

**NAMSDL METHAMPHETAMINE PRECURSOR TRACKING ADVISORY
COMMITTEE (COMMITTEE)
DRAFT RECOMMENDATIONS RE: PSEUDOEPHEDRINE (PSE)
TRACKING SYSTEMS
(6-2-08 version)**

Domestic production of methamphetamine continues to be a deadly and serious threat to public safety. State and federal restrictions have markedly reduced the number of meth labs. However, domestic clandestine laboratories are still far too common and pose a continuing danger.

Currently, the key ingredient in the production of methamphetamine is pseudoephedrine, commonly found in over-the-counter cold medications. Historically, two additional over-the-counter cold medications had been used in clandestine labs: ephedrine, which reduces to methamphetamine, and phenylpropanolamine, which reduces to amphetamine. However, certain over-the-counter ephedrine and phenylpropanolamine products have effectively been removed from the market by federal action. *See* 59 Fed. Reg. 51,365 (Oct. 11, 1994) (DEA final rule eliminating thresholds for the regulation of ephedrine under the federal Controlled Substances Act); 66 Fed. Reg. 42,665 (Aug. 14, 2001) (FDA proposal to remove phenylpropanolamine drugs from the market); 69 Fed. Reg. 6,788 (Feb. 11, 2004) (FDA final rule declaring dietary supplements containing ephedrine alkaloids adulterated); 70 Fed. Reg. 40,232 (July 13, 2005) (FDA proposed rule to ban certain ephedrine combination products from over-the-counter sales). *But see* 70 Fed. Reg. 40,237 (2005) (FDA proposed rule to require relabeling of certain over-the-counter ephedrine products and to withdraw its earlier proposed rule in 60 Fed. Reg. 38,643) (1995) to ban the use of ephedrine in those products).

Methamphetamine producers have adapted and developed ways to circumvent these over-the-counter sales restrictions, usually through organized multiple purchases in multiple locations, known as ‘smurfing’. As a result, some states have reported a resurgence in the number of small toxic labs and an increase in capacity at some clandestine laboratories.

Federal law now requires purchasers of over-the-counter cold medications containing pseudoephedrine to sign a logbook and to show photo-identification. Some states have further restricted access by requiring over-the-counter sales to be conducted by licensed pharmacy employees. In response to the multiple-sale problems created by ‘smurfing’, states are developing further improvements by using technology to collect sales data electronically. These efforts have provided law enforcement with more efficient access to information regarding excessive and prohibited sales of the products.

As more federal resources are redirected to international threats, both from international drug trade as well as from terrorism, it must be recognized that local authorities and private industry have an increasingly vital role in addressing local drug production.

To protect our children, the environment, public safety, privacy rights, and freedom of legitimate retailers and consumers, it is imperative that current productive efforts against

clandestine labs continue, and that new approaches be developed to respond to the evolving dangers created by the illegal production of methamphetamine.

The NAMSDL Methamphetamine Precursor Tracking Advisory Committee (Committee) recommends a multi-disciplinary partnership to create a comprehensive and uniform approach to the changing methamphetamine production threat. The Committee adopts the following recommendations for states to consider in developing their own responses to the goal of reducing the number and capacity of clandestine laboratories.

I. Precursor Tracking: Each state should consider creating an electronic tracking system to prevent pseudoephedrine sales over legal limits and/or to identify individuals who purchase illegal amounts of pseudoephedrine. The Committee recommends such programs be set up with the following characteristics:

- **Data collection**
 - States are strongly encouraged to create electronic data collection in standardized formats to enhance statistical collection and enable medical and public safety checks across state lines.
 - The system should record certain minimum data elements for each transaction, but individual state statutes or regulations may authorize more:
 - the date and time of sale;
 - store transaction number;
 - buyer's full name (first-middle-last) and date of birth;
 - government ID number, state of origin and type;
 - brand name purchased;
 - amount of meth precursor as an active ingredient, in mg;
 - number of packages;
 - purchaser's street address, including Apt, City, County, State, Zip; and
 - store name, address and phone number and DEA number if pharmacy, DEA Self Certification number if retailer, including expiration date.
 - Access to either the actual signature or the electronic signature file is critical, but duplicative collection and storage at the central repository is not necessary.
 - The information required is most useful for investigative purposes. A state with a 'stop sale' approach, where the sale is not allowed, might not utilize all the data on a regular basis. However, even in those systems, procedures allow for sales to occur where the pharmacist or retailer perceives personal danger in denying a sale. Further, since the system will be used to gather data on offenders where only the multistate total is prohibited, it is felt that the basic identifying information should be collected.
- **'Stop Sale' versus 'Suspect Identification' Systems**
- States have utilized the data in two distinct approaches, each with their own advantages and disadvantages.
 - Stop Sale System
 - Notifies the retailer in 'real time' of attempted purchase that the sale appears to be in violation of state or federal law. The sale would not

be consummated unless the retailer had reason to be concerned for personal safety in denying the sale.

