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University of Kentucky

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Kentucky Pharmacist Opinions of the Potential Reclassification of Pseudoephedrine as a Legend Drug

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Graduate Capstone
Martin School of Public Policy and Administration
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Executive Summary

Methamphetamine is a drug of abuse, which is often produced in clandestine laboratories. Recent efforts to curb methamphetamine abuse are aimed at controlling access to precursors, including pseudoephedrine (PSE), used in illicit methamphetamine production. Currently, access to PSE is controlled in Kentucky by placement behind pharmacy counters, retail quantity limitations and electronic tracking. Recent legislation proposed in Kentucky to change PSE from non-prescription to a legend medication was unsuccessful and highly controversial. The objective of this project is to collect and analyze pharmacists' opinions on the effectiveness of current precursor controls, proposed legislation to make PSE a legend drug and impact on their practice and patients.

This research has been approved by the University of Kentucky Institutional Review Board and utilizes survey methodology to obtain opinions of Kentucky pharmacists regarding the recent proposed legislation to make PSE a legend drug. Survey questions included perceived efficacy of current precursor controls, anticipated impact on individual pharmacy practice and patients and current opinion in regards to the proposed legislation. For this project, all surveys were conducted anonymously with no identifying information collected. A simple random sample of pharmacists (n=2000) was drawn from a list of all licensed pharmacists in the Commonwealth of Kentucky, excluding pharmacists with an out-of-state practice address. The survey response rate was 30.6%. Pharmacists practicing in a hospital or "other" setting were excluded from the analysis, as their practice sites are not directly impacted by PSE sales. The final group for analysis included 431 pharmacists practicing in a chain or independent community pharmacy setting.

Descriptive statistics were generated, including frequencies and proportions. Bivariate analyses were conducted using the Chi-squared test and t-test. Multivariate logistic regression was performed to investigate the impact of independent variables on pharmacists' support of or opposition to the legislation to make PSE available by prescription-only. Independent variables utilized in the regression model include: chain versus independent pharmacist status, anticipated impact of making PSE prescription-only on time spent on PSE-related activities and pharmacy profits, Kentucky region of pharmacy practice, anticipated impact of making PSE prescription-only on methamphetamine abuse and laboratory incidents, confidence in identifying patients utilizing PSE for a legitimate medical purpose and grams of PSE sold per county resident.

The *2012 Pseudoephedrine Survey for Pharmacists* showed that 56.2% of Kentucky pharmacists practicing in a community pharmacy support the proposed legislation to make PSE available by prescription-only, 30.7% oppose the legislation and 13.1% are unsure. Furthermore, independent and chain pharmacists significantly differ in the average number of prescriptions filled per day, number of PSE purchases per day and the number of years in practice. Practice site significantly impacts support for the proposed legislation with chain pharmacists being 2.90 times more likely to support the legislation to make PSE prescription-only. One possible explanation for this difference is that independent pharmacists may exhibit more autonomy in the decision making process to sell or not sell PSE to potential customers. Additional factors that influence pharmacist support of the legislation include: anticipated impact of making PSE prescription-only on time spent on PSE-related activities and pharmacy profits, Kentucky region of pharmacy practice, and anticipated impact of making PSE prescription-only on methamphetamine abuse and laboratory incidents. Kentucky region of pharmacy practice appears to have a large impact on pharmacist support of the legislation. Regions, such as

western, eastern, and southern Kentucky, associated more strongly with methamphetamine appear to more strongly support the proposed legislation.

Background

Methamphetamine Overview

Description of Methamphetamine and History

Methamphetamine is a synthetically produced stimulant medication belonging to the amphetamine group, which results in activation of the brain. Amphetamines, including methamphetamine, were widely available in the United States without a prescription until 1951. During the 1960s, methamphetamine became widely abused and diverted following use as treatment for heroin addiction.¹ Drug users began injecting methamphetamine intravenously and obtaining the drug through black markets. In 1971, methamphetamine was rescheduled as a Schedule II controlled substance by the Drug Enforcement Administration (DEA), which resulted in an immediate reduction in abuse and diversion.¹

In the 1980s, ephedrine and pseudoephedrine (PSE) were approved by the Food and Drug Administration (FDA) as nasal decongestants for over-the-counter (OTC) use, and shortly after the approval, resurgence in methamphetamine abuse was observed. Ephedrine and PSE are two precursor ingredients used in illicit methamphetamine production in clandestine laboratories.² Today methamphetamine is recognized as medical treatment, available by prescription, for narcolepsy, attention deficit disorder, attention deficit hyperactivity disorder, depression and obesity.¹ However, given the significant associated risks and adverse effects of methamphetamine, alternative therapies are generally preferred and medical use of methamphetamine remains extremely limited.

