National Association of State Controlled Substances Authorities

Impact of State Laws Regulating Pseudoephedrine on Methamphetamine Production and Abuse

A White Paper of the National Association of State Controlled Substance Authorities

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I. Introduction

Precursor laws have been implemented at both state and federal levels with the aim of stopping the diversion of drugs, including pseudoephedrine (PSE), ephedrine and phenylpropanolamine (PPA), to the illicit production of methamphetamine. Most recently, state laws have focused on regulating the sale and distribution of PSE at the retail level, with significant interest by states to follow the lead of Oregon and Mississippi and reclassify PSE as a legend drug, available by prescription only. Since 2010, over 100 bills have been filed in 27 states with prescription only provisions yet Oregon and Mississippi remain the only two states with prescription-only mandates.[1] As states continue to consider policy solutions to mitigate the hazards associated with methamphetamine production and abuse, an assessment of the impact of current policy solutions is needed.

II. Scope of Work

The National Association of State Controlled Substance Authorities (NASCSA) engaged researchers at the University of Kentucky Institute for Pharmaceutical Outcomes and Policy to update the 2012 white paper summarizing the impact of state and federal precursor laws on methamphetamine trafficking and abuse. The white paper will inform public officials and legislators regarding the laws that may have the greatest impact on preventing PSE diversion for methamphetamine production and abuse. The paper will serve as a guide for future policy decisions relative to PSE regulation. To complete the white paper, the following components were outlined in the scope of work:

1) Conduct a review of current state and federal laws regulating PSE
2) Conduct a review of current findings from the literature relative to PSE laws and their impact on methamphetamine production and abuse
3) Prepare a summary of successes and failures relative to state PSE laws
4) Identify areas for further study on reducing methamphetamine abuse and PSE diversion for methamphetamine production through federal and state laws

III. Review of Federal Laws in the US, Canada and Mexico Regulating Precursors

Since 1988, the U.S. has taken action to regulate precursor chemicals to prevent PSE from being diverted to the illicit production of methamphetamine. The most current law,

[1]Alex Brill. Understanding the True Causes of the US Methamphetamine Problem. Available at http://static1.1.sqspcdn.com/static/f/460582/26648291/1446580663720/MGA_Pseudoephedrine_Study_November_2015.pdf?token=ce8YmNmOkkKkSnujHEIZ4IXLvuE%3D. Accessed March 28, 2016.

the Combat Methamphetamine Enhancement Act of 2010, became effective in April 2011.[2] The earlier precursor control laws are discussed in-depth in the prior study by the University of Kentucky, College of Pharmacy.[3] Since the previous white paper, no additional U.S. federal laws have been enacted. Current federal law limits PSE purchased in a pharmacy to 3.6 grams per day and 9.0 grams in 30 days. Pharmacies are required to keep a log of who purchases these precursors.

The U.S., Canada and Mexico are closely linked in the production and distribution of methamphetamine. It is important to understand the controls that the other North American countries have put on precursor chemicals to curb methamphetamine production in the U.S.[4] Both Canada and Mexico have implemented federal laws to control the flow of PSEs within and across their borders. As in the U.S., the goals of these laws are not only meant to control the PSE diverted for domestic production of methamphetamine, but also to reduce methamphetamine production in North America. Additionally, there has been international pressure to limit access to precursors as a means to control the world-wide illicit production of methamphetamine.[5] In 2009, the United Nations Commission on Narcotic Drugs set as a drug policy goal to "eliminate or reduce significantly and measurably ... the production and trafficking of synthetic drugs (such as methamphetamine) and the diversion and trafficking of precursor chemicals used in the manufacture of illegal drugs."[6]

Between 2003 and 2005, Canada enacted three federal laws controlling the flow of PSE and other precursor chemicals inside the country and across its borders. In January 2003, the first law regulated that distributors that import, export, manufacture, provide or sell PSE be licensed.[7] In July 2003, the second law further regulated these entities by requiring end-use declarations to be signed between the licensed entities and non-

[2] For a full discussion of this law please refer to the DEA website http://www.deadiversion.usdoj.gov/fed_regs/rules/2011/fr0413_2.htm; accessed March 28, 2016.

[3] The first paper in this series may be found at http://www.nascsa.org/PDF/NASCSApseudoephedrineWhitePaper4.12.pdf; accessed March 28, 2016.

[4] Maxwell, Jane Carlisle, and Beth A Rutkowski. 2008. "The prevalence of methamphetamine and amphetamine abuse in North America: a review of the indicators, 1992-2007." *Drug and Alcohol Review* 27: 229-235.

[5] Callaghan, Russell C., James K. Cunningham, J. Charles Victor, and Lon-Mu Liu. 2009. "Impact of Canadian federal methamphetamine precursor and essential chemical regulations on methamphetamine-related acute-care hospital admissions." *Drug and Alcohol Dependence* 105: 185-193.

[6] U.S. Congressional Research Service. 2013. "International Drug Control Policy: Background and U.S. Responses." RL34543, Washington, DC. Available from www.crs.gov.

[7] Ibid, Callaghan, et al. 2009.

licensed persons.[8] Finally in 2004, distributors were required to register with the federal government to operate in Canada. In addition to the PSE dealers, companies dealing in acetone, hydrochloric acid and toluene, chemicals all used in methamphetamine production, were also required to register. The Canadian laws mirrored the U.S. federal laws passed starting in 1988 that focused on distributors of precursor chemicals.

In 2006, Canada classified single entity PSE and ephedrine in Canada as Schedule II drugs and in combinations as Schedule III drugs under the Canadian classification system.[9] Thus, single entity PSE and ephedrine products may be sold by a pharmacist on a nonprescription basis and must be retained in the Professional Service Area (I.e. behind the counter) of the pharmacy where there is no public access and no opportunity for patient self-selection, while the schedule III PSE combination products may be sold to any person from the self-selection Professional Products Area of a licensed pharmacy. The provinces may add additional restrictions to the sale of these drugs.

The Consumer Health Products of Canada implemented a Meth Watch program in 2004 similar to the Meth Watch that was originally established by CHPA in the U.S. This voluntary program works with retailers, pharmacies, national and local law enforcement, community organizations and industry to help fight against domestic methamphetamine labs.[10] The program is designed to educate people involved to recognize situations where PSE could be diverted for methamphetamine production. If suspicion arises, this is reported to the Royal Canadian Mounted Police's centralized chemical diversion hotline.

In 2005, Mexico enacted the first of its controls on precursor chemicals after a 2004 study determined that the country imported more pseudoephedrine than needed for legitimate use.[11] Mexico moved rapidly to control PSE. The first federal law monitored and limited imports of PSE. In 2006, Mexico began to limit PSE sales in pharmacies, require pharmacists to report the loss of PSE by theft or diversion and to maintain logs

[8] Regulatory Requirements under the Controlled Drugs and Substances Act, Health Canada, 2013. Available from http://www.hc-sc.gc.ca/hc-ps/substancontrol/chem-chim/domestic-eng.php; accessed March 28, 2106.

[9] Drug Schedules Regulation. Pharmacy Operations and Drug Scheduling Act of British Columbia. Available from http://library.bcpharmacists.org/D-Legislation_Standards/D-4_Drug_Distribution/5012-Drug_Schedules_Regulation.pdf; accessed March 28, 2106.

[10] Consumer Health Products Canada. Available from http://www.chpcanada.ca/en/consumer-health-products-canada-wins-associations-make-better-canada-award; accessed March 27, 2016.

[11] Cunningham, James K, JC Maxwell, O Campollo, Lon Mu Liu, WJ Lattyak, and RC Callaghan. 2013. "Mexico's precursor chemical controls: emergence of less potent types of methamphetamine in the United States." *Drug and Alcohol Dependence* 129 (1-2): 125-36.

of sales by distributors. The following year, Mexico introduced a prescription-only law to acquire PSE in a pharmacy. Finally, in 2008 Mexico banned all sales of ephedrine and PSE in the country[12]. Figure 1 summarizes the timeline for introduction of federal laws in the U.S., Canada and Mexico. Mexico has imposed the strictest ban on PSE, followed by the U.S. and then Canada. The next section discusses the changes in the state laws in response to the diversion of PSE to the illicit production of methamphetamine.

Figure 1: U.S, Canada and Mexico Federal PSE Regulations

IV. Review of State Laws Regulating Precursors

[12]Ibid, Cunningham, et al, 2013.

The majority of states have enacted laws controlling the sale of PSE- and ephedrine-containing products that are more stringent than the current federal laws. Electronic tracking and block of sales to those exceeding quantity limits is the most common approach states are using, with 32 states having taken this approach to regulate access to PSE. Additionally, some states have chosen to restrict purchase quantities to amounts that are less than currently allowed by federal regulations (CMEA restricts retail purchases to <9 grams per 30 days). Other states have chosen to reclassify PSE as a Schedule III controlled substance. More recently, some states have passed mandates to establish a registry of individuals with methamphetamine-related convictions and block the sale of PSE to these individuals. Table 1 provides a summary of state approaches.