- Advantages are that this system normally prevents the product from reaching the criminal and thus prevents the manufacture of the methamphetamine.
 - Disadvantages include a higher cost and concerns of retailers regarding their role in enforcing criminal law.
- Suspect Identification System
 - Data is collected and analyzed to identify apparent violators. Law enforcement agencies are then provided the information for use in developing prosecutable cases.
 - Advantages are a lower up front cost and the identification of possible suspects.
 - Disadvantages are the time lag may well allow the illegal substance to be manufactured and distributed, with consequential dangers. Further, there are additional costs to investigative and prosecutorial resources in working meth labs that might not have occurred.
- **Technological standards**
 - Interoperability:
 - Systems must be set up using technological standards to ensure ability to share data across all jurisdictional lines and between publicly and privately developed systems. While states are not required to enforce federal PSE statutes, consideration should be given to adopting the federal standard for interoperability purposes.
 - The American Society for Automation in Pharmacy (ASAP) and the IJIS Institute have developed standards to foster seamless data sharing between states or between a state and a national information sharing system. Standards must balance the need for uniformity and interoperability with the flexibility that states require in developing their own systems.
 - Databases for interstate sharing system could be designed so that all purchases of pseudoephedrine are collected in a central repository. Suspicious or illegal transactions would then be screened by the database and placed into a second, shared database. Consequently, the latter database establishes a criminal predicate making the data accessible to law enforcement agencies. Additionally, law enforcement would have access to search the former database if an individual is part of an active investigation.
 - Interoperability should provide for an information sharing system that would capture data on individuals who exceed federal limits of pseudoephedrine in the aggregate, but do not exceed the legal limit in any one particular state.

- Access to Data
 - The states should consider privacy concerns and develop a system that is secure and ensures privacy as required.
 - If possible under state law, data should be accessible to both regulatory agencies, such as a state board of pharmacy, as well as federal, state and local law enforcement agencies.
 - Requestors of program information should demonstrate that they have
 - a specific need for the information, and
 - the training necessary to responsibly and properly use the information they receive from the program.
 - Those states that share data should store, handle and purge the information in compliance with federal and state laws regulating the use and storage of intelligence files.
 - Data Analysis Systems should be able to act as a proactive investigative tool and identify pertinent leads and information on buying patterns, including:
 - Grams per address
 - Multiple purchases
 - Individuals that purchase pseudoephedrine together
 - Suspicious activity reports
 - Identify retailers who may need additional training.
- A national information sharing system would need to be developed to accommodate three different sharing situations:
 - states with their own system that want to share data nationally
 - states without their own system that want to access data nationally
 - states that want to share information on a regional basis

II. Prescription Requirement for Pseudoephedrine

An alternative approach, which might be much more cost effective, would be to follow the Oregon approach of requiring a prescription for each purchase of pseudoephedrine. The state of Oregon has demonstrated impressive effectiveness in reducing clandestine laboratories with this approach.

The development of products utilizing phenylephrine has substantially replaced the legitimate needs for over-the-counter pseudoephedrine products. The pharmaceutical industry notes that consumer requests for pseudoephedrine products are decreasing as alternatives become available. Therefore, requiring a prescription for pseudoephedrine products would minimally affect legitimate consumers. Pseudoephedrine would still be available as a prescription drug, if needed.

It should be noted that there are also corresponding international initiatives. Mexico required a prescription for pseudoephedrine in 2007, banned the importation of pseudoephedrine in 2008, and is slated to ban the sale of pseudoephedrine in 2009. In April 2008 Great Britain also required a prescription for pseudoephedrine.

Concerns have been raised that a prescription requirement could place additional burdens on doctors, pharmacists, insurance companies or consumers. However, representatives from Oregon have reported those concerns have not been realized and that pharmacists find this approach less burdensome than keeping the otherwise required logs.

Due to the use of prescriptions, this alternative, particularly if coupled with a strong state prescription verification system, offers an effective and economical approach to reducing the clandestine manufacture of methamphetamine. This approach could result in substantial initial and ongoing savings to taxpayers, literally in the millions of dollars.