Methamphetamine Abuse

According to the United Nations Office on Drugs and Crime (UNODC) World Drug Report 2012, Methamphetamine abuse affected between 14 and 53 million people or 0.3-1.2% of

the worldwide population in 2010.³ Methamphetamine can be taken through a variety of routes including swallowing orally, smoking, snorting or injecting intravenously. The most common means of illicit methamphetamine use in the United States is through snorting or intravenous injection.¹

Methamphetamine produces an initial euphoric ‘rush’, which often prompts the user to continue using methamphetamine. After continued use of methamphetamine, anorexia, weight loss, insomnia, aggression, hallucinations, paranoia, convulsions, stroke, cardiac arrhythmia, and hyperthermia may occur.² As chronic abuse occurs, irreversible brain and heart damage, memory loss, psychotic behavior, rages, violence and ultimately the inability to care for oneself and one’s children is often observed.² In addition to the known physical and emotional harms associated with methamphetamine abuse, methamphetamine production is associated with significant harms.

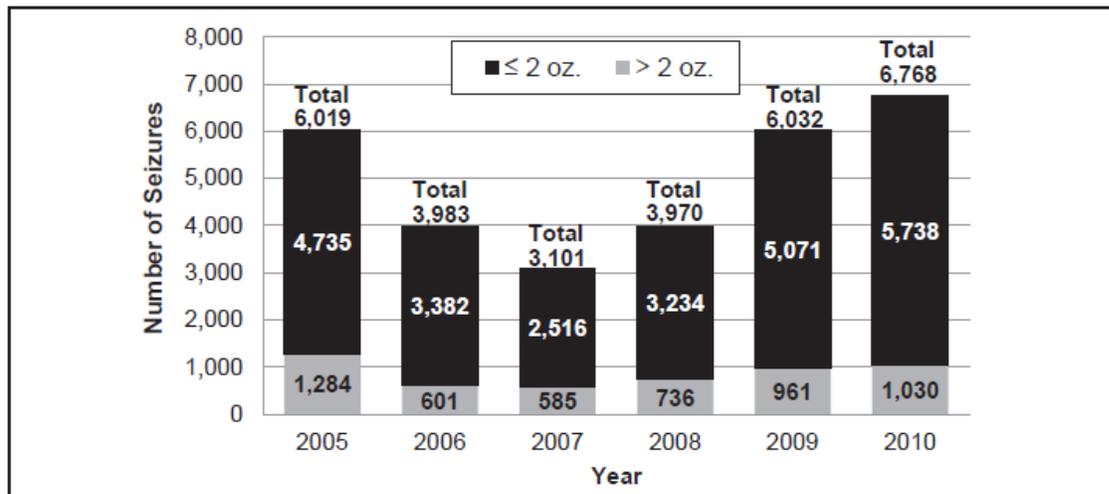
Methamphetamine Production and Description of Pseudoephedrine

Prior to the 1971 rescheduling as a Schedule II controlled substance, methamphetamine was primarily obtained through the black market, which consisted of diverted supplies from pharmaceutical companies, distributors and physicians.¹ Upon the rescheduling, illicit methamphetamine laboratories began emerging. Initially, methamphetamine was produced using two organic compounds, phenyl-2-propanone (“P2P”) and methylamine, as precursor chemicals.⁴ Motorcycle gangs manufactured and distributed methamphetamine beginning in San Francisco and spreading along the Pacific Coast and then moving westward.⁴

In 1980, phenyl-2-propanone became a Schedule II controlled substance, and manufacture shifted towards using OTC ephedrine and PSE as chemical precursors to produce methamphetamine through a reduction method.⁴ The reduction method proved to be simpler and

led to a more potent form of methamphetamine. Today, the DEA estimates that more than 80% of methamphetamine in the United States comes from clandestine “super” labs in Mexico and California, which are operated by Mexican drug trafficking organizations.¹ The remaining 20% of methamphetamine in the United States is reported to come from small, amateur, clandestine laboratories.¹ Small quantities of methamphetamine are relatively easy and cheap to manufacture and little knowledge, skill or equipment is necessary. However, small-scale, clandestine laboratories are extremely dangerous due to the nature of the volatile chemicals used in the manufacturing process.¹ Fires, explosions and environmental contamination are common.¹ Laboratory seizures have been reported in a wide range of locations, including “sleeping areas, kitchens and eating areas where food is prepared and stored, garages, vehicles, hotel and motel rooms, storage lockers, mobile homes, apartments, ranches, campgrounds, rural and urban dwellings, abandoned dumps, restrooms, houseboats, and other locations” which represents a large public safety concern.¹ According to the DEA National Seizure System, a record number of methamphetamine laboratory seizures was reported in 2010 and the number of seizures has increased steadily since 2005, as shown in Figure A.⁵

