing ephedrine or related compounds to Florida consumers to submit required information to the system (as specified in the bill) before completing the transaction.
- Specifies that data submitted to the system must be retained for no less than 2 years from the date of entry.
- Specifies entities exempt from the application of s. 893.1495, F.S.
- Specifies that information contained in the system must be disclosed in a manner authorized by state or federal law.
- Provides that a person who sells any product containing ephedrine or related compounds who in good faith complies with the requirements of s. 893.1495, F.S., is immune from civil liability for the release of the information.
- Requires FDLE to contract with a private third-party administrator to implement the electronic recordkeeping system.
- Requires FDLE to promulgate rules necessary to implement s. 893.1495, F.S.

B. Amendments:

Barcode 307924 by Health Regulation on March 26, 2010:
Restricts the use of information in the logbook to law enforcement purposes or to facilitate a product recall. (WITH TITLE AMENDMENT)