

Considerations in Adding Pseudoephedrine as a Schedule III Controlled Substance

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Michele Chesser, Ph.D.
Senior Health Policy Analyst

Purpose of Study

- In 2010, Senate Bill 878 (Senator Wm. Roscoe Reynolds) proposed legislation to amend the *Code of Virginia* § 54.1-3450 to add pseudoephedrine (PSE) to Schedule III of Virginia's Drug Control Act which would prohibit the sale of the drug without a prescription.
- The bill was passed by indefinitely in the Senate Education and Health Committee, and JCHC members voted to have the issue studied and reported in 2011.

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THE METHAMPHETAMINE PROBLEM



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Methamphetamine (Meth)

- Meth is a stimulant that causes the release of large amounts of dopamine, resulting in an extreme and prolonged sense of pleasure or euphoria.
- With repeated use, meth depletes the brain's stores of dopamine and destroys dopamine receptors which can take over a year to re-grow. Until then, addicts can not experience pleasure without meth, and most slip into a deep depression that may cause them to relapse.
- As a result, meth addiction is difficult to treat and usually requires extensive treatment for at least one year.
- Chronic use can lead to severe tooth decay, skin lesions, brain damage, psychosis, heart attack, stroke, and death.

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Faces of Meth



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Faces of Meth



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Use of PSE for Meth Production

- Meth production requires ephedrine, pseudoephedrine, or phenylpropanolamine (PPA).
- Meth production also includes several flammable and toxic chemicals such as ammonium nitrate, camping fuel, lye, red phosphorous, acetone, brake cleaner, racing fuel, battery acid, drain cleaner and muriatic acid.
- One 15-count box of a 24-hour allergy medicine = 3.6 grams of PSE
- 10 grams of PSE yields 6 to 8 grams of meth (depending on the method used)
- Approximately 90% of meth is produced by Mexican drug cartels in superlabs; however, as Virginia law enforcement officials continue to reduce the amount of trafficking, local small-scale production is increasing.
- Most of the PSE for these small meth labs is acquired by using a fake ID and/or "smurfing." (The process by which meth lab producers have individuals purchase legal amounts of PSE, often going to multiple retailers in a day, in exchange for money or meth.)

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Meth Costs

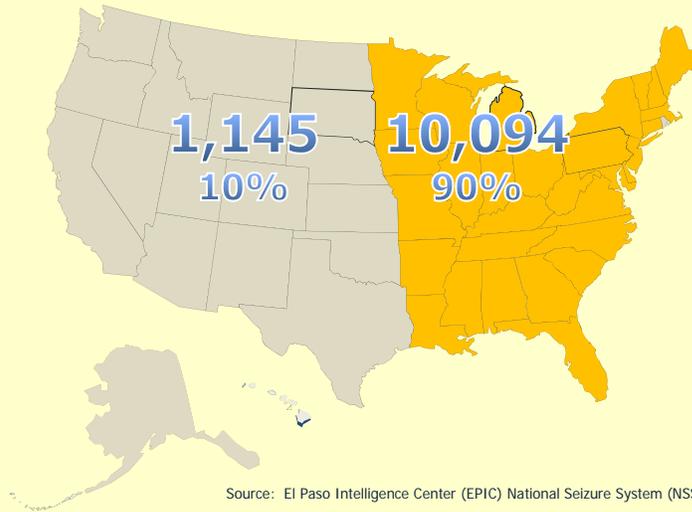
- Treatment
- Meth-related health care
- Productivity losses
- Meth-related crime
- Meth-related child maltreatment and foster care
- Meth production
 - Environmental clean-up: \$1500-\$5000 per site
 - Physical injuries and death
 - Personal decontamination, shelter, evacuations



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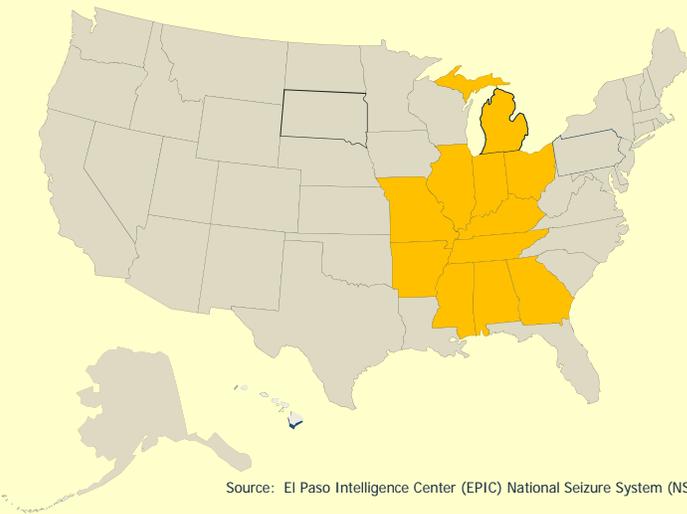
Meth Lab Incidents in 2010