Figure A. Reported Methamphetamine Laboratory Seizures in the United States, by Capacity, 2005-2010



Source: Drug Enforcement Administration, National Seizure System.

*Data as of July 7, 2011.

Source: U.S. Department of Justice National Drug Intelligence Center, National Drug Threat Assessment 2011⁵

Today, amateur, clandestine laboratories obtain PSE largely through a process called “smurfing”. Federal legislation restricts the amount of PSE that may be purchased OTC by an individual (see Methamphetamine Precursor Control Legislation below). In order to circumvent the quantity limitation of PSE, a group of individuals is paid “to go from store to store making purchases of products containing pseudoephedrine or ephedrine under the threshold requirements...this process was and is repeated day after day in store after store”.⁶ Furthermore, the individuals evade any logbook or electronic system by using various forms of identification.

Methamphetamine Precursor Control Legislation

Federal Laws

A series of federal laws have been enacted in order to control access to methamphetamine precursor chemicals. Federal methamphetamine precursor laws have been aimed at increasing reporting and record keeping requirements, requiring registration with the DEA, implementing packaging requirements, quantity limits, and placement behind the pharmacy counter. Federal

laws have targeted bulk precursor chemicals, OTC products containing PSE and combination products containing PSE. Table 1 summarizes the major federal laws implemented to control methamphetamine precursor chemicals.²

Table 1. Summary of Federal Efforts to Limit Access to Methamphetamine Precursors

Act	Primary Implications	Year
Chemical Diversion and Trafficking Act (CDTA)	Regulated bulk ephedrine and PSE by requiring record keeping, reporting requirements, and import/export notifications. Did not include OTC tablets, capsules and other products containing ephedrine or PSE.	1988
Domestic Chemical Diversion Control Act (DCDCA)	Required distributors, importers and exporters to register with the DEA and gave the DEA power to revoke registration. Additionally, removed the record-keeping and reporting exemption for single entity ephedrine products.	1993
Comprehensive Methamphetamine Control Act (MCA)	Broadened federal regulation of chemicals to include combination OTC medicines containing precursor ingredients and increased penalties for methamphetamine and methamphetamine precursor trafficking and production.	1996
Methamphetamine Anti-Proliferation Act (MAPA)	Established quantity restrictions for a single purchase of OTC medications containing ephedrine, PSE and phenylpropanolamine. Additionally, new packaging precursor quantity limitations were included in MAPA.	2000
Combat Methamphetamine Epidemic Act (CMEA)	Included the following key requirements: <ul style="list-style-type: none">• Quantity limit of 3.6 grams of precursor base (PSE) per customer per day and 9 grams per customer per month;• Store all methamphetamine precursor containing products behind the counter;• Maintain a logbook for two years containing the time and date of sale, name and quantity of product sold and name and address of each purchaser;• Require purchasers to present identification and sign the logbook.	2005
Combat Methamphetamine Enhancement Act	Placed restriction on distributors and retailers who sell products used in illicit methamphetamine manufacture.	2010

Multiple studies have examined the impact of early federal methamphetamine precursor regulations on a variety of indicators of methamphetamine use and production. A 2003 study by James Cunningham and Lon-Mu Liu examined the impact of four federal ephedrine and PSE regulations that were implemented between 1989 and 1997 on methamphetamine-related hospital admissions in California. Three regulations focused on large-scale laboratories, while one regulation targeted small-scale clandestine laboratories by regulating combination ephedrine products. The study showed a 35-71% drop in methamphetamine-related hospital admissions following the implementation of each of the regulations targeting large-scale clandestine laboratories.⁷ However, the reduction in admissions resurged beginning 6-24 months after each regulation was implemented. No effect was seen following the regulation targeting small-scale clandestine laboratories. The study noted possible reasons for the resurgence of admissions, including producers accessing alternative supplies of precursors and importing precursors from foreign countries.