Table 1: State Approaches to Pseudoephedrine Regulation

Regulatory Approach	States with Mandates
Electronic Tracking and Block of Sales when Quantity Limits Exceeded	AL, AR, AZ, DE, FL, HI, IA, ID, IL, IN, KS, KY, LA, ME, MI, MO, MT, NE, NV, NC, ND, OH, OK, PA, SC, SD, TN, TX, VT, VA, WA, WV
Prescription-only Status	MS, OR, AR (non-residents)
Schedule V Controlled Substance	AR, GA, IA, IL, KS, LA, MN, MO, NM, OK WI, WV
Schedule III Controlled Substance	MS, OR
Greater Restrictions on Purchase Quantities than Required by CMEA	AK, AL, IA, IL, IN, KY, MN, OK, TN, WI, WV
Registry/Block of Sales to Those with Previous Methamphetamine-related Convictions	AL, IL, KY, MI, OK, TN
Pharmacist Determination of Legitimate Medical Need for Non-Prescription Sale	AR, IN

Electronic Tracking and Block of Sales

Since 2006, pharmacies and retail outlets have been required to keep a log book documenting the sale of PSE to meet the provisions of the CMEA. While logging PSE sales at individual pharmacies and other retail outlets can be used to track and compare purchases within an individual outlet, this approach has been less than effective at controlling PSE purchases for illicit uses, as persons with the intent of purchasing PSE for methamphetamine production can travel from pharmacy to pharmacy making

multiple PSE purchases. With electronic tracking, the purchaser's driver's license or other allowed identification is scanned at the point of sale of PSE-containing products. The sale is then logged by the electronic tracking system documenting the date and amount of the PSE purchased. Future attempts to purchase PSE will be scanned and logged in the same manner at any retail purchase outlet. Sales data is stored centrally and can be shared among pharmacies and retail outlets in a state and, in some cases depending on the tracking system used, across state lines. Once purchase thresholds have been reached, the individual completing the sale is alerted and the sale can be blocked. Thus, the major advantage of electronic tracking over paper log books is the sharing of aggregate data in real time that allows those selling PSE to more accurately determine if a PSE purchase would exceed an individual's legal limit. Additionally, electronic tracking systems can be used to alert law enforcement when individuals attempt to purchase more than the legal limit of a methamphetamine precursor in a more efficient and expedient manner than reviewing multiple paper logs.

Oklahoma became the first state to require electronic tracking in 2004 using an internally developed system maintained by the Oklahoma Bureau of Narcotics. Arkansas and Kentucky soon followed suit; Arkansas has been using MethMonitor[13] to track methamphetamine precursor sales since 2006, and in 2008, Kentucky became the first state to pilot a new electronic system, MethCheck, for the tracking of PSE sales. Since 2008, the use of electronic tracking has increased substantially with 32 states having passed laws as of January 2016 requiring the electronic tracking of PSE sales (Table 1). By far, the most common approach taken by states has been to use the National Precursor Log Exchange (NPLEx) described in further detail below.

National Precursor Log Exchange

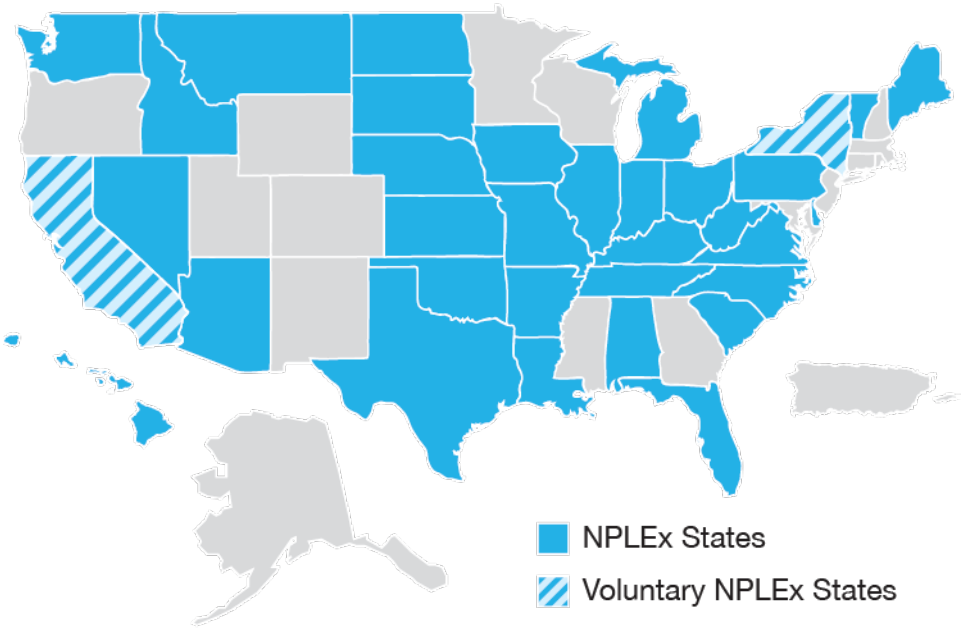
The National Precursor Log Exchange (NPLEx) is a real-time electronic logging system used by pharmacies, retail outlets and law enforcement to track sales of OTC cold and allergy medications containing methamphetamine precursors. To date, laws authorizing the use of NPLEx have been implemented in 32 states (Figure 2). Arkansas, which originally utilized MethMonitor, has recently moved to the NPLEx platform.

The National Association of Drug Diversion Investigators (NADDI) is the provider of the service and Appriss, Inc., is the technology vendor whose product, MethCheck, won the competitive bid to provide the service. NPLEx is provided free of charge (sponsored by the manufacturers of PSE-containing OTC products) on a permanent basis to state governments that pass appropriate legislation and regulations. Services provided

[13] LeadsOnLabs MethMonitor. Available from https://www.leadsonline.com/main/services/methmonitor.php.

include implementation to all retailers, access to law enforcement, technical support, training for retailers and law enforcement, and maintenance and upgrades.[14]

Figure 2: States Tracking Pseudoephedrine Sales using National Precursor Log Exchange



Source: NPLEx Current as of March 2016

Retailers using the system voluntarily block the sale of precursors that would exceed the legal quantity limits (3.6 grams per day and 9 grams in 30 days per CMEA or more stringent requirements per relevant state laws). When a transaction is submitted by a retailer that would exceed the limits, a message is instantly transmitted recommending denial of the sale. A manual override can be used if the clerk feels in danger, and law enforcement is notified that the sale may have exceeded the limits. According to NPLEx, currently over 38,000 retailers and 6,591 law enforcement agents use the electronic system to log and track sales.

Prescription-only Status/ Schedule III Controlled Substance

Two states – Oregon and Mississippi – have adopted the strictest PSE laws to date, making PSE a Schedule III controlled substance available by prescription only and subject to the states' prescription drug monitoring program (PDMP). In 2011, legislation was passed in Arkansas limiting the OTC sales of PSE to Arkansas residents and

[14] National Precursor Log Exchange, available at http://www.nplexservice.com/.

imposing new duties on pharmacists. Specifically, the new law makes it illegal to dispense any product containing PSE (or ephedrine or PPA) without a prescription, unless the purchaser can provide an Arkansas-issued Driver's License or ID card, or an identity card issued by the U.S. Department of Defense for active-duty military personnel. Additionally, the law requires pharmacists to verify the legitimate medical need of individuals purchasing products containing PSE, based on a pharmacist-patient relationship, before allowing the purchase of a PSE (or ephedrine or PPA) containing product. Prior prescription history and/or information obtained during patient screening can be used to provide professional reassurance to the pharmacist that a legitimate medical need exists.

Schedule V Controlled Substance

Twelve states have reclassified PSE as a Schedule V controlled substance - Arkansas, Illinois, Iowa, Kansas, Louisiana, Minnesota, Missouri, New Mexico, Oklahoma, West Virginia and Wisconsin. As Schedule V, products are available OTC with specific requirements for purchasing, including maintaining a log of all transactions and presentation of identification showing proof of age (18 years or older). Additionally, the classification of PSE and other precursors as Schedule V substances restricts their purchases to pharmacies. States with PDMPs that monitor Schedule V substances may require data on Schedule V PSE sales to be transmitted to the PDMP. Such is the case with Oklahoma, which has classified all PSE-containing medications as Schedule V prescriptions and requires that they be submitted to the Oklahoma PDMP database.