11,239 Total US Labs



Meth Lab Incidents in 2010

78% of labs are concentrated in 11 states



Number of Meth Lab Incidents in Virginia by County and Year (2005-2011*)

Southwest	41	17	16	16	26	101	146
Northwestern	4	2	6	3	1	3	0
Central	1	2	0	0	1	2	4
Eastern	7	0	0	0	0	2	2
Northern	0	0	0	0	0	0	0
Total	53	21	22	19	28	108	152
	2005	2006	2007	2008	2009	2010	2011*

Incidents include lab seizures and the finding of dumpsites, chemicals, or equipment.

* For 2011, data are for January 1 – September 1

For all years, additional incidents may have occurred, but were not reported to EPIC (There is no mandatory centralized reporting system in Virginia.).

Source: Virginia State Police

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Meth Lab Seizures in Virginia (FY 2011)



Source: Virginia State Police, Drug Enforcement Section

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Meth Lab Seizures in SW Virginia (FY 2011)



Source: Virginia State Police, Drug Enforcement Section

ADDRESSING THE METH PROBLEM

PSE as a Schedule III Drug Requiring a Prescription

- 19 states have considered prescription-only legislation
- Currently, Mississippi and Oregon are the only states with a prescription-only law
- States with prescription-only bills in 2011
 - Still Active: Alabama, Nevada, Oklahoma and Tennessee
 - Defeated or Withdrawn: Arkansas, Kansas, Kentucky, Missouri, North Carolina and West Virginia

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PSE as a Schedule III Drug Requiring a Prescription

- The number of meth lab seizures decreased dramatically after Oregon and Mississippi enacted their prescription-only laws.
 - Oregon's law was enacted in 2006.

Number of Meth Lab Seizures by Year				
Meth Lab Seizures	525	63	20	13
Year	2002	2006	2007	2010

- In Mississippi, which adopted a prescription-only law in 2010, meth lab seizures have decreased by almost 70 percent.
- There is current disagreement as to whether the reduction in lab seizures was a result of the prescription-only laws, given that lab seizures in other states decreased as well during the same time period.
- There has been little to no negative reactions among consumers after the prescription laws were introduced.

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PSE as a Schedule III Drug Requiring a Prescription

- According to an informal opinion by Howard Casway, a Senior Assistant Attorney General, PSE does not satisfy the statutory conditions required to be classified as a Schedule III drug because it is not considered to be an addictive substance.
- As a Schedule III drug, PSE sales would need to be reported to the Prescription Monitoring Program (PMP).
 - This would increase the workload of the few law enforcement officers that have access to the PMP.

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PSE as a Schedule III Drug Requiring a Prescription

- For consumers, requiring a prescription would result in the added inconvenience and cost of having medical appointments with a physician in order to receive and renew prescriptions.
- Individuals without health insurance or who live in medically-underserved areas may be unable to obtain cold and allergy medicines.
- It is likely health care system costs would increase.
- The law would reduce the level of State tax revenue generated by over-the-counter PSE sales.

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Retailers Reporting to NPLeX



Retailers' Use of the NPLeX Real Time Electronic Tracking System

- Provided to pharmacies and other PSE retailers at no charge
 - Free services provided to the retailer include:
 - Training: multiple on-site, regularly scheduled web meetings and web tutorials
 - Live support, 7/24/365
 - Maintenance of all transaction data for 2 years for law enforcement or product recall as provided by the Combat Methamphetamine Epidemic Act (CMEA) of 2005
 - Transaction history report for government audits
 - Maintenance and upgrades
- System is funded by manufacturers of PSE products
- Pharmacies and retailers can easily access NPLeX through:
 - Web portal via an internet-connected computer, with a secure password (no software installation required)
 - Integration of the retailer's existing POS system with the NPLeX system. NPLeX can link with POS systems regardless of whether they are maintained in-house or by a third party vendor.
 - The technology vendor, Apriss Inc., is required to carry out this integration at no charge to retailers and to provide up to 16 hours of technical support.