A 2005 study by Cunningham and Liu investigated the impact of federal precursor chemical regulations on methamphetamine related arrests in California. The study examined the impact of the same four federal methamphetamine precursor regulations as the 2003 study. The study concluded that methamphetamine arrests stopped rising and decreased by 31-45% following the implementation of each of the three regulations involving large-scale producers.⁷ However, little or no effect was seen following the implementation of the regulation involving small-scale producers. Additionally, arrests rebounded fully within two to three years, which is likely due to the fact that producers were able to circumvent regulations or the increased regulations pushed users into self-production.

A 2008 study by Cunningham and Liu examined the impact of methamphetamine federal precursor chemical regulations on the demand for drug treatment. The study showed a decline in voluntary methamphetamine treatment admissions following the precursor regulations of 1995 and 1997 by 39% and 31%, respectively.⁷ However, the first decline rebounded within two years and the second rebounded within four years.

The 2011 study conducted by Nonnemaker, Engelen and Shive examined the impact of retail-level methamphetamine precursor laws in reducing indicators of domestic production, methamphetamine availability, and consequences of methamphetamine use. The implementation of MAPA and a state level restriction, the California Uniform Controlled Substances Act (UCSA), enacted in 2000 was studied. The California UCSA further restricted precursor access by including all ephedrine and PSE products, regardless of packaging. The study found no evidence of a decrease in methamphetamine indicators following implementation of the federal MAPA and some evidence for the effect of the California UCSA.⁸ Overall, rises in methamphetamine purity and lower prices have called into question the net benefit of domestic precursor controls. The authors suggest that the strict domestic control of methamphetamine precursors may be causing unintended consequences as seen by increased supply from international trafficking.

State Laws

In addition to the federal legislation regarding methamphetamine precursor control, many states have enacted additional laws to further control the sale of PSE and ephedrine. A variety of additional methamphetamine precursor control laws have been enacted across the United States.

Electronic Tracking and Block of Sales

Following the passage of CMEA, pharmacies and retail outlets were required to maintain a logbook of individual PSE sales. While the logbook requirement can be effective at preventing excessive PSE purchasing within a single store, the legislation did not actively prevent purchasing PSE from multiple stores, as seen in the practice of smurfing. Multiple states have implemented regulations which require the electronic tracking of PSE purchases. Electronic tracking utilizes the purchaser's driver's license or alternate identification and records the date and amount of PSE sold. The data is stored centrally and can be shared among all stores within the network to prevent the purchase of PSE that would exceed the legal limit. As of July 2011, twenty states have passed electronic tracking laws.² The most common electronic tracking system utilized by states is National Precursor Log Exchange (NPLEx).² NPLEx is provided by the National Association of Drug Diversion Investigators (NADDI) free of charge, and the program is sponsored by manufactures of OTC PSE products.

Purchase Quantity Restrictions

The 2005 CMEA restricted retail purchases of PSE to 9 grams per 30 days.² However, five states, as of December 2011, have implemented more stringent laws restricting PSE purchase to between 6 and 7.5 grams per 30 days.² The maximum daily dose of PSE is 240mg per day, which corresponds to a thirty day maximum dose of 7.2 grams. Thus, a quantity restriction of 7.2 grams per 30 days should not impact individuals purchasing PSE for legitimate uses.

Schedule V Controlled Substance

As of December 2011, eleven states have reclassified PSE as a Schedule V controlled substance.² Schedule V products are available OTC. However, additional requirements exist

including maintaining a log of all transactions, requirement for proof of age (18 years or older) and restriction to purchase in a pharmacy. Furthermore, states with prescription monitoring programs (PMPs) that include Schedule V controlled substances may require transmission of data to the PMP.

Methamphetamine Registry/Block of Sales to those with Previous Methamphetamine-related Convictions

Oklahoma passed legislation in 2010 which requires all individuals convicted of possession, manufacture, distribution or trafficking of methamphetamine to register with the state.² Additionally, the registered individuals are prohibited from purchasing and possessing PSE. The convicted methamphetamine registry is linked with the electronic PSE tracking system and blocks sales to individuals with methamphetamine-related convictions, regardless of quantity limitations.²

Prescription-only Status/ Schedule III Controlled Substance

Two states, Oregon and Mississippi, have made PSE a Schedule III controlled substance available by prescription-only.² Medications which require a prescription to dispense are often referred to as legend drugs. Arkansas passed legislation in 2011, which requires a prescription for PSE unless the purchaser can provide an Arkansas Driver's License or ID card.² Additionally, the pharmacist must confirm medical need for individuals purchasing products containing PSE in Arkansas.