Additional Purchase Quantity Restrictions

Since the passage of the CMEA in 2005, retail purchases of PSE have been limited to 9 grams per 30 days. A total of ten states have implemented more stringent laws restricting the retail purchase of PSE to less than the federal limit, including limits of 7.5 grams per 30 days in Alabama, Illinois, Iowa and Wisconsin or as in the case of Indiana, Kentucky, Oklahoma and West Virginia limits of 7.2 grams per 30 days and in Alaska and Minnesota a limit of 6 grams per 30 days. The most stringent restriction on monthly PSE purchases is in Tennessee, which as of 2014, limits PSE purchases to 5.8 grams per month. The maximum daily dose of PSE is 240 mg, thus if a person requiring PSE takes the maximum dose every day for 30 days, a quantity of 7.2 grams would be needed for the 30-day supply. Restricting quantities to a maximum of 7.2 grams per 30 days should have no impact on persons purchasing PSE for legitimate self-care uses. Additional states are considering legislation to restrict purchase quantities to this limit.

Finally, some states have imposed yearly limits in addition to the 30-day limits. For example, Kentucky has limited the non-prescription (OTC) sale of PSE to 24 grams per year, West Virginia limits OTC sales to 48 grams annually, Tennessee limits OTC sales

to 28.8 grams annually, Oklahoma limits OTC sales to 60 grams annually and finally, Indiana limits non-prescription sales to 61.2 grams per year.

Methamphetamine Registry/Block of Sales

Oklahoma passed legislation, effective November 2010, requiring all individuals convicted of possession, manufacture, distribution or trafficking of methamphetamine to register with the state and Kentucky followed suit in July 2011. Subsequently, Alabama, Illinois, Michigan and Tennessee have also passed registry laws.[15] Pharmacies and other retail outlets who register with the state to sell or dispense PSE-related products and law enforcement agencies can access the registry through a central repository and the state's PMP. Customers listed in the registry due to a previous methamphetamine-related conviction will be blocked at the point of sale from buying PSE and are prohibited from possessing "any detectable quantity" of the drug. When a pharmacy sells PSE OTC, the purchaser's name is checked against the Meth Registry and the sale will be blocked if the individual has a prior methamphetamine-related conviction, without regards to quantity limits.

Pharmacist Determination of Legitimate Medical Need

In 2011, Arkansas became the first state to mandate new duties of pharmacists when selling PSE without a prescription. Specifically, the law requires pharmacists to make a "professional determination, based on a pharmacist-patient relationship, as to whether or not there is a legitimate medical and pharmaceutical need for the drug" before making any OTC dispensation of any non-exempt product containing EPH, PSE, or PPA. Indiana followed suit during the 2016 legislative session with the passage of SB 80, which requires pharmacists to determine that a purchaser of EPH or PSE has a relationship on record with the pharmacy. If no record of relationship exists, the pharmacist is required to "make a professional determination as to whether there is a legitimate medical or pharmaceutical need before selling EPH or PSE to an individual."[16]

Reporting of Sales to Prescription Drug Monitoring Program

[15] Chapman R., Et. Al. Managing Access to Pseudoephedrine: Potential Impacts of a Prescription-Only Policy versus Real-time Stop Sale Technology. Avalere Health, April 2014. Available at http://avalere.com/expertise/life-sciences/insights/managing-access-to-pseudoephedrine-potential-impacts-of-a-prescription-only.

[16] Senate Enrolled Act No. 80; 119th General Assembly of Indiana, 2016 Available at http://iga.in.gov/legislative/2016/bills/senate/80#document-86691c1b. Accessed March 29, 2106.

In addition to Oregon and Mississippi, which require PSE sales to be reported to the state prescription drug monitoring program (PDMP) as a result of their classification as Schedule III controlled substances, states that have classified PSE as a Schedule V that also have laws that mandate reporting of Schedule V substances to the PDMP would also require reporting. These states include Arkansas, Georgia, Illinois, Louisiana, New Mexico, Oklahoma and Wisconsin. Additionally, Kansas has added PSE to the "drugs of concern" list and requires PSE prescriptions to be reported to the Kansas PDMP.

Tamper (Conversion) Resistant Products

Two new PSE-containing products - Zephrex-D®[17] and Nexafed®[18] - designed to limit the ability to extract PSE for use in the illicit production of methamphetamine, are available in the US. Currently available evidence suggests that Nexafed® yields 44% less methamphetamine compared to pseudoephedrine tablets when standard extraction methods are employed.[19] The makers of Zephrex-D® claim that virtually no PSE can be extracted from its patented Tarex® formulation. Despite the fact that these two PSE products are tamper (conversion) resistant and, as such, the DEA was petitioned to exclude them from the CMEA requirements, they remain subject to the same quantity restrictions and placement behind the counter as other PSE containing products and remain subject to the prescription-only mandate in Mississippi and Oregon.

Although no peer-reviewed literature is available on the impact of Nexafed® and Zephrex-D® on methamphetamine production in clandestine laboratories, several local jurisdictions have reported positive impact as a result of local pharmacies replacing traditional single-ingredient PSE products with tamper-resistant formulations.[20] For example, after pharmacy chains in West Virginia, including CVS Health, Rite Aid, Walgreens and Fruth Pharmacy, discontinued stocking single-ingredient PSE products, a 40% reduction in meth lab incidents was noted[21]. Similar results were noted by law enforcement in two Tennessee counties where pharmacies stocked only the tamper-

[17] Product information available at http://zephrex-d.com.

[18] Product information available at https://www.nexafed.com.

[19] Brzeczko AW, Leech R, Stark JG. The advent of a new pseudoephedrine product to combat methamphetamine abuse. *Am J Drug Alcohol Abuse*. 2013;39(5):284-290.

[20] Reduction in Meth Lab Seizures Following Adoption of Meth-Resistant Nexafed. http://www.pharmacytimes.com/publications/issue/2015/january2015/r681_january2015

[21] Eyre E. Meth lab busts drop in W.Va. West Virginia Herald Dispatch website. www.wvgazette.com/article/20141202/GZ01/141209787/1419. Published December 2, 2014.

resistant products of PSE.[22] It is difficult to tease out the direct impact of these policy changes, however, given that West Virginia and Tennessee both implemented annual quantity restrictions during this same time frame.

V. Impact of State Laws Regulating Precursors

To assist state and federal policy makers with identifying policy solutions that have the greatest impact on methamphetamine production, diversion and abuse indices, a review of the literature from 2012 to 2016 was conducted. For studies conducted prior to 2012, the reader is referred to the original white paper.[23] Additionally, data on indicators of methamphetamine production (lab incidents and sales/blocks of PSE products) and methamphetamine use (treatment admissions) were collected and trends analyzed. We have limited our discussion to the global impact of supply side interventions and the specific impact of four state approaches 1) prescription only (CIII) mandate; 2) electronic tracking and block of sales when quantity limits exceeded; 3) quantity restrictions greater than that required by the CMEA, and 4) pharmacist determination of legitimate medical need. The original white paper showed that the Schedule V mandate had no sustained impact on indicators of methamphetamine production or use.

Overall Impact of Supply-Side Interventions

A comprehensive report on state approaches to control access to methamphetamine precursors and their impact on domestic meth labs was prepared by the United States Government Accountability Office (GAO).[24] According to the GAO report, nationwide meth lab incidents decreased as a result of state laws restricting sales of precursors and the federal Control Methamphetamine Epidemic Act (CMEA) passed in 2005, and reached a low in 2007. Lab incidents then rose to more than 15,000 in 2010, almost double that of the low noted in 2007. Since 2010, additional states have implemented electronic tracking and several states have further restricted purchase quantities of PSE as previously discussed. Therefore, it is interesting to view the trend in meth lab incidents reported since 2010. Accordingly, Figure 3 presents data on the number of meth lab incidents nationwide from 2002 to 2014.

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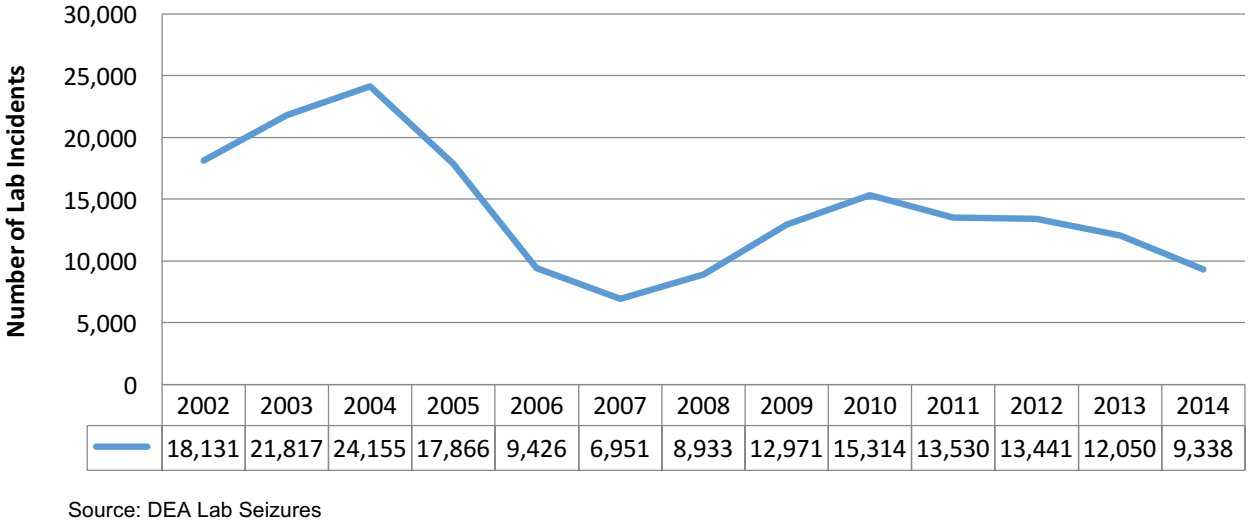
[22] Tennessee Meth & Pharmaceutical Task Force. 2014 seizures report through March 2014.