Retailers' Use of the NPLeX Real Time Electronic Tracking System

- If a sales clerk feels uncomfortable denying the sale, the system includes a safety override that allows the sale to go through without notice to the customer.
- Law enforcement can access purchase records from a separate, secure web portal, in keeping with CMEA. Federal law prohibits manufacturers' access to this data.
- Simple, user-friendly logging system:
 - Auto filling of data fields when purchaser's ID (DL, Military ID, Passport, etc.) is entered if the individual has purchased through the system before
 - Product drop down tables which display only those items sold by the store processing the transaction
 - Less time-consuming than maintaining a paper log
- Data transmitted via NPLeX is secure and inaccessible to unauthorized individuals
- System would be overseen by a Virginia law enforcement agency

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Retailers' Use of the NPLeX Real Time Electronic Tracking System

- Will prevent individuals from going to more than one retailer to illegally purchase multiple boxes of PSE
 - However, it will not stop smurfs who buy no more than the legal limit or use a fake ID*
 - Some meth users have formed co-ops: Multiple individuals buy small legal amounts of PSE which are combined into one batch in exchange for money or a share of the meth
- The number of meth lab seizures tend to decrease immediately after NPLeX is implemented; however, in some states the number has started to increase again. This could be a result of:
 - Increased use of smurfing and fake IDs, or
 - Law enforcement officials being better able to track sales and link them to meth labs, resulting in more meth lab seizures

*Appriss, Inc. plans to have a system in place by the 1st quarter of 2012 that can validate an NPLeX submitted ID by comparing it with public data to guard against false ID usage. The system was tested in Massachusetts and 95% of the 810,000 ID scans were validated using DMV records.

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Illegal PSE Purchases Blocked by NPLEx

Total Amount of PSE Blocked by NPLEx in the U.S.
1st Quarter of 2011

Blocked Illegal Activity	Non-NPLEx States	NPLEx States	Total NPLEx Coverage
Number of Sales Blocked per Month	19,535	47,866	54,462
Percent of Boxes Blocked	1.4%	4.09%	2.75%
Total Grams of PSE Blocked	151,399	379,404	530,803

Total Amount of PSE Blocked by NPLEx in the U.S., 2006-2011

GRAMS SOLD	GRAMS BLOCKED	BOXES SOLD	BOXES BLOCKED
39,059,165.1	<u>1,060,502.211</u>	20,257,374	437,929

Source: Consumer Healthcare Products Association

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Examples of Successful Uses of NPLEx for Lab Seizures and Arrests of Smurfs

FLORIDA: NPLEx Lead Ends with Seizure of Large Clandestine Meth Lab

Narcotics detectives with the Santa Rosa County Sheriff's Office in Milton, FL located an offender while conducting an exceedance check. During interrogation, the offender admitted to making more than 80 PSE purchases at various pharmacies over a three-month period. With his cooperation, the Sheriff's office made four additional arrests, on a charge of possession of a listed chemical with the intent to manufacture a controlled substance. A large clandestine methamphetamine lab was seized and all suspects are facing the prospect of long prison sentences.

"MethCheck is my weapon of choice in the war against methamphetamine."

Det. Blake Weekley, Clandestine Laboratory Investigator, Santa Rosa County Sheriff's Office

KANSAS: NPLEx Helps Kansas Authorities Put Meth Lab Out of Business

The Kansas Bureau of Investigation, using MethCheck, tipped Bonner Springs police about two suspected "smurfers" at local pharmacies. Detectives, arriving at the suspects' address, found an active meth lab. The two were arrested and the house was condemned because of the chemical damage.

"MethCheck put two suspects on the radar screen that would have otherwise gone unnoticed. The end result was another meth lab seizure."

Lt. Rick Schubert, Bonner Springs Police Department

KENTUCKY: Louisville Police Credit NPLEx with Targeting "Smurfers"

The Louisville, Kentucky Metro Police Department has been working to eliminate the problem of "smurfing." Investigators recently arrested two individuals by using MethCheck to identify six "smurfers," who were supplying PSE.

"Thanks to MethCheck, our unit can spend less time driving to pharmacies and more time aggressively looking for meth cooks. MethCheck is directly responsible for the apprehension and seizure of several meth labs and their cooks."