The most recent 2012 study by Cunningham, et al., examined the impact of prescription-only status of methamphetamine precursor products on clandestine laboratory seizure, an indicator of laboratory prevalence. Two states, Oregon (7/2006) and Mississippi (7/2010), have implemented regulations to classify ephedrine and PSE as Schedule III controlled substances

available by prescription-only.⁹ The results of the study showed that Oregon's laboratory seizures were not significantly affected by the prescription regulation. However, the number of seizures began declining months before implementation of the regulation and remained low for more than five years following the prescription precursor regulation. Additionally, the same trends were seen in Oregon's border states. On-the-other-hand, laboratory seizures in Mississippi dropped approximately 50% following prescription regulation of methamphetamine precursors, while nearby non-border states exhibited increases in laboratory seizures.⁹ The study suggested that states with more laboratory seizures, such as Mississippi, would likely benefit from prescription precursor regulation, while states with less laboratory seizures and more methamphetamine trafficking from Mexico, such as Oregon, would experience less benefit from prescription precursor regulation.

A 2010 study by Hendrickson, Cloutier and Fu examined the impact of the 2006 prescription methamphetamine precursor requirement in Oregon on methamphetamine-related Emergency Department (ED) visits. The results showed a 35% decrease in the number of methamphetamine-related ED visits from the pre-legislation period to the post-legislation implementation period.¹⁰

In conclusion, a number of federal laws have been enacted to control access to methamphetamine precursors. Furthermore, many states have implemented additional legislation to more strictly control access to methamphetamine precursors. Multiple studies have evaluated the impact of federal legislation on indicators of methamphetamine abuse. Overall, the studies have shown an initial impact following implementation of legislation targeting large-scale methamphetamine production.^{7,8,11,12} However, the initial decline in methamphetamine indicators was followed by a rebound. Federal legislation aimed at small-scale methamphetamine

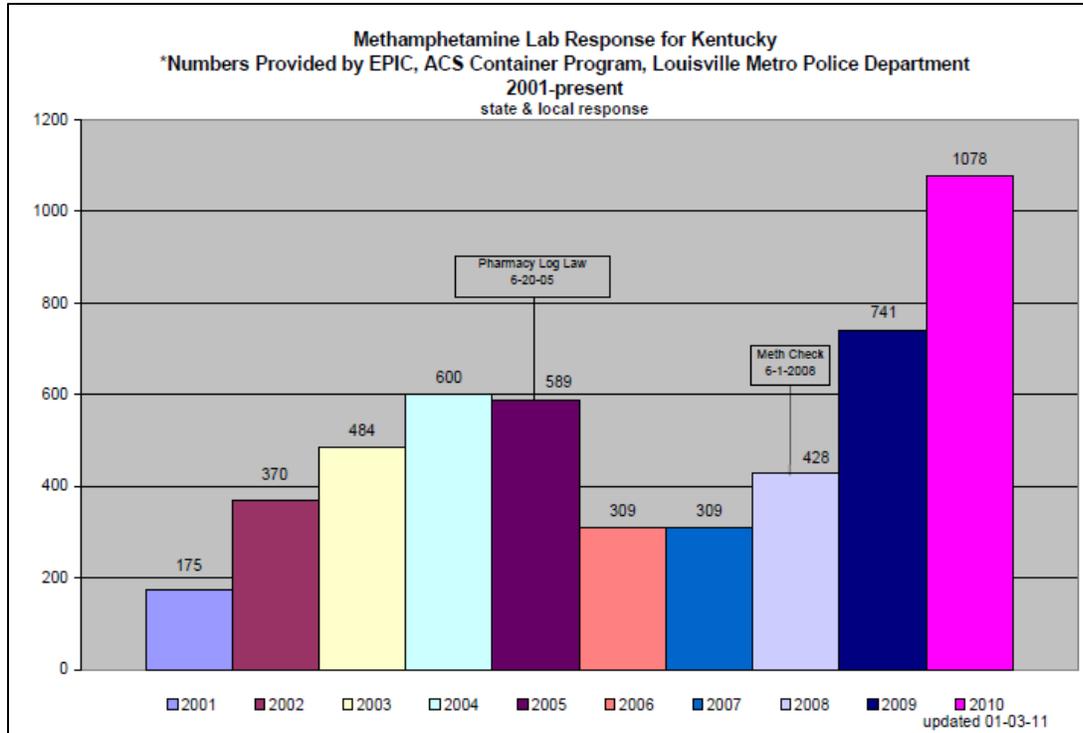
production has not been shown to have a significant impact on methamphetamine indicators. The studies evaluating the impact of state legislation on methamphetamine indicators have evaluated the prescription-only requirements in Oregon and Mississippi. One study showed no change in Oregon's laboratory seizures while a second study showed a drop in methamphetamine-related ED visits in Oregon following the implementation of the prescription-only PSE requirement.^{9,10} Additionally, the first study showed a 50% drop in laboratory seizures in Mississippi following the prescription-only PSE requirement and attributed the difference between Oregon and Mississippi to the greater number of clandestine laboratories in Mississippi and more methamphetamine importation from Mexico in Oregon.⁹