[23] The first paper in this series may be found at http://www.nascsa.org/PDF/NASCSApseudoephedrineWhitePaper4.12.pdf.

[24] State approaches taken to control access to key methamphetamine ingredient show varied impact on domestic drug labs. United States Government Accountability Office, GAO 13-204. Available from http://www.gao.gov/products/GAO-13-204.

Since 2010, the number of meth lab incidents nationwide decreased each year from 15,314 to 9,338 in 2014, a figure close to that observed in 2006 following passage of the CMEA. These data suggest that, nationwide, these additional state efforts to control access to meth precursors is having an impact on clandestine lab incidents. It should be noted that from February 2011 to September 2011, no DEA funds were available for cleanup of lab incidents. Thus, the GAO report suggests that lab incidents in 2011 are likely underreported. Further discussion of the impact of individual state approaches on clandestine methamphetamine lab incidents is provided in the next section.

Figure 3: Methamphetamine Lab Incidents Nationwide, 2002-2014

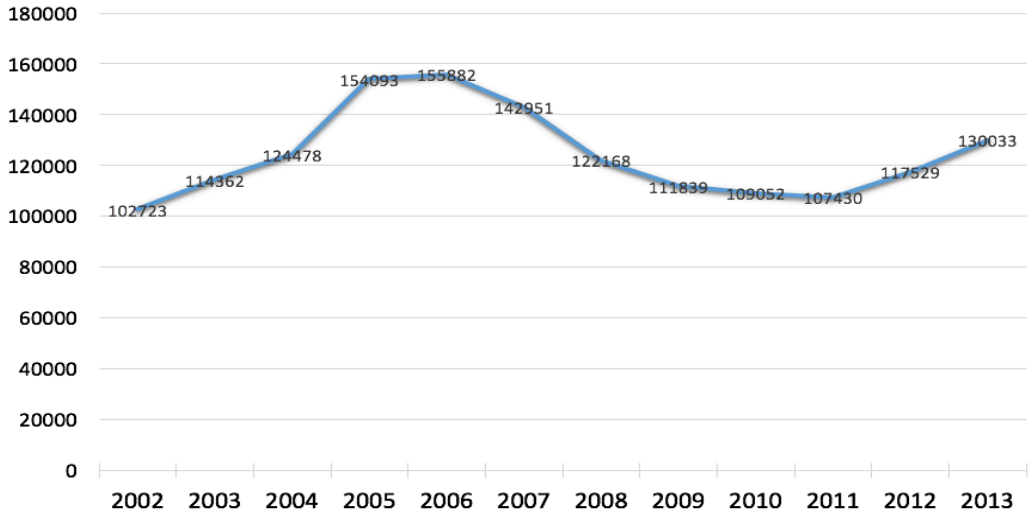


	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
	18,131	21,817	24,155	17,866	9,426	6,951	8,933	12,971	15,314	13,530	13,441	12,050	9,338

Source: DEA Lab Seizures

Figure 4 presents the number of methamphetamine-related admissions to substance abuse treatment facilities between 2002 and 2013, the last year for which data on treatment admissions are publically available. Nationwide, methamphetamine-related admissions to substance abuse treatment facilities peaked between 2005 and 2006 during the period immediately following implementation of the CMEA and then declined significantly each year from 2006 to 2011. Since 2011, treatment admissions where primary substance is coded as methamphetamine have been trending upward.

Figure 4: Methamphetamine-Related Treatment Admissions, 12 Years and Older, Nationwide, 2002-2013



SOURCE: Center for Behavioral Health Statistics and Quality,
Substance Abuse and Mental Health Services Administration, Treatment Episode Data Set (TEDS).

A comprehensive study designed to evaluate the effectiveness of supply side regulations targeting methamphetamine precursors was conducted last year by Dobkin and colleagues.[25] The investigators constructed monthly measures for each state using administrative records, including data on number of methamphetamine labs, the price and purity of methamphetamine, positive drug tests for amphetamine among workers and hospital inpatients, and drug-related arrests from 2000 - 2008 and staggered implementation of state laws targeting over-the-counter medicines during this time period. Key findings from this study were that supply-side interventions successfully reduced the number of meth labs operating in a state by 36%. The authors found no evidence of changes in methamphetamine consumption or arrest for drug possession, suggesting external sources of supply over national borders.

Most recently, Cunningham and Finlay demonstrated that targeted interventions aimed at controlling access to methamphetamine precursors resulted in temporary increases in retail street prices for methamphetamine, which returned to baseline levels within 6 – 12 months.[26] The authors conclude that these findings, coupled with the observation that methamphetamine consumption is only weakly responsive to higher street drug prices, demonstrate that precursor control is associated with short-term effects on

[25]Dobkin, Nicosia and Weinberg. Are supply-side drug control efforts effective? Evaluating OTC regulations targeting methamphetamine precursors. Journal of Public Economics 120 (2014) 48-61.

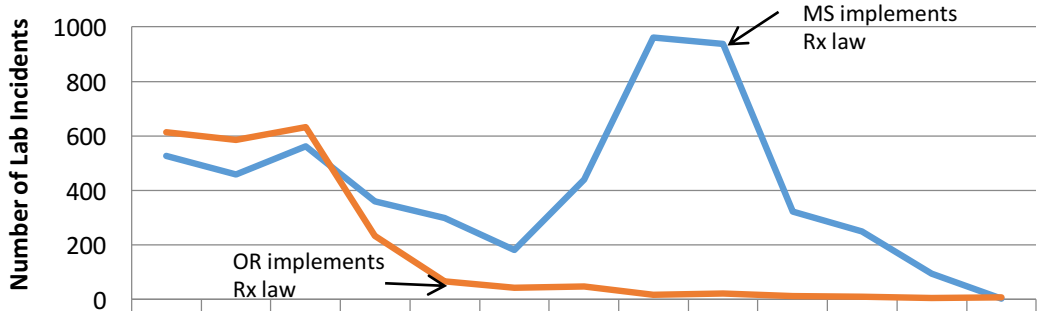
[26] Cunningham and Finlay. Identifying demand responses to illegal drug supply interdictions. Health Economics (2015) DOI: 10.1002/hec.3213.

consumer demand for methamphetamine. Further, the authors suggest that "alternative policies which block illegal manufacture of PSE to meth without imposing unnecessary burden on legitimate consumers of PSE would be preferable."[27]

Impact of Prescription-Only Laws

Oregon's law making PSE-containing products CIII scheduled drugs available by prescription only went into effect in July 2006 and Mississippi's law was effective July 2010. The trends in lab incidents in Oregon and Mississippi are depicted in Figure 5.

Figure 5: Meth Lab Incidents in States with Prescription Laws, 2002-2014



	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Mississippi	527	459	561	359	299	182	440	960	937	321	248	94	2
Oregon	614	584	632	232	67	43	48	17	21	11	10	5	7

Source: DEA Lab Seizures

Oregon's meth labs decreased significantly in the years leading up to implementation of the Rx only law and were already at a very low number (64) in 2006 when the law took effect. In contrast, Mississippi had significantly greater numbers of lab seizures reported in 2010 when the law was implemented and labs in Mississippi have continued to decline by significant numbers each year to a low of 2 in 2014.

One study in the peer-evaluated literature examined the impact of these laws on methamphetamine clandestine laboratory seizures. Cunningham and colleagues used a time-series analysis to more rigorously evaluate the regulations' impact on clandestine lab seizures over the simple pre-post comparisons that had been previously described.[28] The authors found no significant impact for Oregon's regulation, as seizures there and in nearby western states had largely bottomed out months before the regulation was implemented. In contrast, the authors report that Mississippi

[27] Ibid.
[28] Cunningham et al. Changing over-the-counter ephedrine and pseudoephedrine products to prescription only: impacts on methamphetamine clandestine laboratory seizures. Drug and Alcohol Dependence 126 (2012) 55-64.

experienced a 50.2% drop in seizures while nearby states exhibited no comparable decline. The authors conclude that Oregon's regulation encountered a floor effect, making any sizable impact infeasible, while Mississippi realized a substantial impact. The authors go on to suggest that clandestine laboratories, if sufficiently extant, can be meaningfully impacted by prescription precursor regulation.