Det. Steve Healey, Louisville Metro Police Department, Metro Narcotics/Clandestine Lab Enforcement Team

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Virginia's Criminal Code Regarding the Purchase and Possession of PSE

- Law enforcement officials have requested changes to the Criminal Code regarding the purchase and possession of PSE to address the growing problem of smurfing and the increasing number of meth labs in Virginia
- The Combat Methamphetamine Epidemic Act (2005) limits all PSE-containing OTCs to behind the counter, with sales per customer of no more than 3.6 grams per day and 9 grams per 30 days, and requires purchasers to show ID and sign a logbook.
 - However, it is not a punishable violation of Virginia law to purchase more than 9 grams of PSE in a 30-day period.
 - Also, under current Virginia law, it is difficult to prosecute a person for:
 - The use of a fake ID to purchase PSE
 - Possession of PSE with the intent to manufacture meth

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Policy Options

Option 1: Take no action.

Option 2: Introduce legislation to amend the *Code of Virginia* § 54.1-3450 to add pseudoephedrine to Schedule III of the Drug Control Act, which would prohibit it from being sold without a prescription. (*OAG informal opinion indicated PSE does not meet the statutory conditions.*)

Option 3: Introduce legislation to amend of the *Code of Virginia* § 18.2-248.8 to require that the log, currently required to be maintained by sellers of products containing ephedrine, pseudoephedrine, or any of their salts, isomers, or salts of isomers, must be kept by a State level law enforcement agency in electronic format, utilizing the National Precursor Log Exchange (NPLeX).

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Policy Options

Option 4: Introduce legislation to amend the *Code of Virginia* § 18.2-248.8 to make the purchase of ephedrine and pseudoephedrine, in excess of statutorily-determined amounts, a misdemeanor offense and to establish the maximum amount of ephedrine and pseudoephedrine that can be legally sold or purchased in a 30 day period:

§ 18.2-248.8. Sale **and purchase** of the methamphetamine precursors ephedrine and pseudoephedrine; penalty.

A. The sale of any product containing ephedrine, pseudoephedrine, or any of their salts, isomers, or salts of isomers, alone or in mixture, shall be restricted when provided or sold by a retail distributor or pharmacy as follows:

1. Retail sales **and purchases** shall be limited to no more than 3.6 grams total of either ephedrine or pseudoephedrine daily and **9 grams within any 30 day period** per individual customer.

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Policy Options

Option 5: Introduce legislation to amend Title 18.2 of the *Code of Virginia* to make it unlawful to possess, receive, or otherwise acquire more than 9 grams of ephedrine, pseudoephedrine, or any of their salts, isomers, or salts of isomers; or phenylpropranolamine in any product, mixture, or preparation within any 30 day period. (This restriction does not apply to any quantity of product, mixture, or preparation obtained pursuant to a valid prescription drug order prescribed by a practitioner with appropriate authority.)

Possession of more than 9 grams of ephedrine, pseudoephedrine, or phenylpropranolamine constitutes a rebuttable presumption of the intent to use the product as a precursor to methamphetamine or another controlled substance. This rebuttable presumption does not apply to:

- (i) A retail distributor of drug products;
- (ii) A wholesale drug distributor, or its agents;
- (iii) A manufacturer of drug products, or its agents;
- (iv) A pharmacist licensed by the Board of Pharmacy; or
- (v) A licensed health care professional possessing the drug products in the course of carrying out professional duties.

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Policy Options

Option 6: Introduce legislation to amend the *Code of Virginia* § 18.2-258.1.A to add ephedrine, pseudoephedrine, or any of their salts, isomers, or salts of isomers to the current list:

§ 18.2-258.1. Obtaining drugs, procuring administration of controlled substances, etc., by fraud, deceit or forgery. A. It shall be unlawful for any person to obtain or attempt to obtain any drug or procure or attempt to procure the administration of any controlled substance, marijuana, ~~or~~ synthetic cannabinoids, ***or ephedrine, pseudoephedrine, or any of their salts, isomers, or salts of isomers:*** (i) by fraud, deceit, misrepresentation, embezzlement, or subterfuge; or (ii) by the forgery or alteration of a prescription or of any written order; or (iii) by the concealment of a material fact; or (iv) by the use of a false name or the giving of a false address. (Class 1 misdemeanor)

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Public Comments

- Written public comments on the proposed options may be submitted to JCHC by close of business on October 6, 2011. Comments may be submitted via:
 - E-mail: sreid@jchc.virginia.gov
 - Facsimile: 804-786-5538 or
 - Mail to: Joint Commission on Health Care
P.O. Box 1322
Richmond, Virginia 23218
- Comments will be summarized and presented during the JCHC meeting on October 17th.

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Internet Address

Visit the Joint Commission on Health Care website:
<http://jchc.virginia.gov>



Contact Information
mchesser@jchc.virginia.gov
900 East Main Street, 1st Floor West
P. O. Box 1322
Richmond, VA 23218
804-786-5445
804-786-5538 fax