In a subsequent study, Cunningham et al. recently provided evidence of the impact of Mississippi's prescription-only law on methamphetamine production in small labs.[29] Using data comparing Mississippi to a synthetic control, the researchers documented the law removed 2,637 small methamphetamine labs in the two years after it became effective, representing a 77% reduction in small labs relative to the synthetic control. The authors further evaluated Mississippi's prescription requirement on meth prices using STRIDE data. Prescription-requirements restrict access to precursor inputs used in the production of methamphetamine and therefore may have some impact on the quantity supplied in the marketplace. Given that demand for meth changes very little with price, the author's state that their failure to find evidence for higher prices suggests that the disruptive effects of prescription-only legislation on meth availability is quite small. This may likely be due to international imports being readily available to displace domestic producers. The authors concluded that while prescription-only laws can reduce the number of domestic small methamphetamine labs in operation, methamphetamine availability is unlikely to be materially impacted.

Most recently, an in-depth review of the current methamphetamine landscape in Oregon and Mississippi was completed by Carnevale Associates, LLC, for the National Alliance for Model State Drug Laws (NAMSDL).[30] The purpose of the report was to provide information to NAMSDL to inform the potential development of model legislation expanding PSE prescription laws to the national level. The researchers investigated trends in meth abuse indicators (supply, illicit substance use, treatment admissions, drug-related arrests and other criminal activity and drug-related mortality) pre-post implementation of PSE prescription laws in Oregon and Mississippi. The authors conclude that the relationship between PSE laws and declines in meth lab incidents are spurious and list a variety of reasons, most focused on the fact that meth supply, use and abuse indicators remain increased while lab incidents are decreased, and

[29] Cunningham, Finlay and Stoecker. Is Mississippi's prescription-only precursor control law a prescription to decrease the production and raise the price of methamphetamine? Int J Drug Policy. (2015) Nov;26(11):1144-9.

[30] Carnevale Associates, LLC. Pseudoephedrine prescription laws in Oregon and Mississippi: A study of the current methamphetamine landscape. Available from http://www.namsdl.org/IssuesandEvents/OR-MS%20Meth%20Report%2006%2030%2015%20Final%20with%20Disclaimer.pdf

recommend that NAMSDL delay developing model PSE prescription legislation until the uncertainties uncovered in their review can be addressed.

The economic impact of requiring prescriptions for PSE products was analyzed by Alex Brill of Matrix Global Advisors.[31] In this report, Brill estimates the unintended consequences of a prescription-only PSE policy to include: $59 million in additional costs to the government, consumers and private insurances companies due to extra doctor visits, increased absenteeism and lost work productivity, higher prices for PSE medicines, increased health insurance premiums due to additional doctor visits and higher PSE drug costs, and an estimated loss of over $200 million in state tax revenues over ten years. While these sweeping estimates are in his analysis, little evidence is provided for how the figures are calculated and, considering the development of the paper was financially supported by the Consumer Health Products Association (CHPA) which funds NPLEx, these estimates should be scrutinized carefully before contemplating any policy action based upon them. Additionally, it is important to note that CHPA represents manufacturers of non-prescription pharmaceuticals, including PSE, and therefore also have a financial bias toward continued OTC availability of PSE.

Finally, Avalere Health, LLC prepared a comprehensive report assessing the impacts of a prescription-only policy versus the real-time stop sale technology solution offered by NPLEx.[32] The authors undertook a two-pronged research approach that involved conducting an extensive literature review of publicly available, peer-reviewed journal articles and constructing an economic impact model using aggregating inputs and assumptions from the literature review and both publicly and privately held data sources.

Similar to the report by Brill, the report focuses on the impact of prescription only mandates on consumers, employers, health plans, providers, and state governments. While the authors acknowledge that a prescription-only requirement would likely reduce PSE purchase for illicit use and curb methamphetamine production and related costs, their model indicated that a prescription-only policy would result in new physician visits, and significant increases in out-of-pocket patient costs as well as public and private payer costs. Additionally, their model suggests that state revenues would decrease due

[31] Alex Brill. An Analysis of the Economic Impact of Requiring Prescriptions for Pseudoephedrine Products. March 4, 2013. Available from http://static1.1.sqspcdn.com/static/f/460582/22085918/1362406459030/PSE.pdf?token=nxWTPF%2BYizo5oOu1tthD%2FcXvIb0%3D.

[32] Chapman R., Et. Al. Managing Access to Pseudoephedrine: Potential Impacts of a Prescription-Only Policy versus Real-time Stop Sale Technology. Avalere Health, April 2014. Available at http://avalere.com/expertise/life-sciences/insights/managing-access-to-pseudoephedrine-potential-impacts-of-a-prescription-only.

to loss of state taxes on sale of non-prescription PSE. The authors conclude that the unintended burdens on these stakeholders from prescription only policies could be avoided by utilizing real-time stop sale technology (NPLEx) to minimize illicit PSE purchases. It should be noted that the Avalere Health report was also funded by CHPA and therefore should be interpreted considering the potential for bias toward stop-sale technology.

As states grapple with the methamphetamine production, diversion and abuse problem, many have considered legislation that would reclassify PSE as a legend drug, available by prescription only. As stated previously, over 100 bills have been filed in 27 states since 2010 that would require prescriptions for PSE and EPH products. These legislative efforts have been heavily opposed by the pharmaceutical industry. Specific efforts to defeat such legislation have been undertaken by CHPA, who hired FP1 Strategies "to help push back on PSE prescription legislation."[33] Working with CHPA, FPI "developed a dynamic and consumer-driven grass roots campaign in key states across the country…and as a result of this comprehensive approach, FP1 reports that not a single state has passed a prescription-requirement bill, while dozens of unfavorable bills were defeated and many favorable ones passed."[34] CHPA's lobbying efforts against PSE prescription legislation continue through its "Stop Meth, Not Meds" campaign.[35] According to data compiled at Open Secrets.org, CHPA reported an average of $1,368,592 annually in lobbying expenses between 2010 and 2015.[36]

While it is clear from these effort that the pharmaceutical industry is opposed to prescription only PSE legislation, little information is available on the opinions of other stakeholders such as pharmacists, physicians and other health care providers. Monson and colleagues at the University of Kentucky used survey methodology to collect Kentucky pharmacists' opinions of the potential reclassification of pseudoephedrine as a legend drug.[37] The main outcomes measures of the study were (1) perceived efficacy of

[33] FP1 Strategies Case Studies. Consumer Health Products Association. Available at http://fp1strategies.com/case_study/consumer-healthcare-products-association-chpa/. Accessed March 29, 2016.

[34] Ibid.

[35] Stop Meth, Not Meds. Available at http://stopmethnotmeds.com. Accessed March 28, 2016.

[36] Open Secrets.org, Center for Responsible Politics. Available at https://www.opensecrets.org/lobby/clientsum.php?id=D000025123&year=2010. Accessed March 28, 2016.

[37] Monson, KE, Freeman PR, Goodin AJ, Talbert J, Blumenschein K. Kentucky Pharmacists' Opinions of the Potential Reclassification of Pseudoephedrine as a Legend Drug. J Am Pharm Assoc. (2014) 54(4):397-405.

current methamphetamine precursor controls, (2) anticipated impact on individual pharmacy practices and patients of proposed legislation to make PSE available by prescription only, and (3) current opinions about the proposed legislation in Kentucky. The authors' analysis of 431 community pharmacists showed that approximately 77% believed proposed legislation to make PSE available by prescription only would be effective in reducing methamphetamine abuse and methamphetamine-related laboratory incidents, with 56.2% indicating support for the proposed legislation. Pharmacists practicing in chain pharmacies were 2.9 times more likely to support the legislation than pharmacists practicing in independent pharmacies. Additional factors influencing pharmacist support included Kentucky region of practice, anticipated impact on time spent on PSE-related activities, pharmacy profit, methamphetamine abuse, and methamphetamine-related laboratory incidents. Pharmacists practicing in regions of Kentucky associated with higher methamphetamine abuse more strongly supported the proposed legislation.

Results from a companion survey of Kentucky physicians were mixed.[38] Analysis of 243 Kentucky physicians showed divided support for legislation to reclassify PSE as a legend drug with 41% in support, 40% in opposition and 19% unsure. The majority of physician respondents anticipated that the proposed legislation would be effective at reducing methamphetamine abuse (58.9%) and lab-related incidents (60.2%). Physicians who reported confidence in their ability to identify legitimate PSE use were 4.77 times more likely to express support for the proposed legislation and those who reported low estimated requests for chronic PSE were 4.61 times more likely to express support. Additionally, physicians in urban counties were 76% less likely to express support for the proposed legislation.

The authors conclude that "gaining a better understanding of issues surrounding the distribution of PSE will enhance the likelihood that future legislation may be crafted to reduce methamphetamine production, laboratory incidents, and abuse while minimizing inconvenience and cost."[39]

Impact of Electronic Tracking and Block of Sales When Quantity Limits Exceeded

The number of states mandating use of NPLEx to electronically track the sale of pseudoephedrine increased from 18 in 2012 to 30 in 2014. As of 2016, all 32 states currently mandating electronic tracking utilize NPLEx as the technology platform. Table 2 presents the number of PSE purchases, grams sold, number of blocks and grams PSE blocked for the states using NPLEx between 2012 and 2015. As additional states

[38] Freeman, PR. Unpublished survey results.

[39] Ibid, Monson et al., 2014.

implement NPLEx, the grams of PSE sold and blocked continue to increase. Each year, between 3.4-4% of all attempted PSE purchases are blocked. As noted in table 2 below, in 2015 blocked sales increased to 5% of all attempted purchases. This is likely due to the implementation of new, more restrictive quantity limits in a few states.

Because the majority of states use this approach to control access to meth precursors, there is much interest in understanding the impact that electronic tracking has on methamphetamine production and abuse. A review of the peer-reviewed literature indicates a dearth of studies devoted to understanding the impact of these regulations.

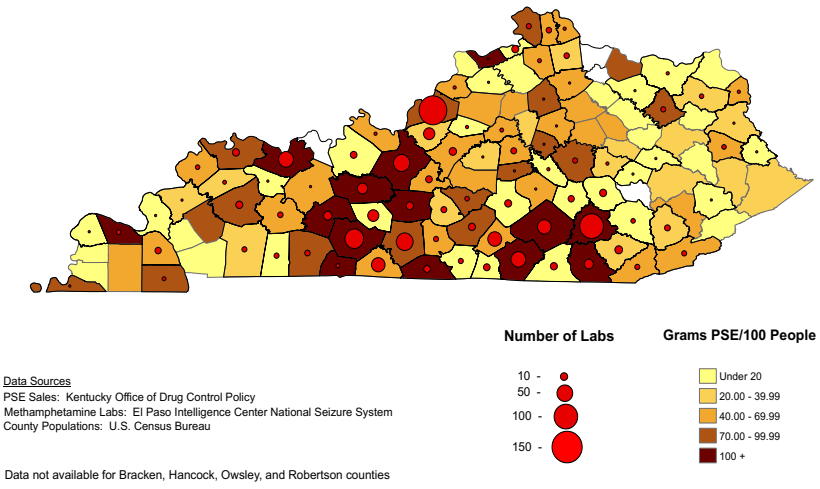
Table 2: Grams PSE Purchased and Blocked, NPLEx, 2012-2015

	2012		2013		2014		2015	
State	Grams Sold	Grams Blocked	Grams Sold	Grams Blocked	Grams Sold	Grams Blocked	Grams Sold	Grams Blocked
AL	3,400,620	227,604	3,051,290	257,816	2,672,307	196,816	2,453,178	189,690
AZ			2,905,404	57,443	2,762,860	63,446	2,728,524	108,963
DE					479,391	17,254	474,349	24,158
FL	8,368,365	329,447	8,488,100	323,555	8,293,189	349,374	7,992,034	440,952
HI			380,839	12,782	376,981	12,363	381,522	13,652
IA	1,862,961	72,717	1,747,564	64,057	1,611,243	61,311	1,547,296	71,860
ID			592,567	11,374	571,700	11,914	579,446	20,143
IL	6,064,947	148,895	5,907,371	133,301	5,577,897	159,365	5,434,562	253,539
IN	4,237,492	224,055	3,898,010	131,956	3,507,983	129,354	3,303,216	174,087
KS	1,723,220	43,102	1,653,615	36,311	1,551,556	38,214	1,502,079	59,830
KY	2,688,484	92,253	1,992,493	159,067	1,769,198	111,162	1,563,191	132,636
LA	2,418,410	73,821	2,340,470	72,294	2,149,019	68,672	1,981,841	78,155
ME			426,841	16,654	428,026	14,850	441,696	16,463
MI	5,355,328	167,140	5,194,160	157,415	4,972,677	153,919	4,894,039	199,045
MO	3,411,999	113,476	2,994,967	96,492	2,695,238	90,807	2,511,817	117,578
NC	4,343,831	155,650	4,367,545	146,957	4,173,686	148,649	4,083,411	166,775
ND	180,262	6,420	178,975	4,990	176,697	4,481	168,127	4,338
NE	1,163,291	35,542	1,115,716	27,539	1,101,773	30,123	1,106,253	48,701
NV							1,071,841	44,488
OH					6,146,092	195,001	5,819,620	262,757
OK			2,630,753	127,260	2,359,808	113,947	2,211,953	125,192
PA							5,669,213	266,346
SC	2,695,897	133,121	2,713,680	146,200	2,525,313	135,384	2,384,276	141,815
SD							482,143	18,867
TN	3,770,731	128,145	3,372,466	90,620	2,702,559	158,048	2,222,160	239,585
TX	12,874,964	378,141	13,093,115	300,132	13,049,107	351,986	12,817,565	535,057
VA			4,404,809	160,930	4,253,572	163,614	4,150,037	185,393
VT					153,952	5,577	159,925	5,847
WA	2,404,873	40,160	2,516,393	45,281	2,477,464	56,118	2,516,409	93,800
WV			920,304	47,667	594,366	37,587	511,547	50,685
Total	**66,965,675**	**2,369,689**	**76,887,445**	**2,628,093**	**79,133,657**	**2,879,337**	**83,163,271**	**4,090,393**

Source: NPLEx, April 2016

In 2012, Talbert and colleagues, using aggregate data from NPLEx on the grams of PSE sold in Kentucky counties in 2010, provided the first direct evidence that PSE sales are associated with lab seizures.[40] In their analysis, PSE sales varied by 565-fold between Kentucky counties. Counties with greater sales were significantly associated with greater numbers of labs (Figure 6). When normalized based on population, a 13-gram increase in PSE sales per 100 residents was associated with one additional meth lab in a county.

Figure 6: Methamphetamine Labs and PSE Sales in Kentucky, 2010



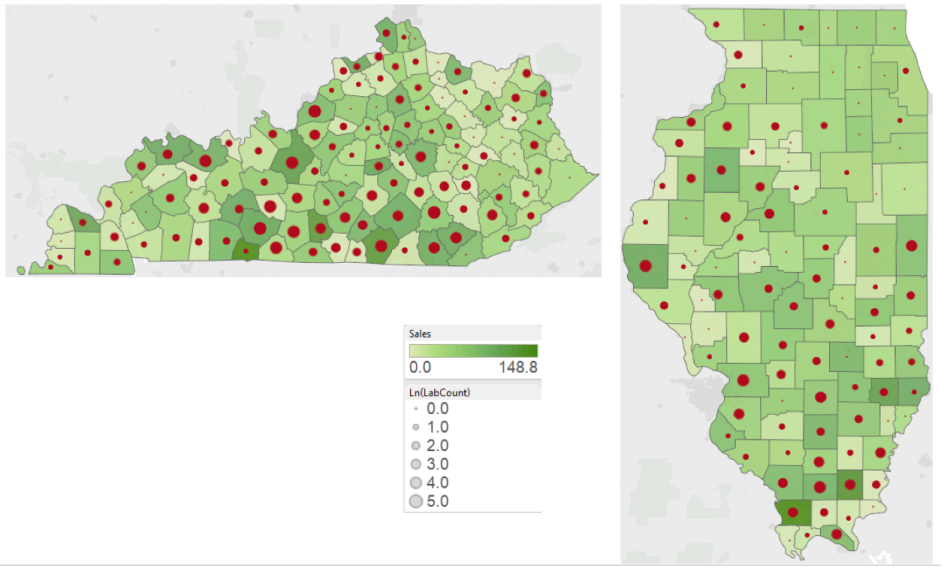
Since publication of the original paper, the finding that greater PSE sales are associated with greater numbers of labs has been confirmed in Kentucky, Illinois and Louisiana over two years.[41] Figure 7 depicts methamphetamine labs and PSE sales in Kentucky and Illinois in 2011. Similar to the original study as reported in JAMA, counties with greater sales were significantly associated with greater numbers of labs.[42] Given the continued significant association observed between PSE sales and labs in multiple states across multiple years, one could hypothesize that any regulatory strategy implemented that limits PSE sales in a given state will be associated with a decrease in the number of clandestine lab incidents observed.

[40] Talbert et al. Pseudoephedrine sales and seizures of clandestine methamphetamine labs in Kentucky. *JAMA.* 2012;308(15):1524-1526.

[41] Troske, Et Al. The relationship between pseudoephedrine sales and clandestine methamphetamine labs. Available from http://www.ispor.org/ScientificPresentationsDatabase/Presentation/56544.

[42] Ibid.

Figure 7: Methamphetamine Labs and PSE Sales (Gm/100 people) in Kentucky and Illinois, 2011



Sources: DEA Lab Seizures
NPLEx
US Census Bureau

Table 3 presents the number of lab incidents for states with electronic tracking and block of sales. It is interesting to note that in many states, lab incidents continue to rise or stay constant in the years following implementation of electronic tracking. For example, in 2008 Kentucky was the first state to mandate use of NPLEx (formerly known as MethCheck) and as noted in Table 3 below, the number of lab incidents reported to the DEA's national seizure system continued to rise over the next several years. It was not until a mandate restricting annual quantity limits was implemented that Kentucky began to see a decrease in lab incidents. Similarly, Arkansas, which began electronically tracking PSE sales with Methmonitor in 2006, continued to have an increasing number of lab incidents reported from 2006 until 2011, when it began requiring a valid Arkansas drivers license for non-prescription sales and posed new duties on pharmacists to determine that consumers purchasing PSE had a legitimate medical need for the product. The impact of these additional mandates are discussed in further detail in the next section.

Table 3: Methamphetamine Lab Incidents in States with Electronic Tracking Mandates, 2004-2014

	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Alabama	803	529	273	249	624	673	719	**291**	**310**	**223**	**112**
Arizona	221	138	48	23	34	24	18	5	22	**5**	**4**
Arkansas	1,361	701	**450**	**380**	**418**	**671**	**824**	**308**	**104**	**65**	**43**
Delaware	3	1	0	0	1	1	3	2	13	5	**5**
Florida	438	470	202	186	214	415	526	**161**	**332**	**527**	**525**
Hawaii	17	18	4	1	0	0	3	0	0	**1**	**0**
Idaho	75	35	23	23	14	17	19	8	**3**	**4**	**3**
Illinois	1,582	1,430	863	399	379	416	**476**	**637**	**802**	**670**	**729**
Indiana	1,384	1,506	838	815	739	1,328	1,243	1,437	**1698**	**1796**	**1471**
Iowa	1,687	914	364	198	241	336	**380**	**413**	**400**	**308**	**143**
Kansas	650	417	194	101	161	184	241	**202**	**149**	**69**	**48**
Kentucky	622	616	336	310	**442**	**743**	**1,359**	**1,758**	**999**	**476**	**468**
Louisiana	178	144	28	54	45	163	**218**	70	117	52	11
Maine	4	5	5	1	4	1	4	5	11	**22**	**33**
Michigan	461	511	290	212	456	716	866	438	**753**	**609**	**750**
Missouri	2,924	2,340	1,326	1,292	1,520	1,810	1,979	**2,114**	1963	1484	1034
Nebraska	327	287	35	30	67	40	27	19	**11**	**6**	**7**
Nevada	153	86	44	24	17	16	13	16	6	3	**1**
North Carolina	473	493	216	161	197	213	237	400	**558**	**571**	**535**
North Dakota	238	175	43	27	35	35	8	**9**	**15**	**6**	**7**
Ohio	535	669	375	232	260	344	381	364	802	**1157**	**939**
Oklahoma	914	329	**223**	**114**	**194**	**784**	**880**	**1,006**	**764**	**438**	**209**
Pennsylvania	138	101	65	18	24	44	39	9	127	208	**211**
South Carolina	343	253	112	68	130	244	344	**338**	**499**	**398**	**357**
South Dakota	36	26	15	13	11	9	22	5	10	15	**19**
Tennessee	2,369	1,751	903	603	834	1,494	2,153	2,326	**1,707**	**1,672**	**961**
Texas	740	442	188	158	250	273	192	88	**56**	**284**	**13**
Vermont	1	2	0	2	0	0	4	0	4	**3**	**1**
Virginia	110	87	22	25	21	29	106	202	317	**387**	**309**
Washington	962	547	337	240	127	70	46	**33**	**12**	**12**	**6**
West Virginia	328	445	166	113	116	139	207	92	132	**67**	**16**

Source: DEA Lab Seizures

Note: ***Bold indicates year electronic tracking mandate implemented.***

Impact of Annual Quantity Limits

Since 2012, several states have implemented annual quantity limits on top of the monthly limits. Table 4 depicts the number of labs in states with annual quantity limits.

Table 4: Methamphetamine Lab Incidents in States with Annual Quantity Limit Mandates, 2004-2014

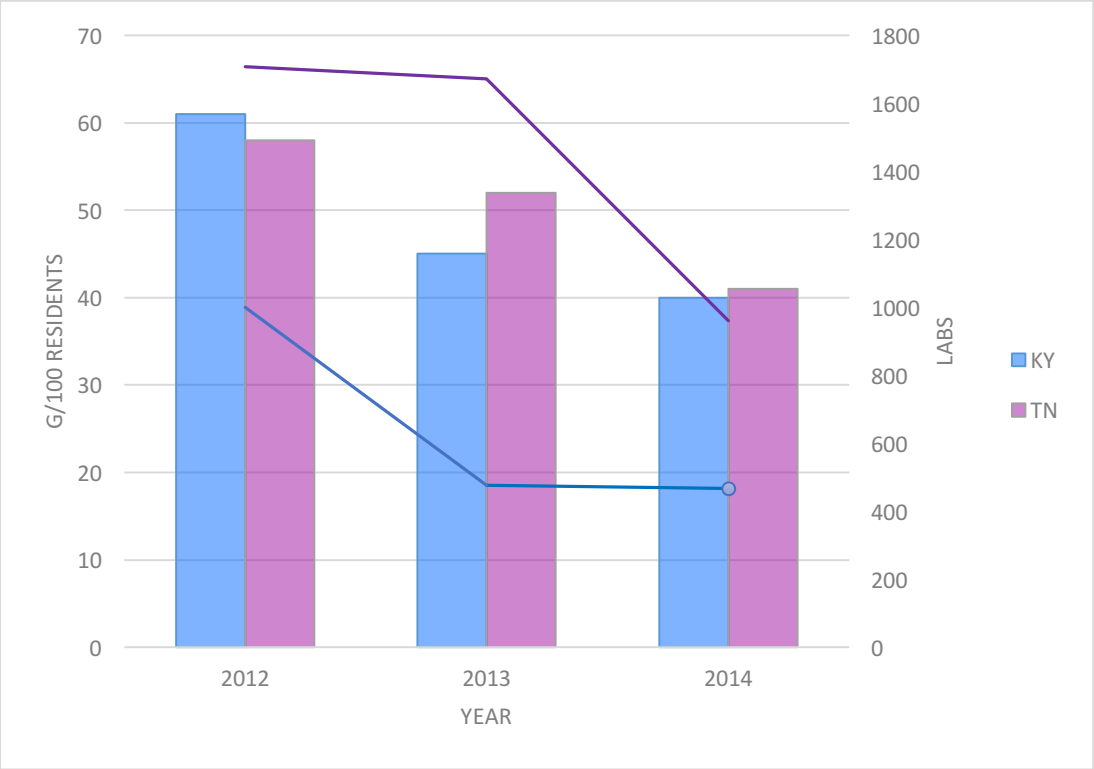
	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Indiana (61.2 gram limit)	1,384	1,506	838	815	739	1,328	1,243	1,437	**1698**	**1796**	**1471**
Kentucky (24 gram limit)	622	616	336	310	**442**	**743**	**1,359**	**1,758**	**999**	**476**	**468**
Oklahoma (60 gram limit)	914	329	223	114	194	784	880	1,006	764	**438**	**209**
Tennessee (28.8 gram limit)	2,369	1,751	903	603	834	1,494	2,153	2,326	**1,707**	**1,672**	**961**
West Virginia (48 gram limit)	328	445	166	113	116	139	207	92	132	**67**	**16**

Source: DEA Lab Seizures

Note: ***Bold indicates year electronic tracking mandate implemented;*** *red indicates year annual limits mandated.*

Kentucky, Oklahoma and West Virginia implemented annual limits on PSE in 2012, Indiana in 2013 and Tennessee in 2014. From Table 4 above, one can easily see that lab incidents decrease most significantly in states where the most restricted annual limits have been mandated. For example, Kentucky restricted PSE sales to 24 grams per year effective July 2012. Between 2012 and 2013, a 52.3% decrease in labs was noted which was sustained during 2014. Similarly, a 42.5% decrease in lab incidents was noted in Tennessee between 2013 and 2014 following quantity restriction to 28.8 grams annually. Figure 8 shows the relationship between grams of PSE sold per 100 residents and the number of lab incidents reported for the two states (Kentucky and Tennessee) that have mandated strict restrictions on annual OTC sales of PSE. As is evident from the chart, large decreases in the sales of PSE normalized per 100 residents are observed following implementation of Kentucky's 24-gram annual limit in 2012 (-35%) and Tennessee's 28.8 gram annual limit in 2014 (-30%). Thus, it appears that state policies that significantly restrict and enforce quantity limits by utilizing NPLEx's real-time stop sale technology block of sales are associated with significant decreases in lab incidents.

Figure 8: Relationship between PSE Sales and Lab Incidents, Kentucky and Tennessee, 2012-2104



Source: NPLEx and DEA National Seizure System

Impact of Pharmacist Determination of Legitimate Medical Need

As stated previously, Arkansas imposed stricter PSE laws in 2011 that required pharmacists to make a professional determination, based on a pharmacist-patient relationship, as to whether or not there is a legitimate medical and pharmaceutical need for PSE before selling it OTC. The law also required an Arkansas drivers license or other state identification for OTC purchase of PSE products, effectively making PSE a prescription-only product for individuals who reside out of state.

According to the Arkansas Democrat-Gazette, PSE sales transactions since then have plummeted, from 975,060 individual transactions in 2009 to 120,435 transactions in 2014.[43] Accompanying these decreases in OTC sales transactions for PSE is a corresponding decrease in lab incidents, from 418 in 2009 to 43 in 2014 (Table 5). Interestingly, although Arkansas began electronic tracking of PSE sales in 2006, as noted in Table 5 below, lab incidents continued to rise until 2011 when the pharmacist

[43] Arkansas Online. Pseudoephedrine laws all but stopped meth labs in state. http://m.arkansasonline.com/news/2016/feb/15/pseudoephedrine-laws-all-but-stopped-me/. Accessed March 27, 2016.

mandates were implemented. It will be interesting to see if similar reductions in labs are observed in Indiana following the implementation Senate Enrolled Act 80.

Table 5: Methamphetamine Lab Incidents in Arkansas, 2004-2014

	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Arkansas	1,361	701	**450**	**380**	**418**	**671**	**824**	**308**	**104**	**65**	**43**

Reporting of Sales to Prescription Drug Monitoring Program

It is difficult to determine impact of policies that require reporting of PSE to the PDMP as the states that require this do so as a result of other precursor control policies (e.g. Sch III and Sch V mandates). Additionally, because states, as a general rule, have not mandated use of the PDMP by pharmacists prior to dispensing, information on PSE sales in a state PDMP is unlikely under present circumstances to be accessed and used by pharmacists at the point of PSE dispensing.

Is it enough to reduce lab incidents?

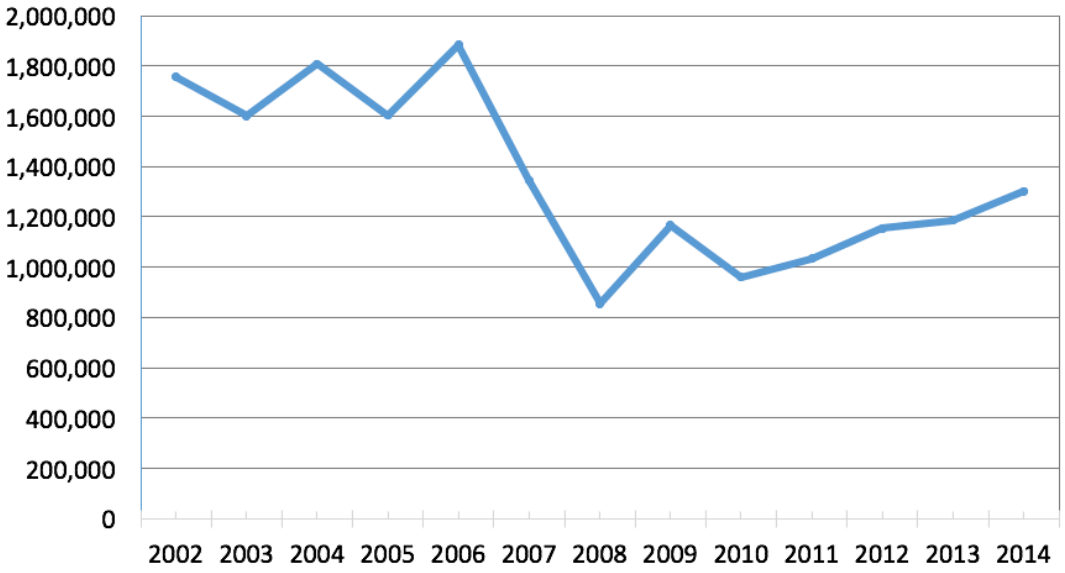
Any policy that decreases the diversion of PSE to the illicit production of methamphetamine and reduces lab incidents will have positive impacts on states. It is estimated that the cost of cleaning up a methamphetamine lab can range from $5,000 - $150,000 depending on the size of the lab. Since 2002, estimates from the Department of Justice show that the DEA has spent well over $142 million for lab clean-up. Additionally, as noted in the original white paper, significant societal costs are associated with the production of methamphetamine in clandestine labs, including harm of children exposed to methamphetamine and the chemicals used to produce it, explosions and burns.

In 2013, the National Conference of State Legislators noted that despite the innovative approaches taken by states to control access to PSE and combat the diversion of PSE to the illicit production of methamphetamine, continued domestic production of methamphetamine remains a serious concern and encouraged federal leadership and provision of resources to assist state governments with addressing methamphetamine production, diversion and abuse issues.[44]

[44] NCSL Comments on Proposed 2014 ONDCP National Drug Control Strategy, October 8, 2013. Available from http://www.ncsl.org/research/civil-and-criminal-justice/byrne-justice-assistance-grant-byrne-jag-program.aspx.

It should be noted that although lab supply-side interventions such as those discussed herein are designed to reduce the diversion of PSE and EPH to methamphetamine production in clandestine labs, they may have little impact on indices of methamphetamine demand. Data from SAMHSA's Survey on Drug Use and Health indicate that the illicit use of methamphetamine continues to be a significant problem in the U.S. As depicted in Figure 9, the illicit use of methamphetamine in individuals 12 years of age and older has been increasing steadily since 2010, with an estimated 1.3 million individuals in the US in 2014 reporting methamphetamine use in the past year.

Figure 9: Methamphetamine
Illicit Drug Use in the Past Year among Persons Aged 12 or Older, 2002-2014



Source: **Table 7.2A** – SAMHSA, Center for Behavioral Health Statistics and Quality, National Survey on Drug Use and Health, 2002-2014.

These trends suggest that in addition to supply-side interventions that can reduce the number of lab incidents, efforts aimed at curbing the abuse and diversion of methamphetamine must also address the demand-side of the methamphetamine abuse problem.

VI. Summary and Recommendations

As states continue to implement various policy solutions to curb the diversion of precursors such as PSE to the illicit production of methamphetamine, identifying the impact of individual policies becomes increasingly difficult. Based on the available evidence, ANY policy which greatly limits the sale of OTC PSE, including prescription-only mandates, strict annual quantity restrictions such as those implemented in

Kentucky and Tennessee, and the law passed in Arkansas and, most recently, Indiana, that limit OTC sales by mandating a pharmacist determine a legitimate medical or pharmaceutical need for PSE prior to its OTC sales, is apt to have a significant impact on production of methamphetamine in small clandestine labs.

Considering the potential negative impacts on patients, providers and payers from a prescription-only mandate, state policies such as strict annual quantity limits or those that require a determination by pharmacists as to a legitimate need for PSE, may be the best policy solutions for states to consider. These policy solutions, which allow for continued access to OTC PSE by consumers who use PSE containing products intermittently for colds and allergy symptoms, yet decrease the total amount of PSE that is purchased OTC in a state and thus reduce the amount of PSE available for diversion to the illicit production of methamphetamine, may provide for the most balance between these competing interests. Individuals with severe, year round allergies are likely seeing physicians or allergists regularly as a result of this chronic condition and thus should be able to receive prescriptions for PSE-containing products during these regular visits. Additional research into the impacts of strict annual quantity limits and the pharmacist mandates on clandestine methamphetamine lab incidents is warranted.

It should be noted, however, the supply-side interventions are not likely to influence the illicit use of methamphetamine as evidenced by the consistent trends in methamphetamine use in recent years as reported by the National Survey on Drug Use and Health and in admissions to substance abuse treatment facilities. Thus, in addition to effective supply side interventions such as those discussed herein, states grappling with methamphetamine abuse problems should also consider policy changes focused on prevention and treatment that impact the demand side of the methamphetamine abuse equation.