Overview of the Methamphetamine Problem in Kentucky

According to the Report on Methamphetamine and Other Drug Use in Kentucky prepared by The University of Kentucky Special Commission on the Study of Methamphetamine and Other Emerging Drugs in Kentucky, lifetime methamphetamine use in Kentucky is estimated to be 2.6% of the population.¹³ The report suggests a slight national decline in methamphetamine use yet a rising methamphetamine problem in Kentucky. The number of laboratory seizures in Kentucky has risen from 428 in 2008 to 741 in 2009 and 1078 in 2010, as shown in Figure B.¹⁴ Despite federal and state legislation aimed at controlling access to methamphetamine precursors, Kentucky manufactures have been able to find alternate methods for methamphetamine production and means of circumventing laws and tracking systems. Smurfing is thought to be a principle method for circumventing PSE quantity restrictions. Furthermore, new production methods, such as the "one-pot cook" method, which is also called "shake and bake", have led to increased production of methamphetamine via less complicated processes. The most common production method in Kentucky is the "one-pot cook" method.¹⁴ In the "one-pot cook" method,

all ingredients are combined at the same time in one bottle. The “one-pot cook” method is particularly dangerous due to the unstable nature of the chemical reactions.¹⁴

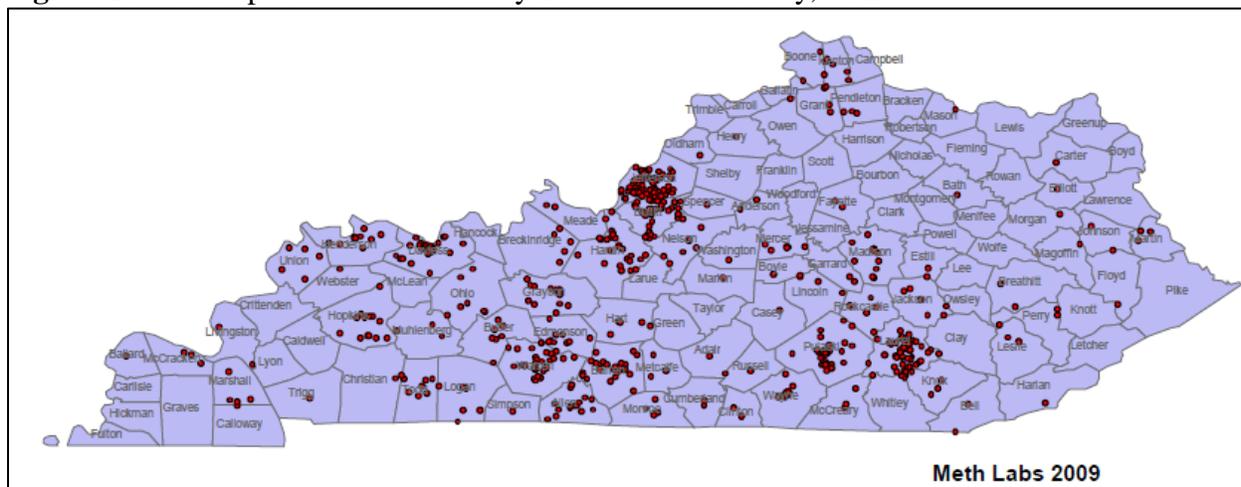
Figure B. Number of Laboratory Seizures in Kentucky 2001 to 2010



Source: Kentucky State Police Report¹⁴

Methamphetamine as a percentage of total drug cases in Kentucky has been increasing from 6% of total drug cases in 2007 and 2008 to 9% in 2009 and 11% in 2010.¹⁴ According to both the Report on Methamphetamine and Other Drug Use in Kentucky and the Methamphetamine Manufacturing in Kentucky 2010 report, methamphetamine has traditionally been associated with western and central Kentucky, as shown in Figure C. However, current trends indicate rising methamphetamine indicators in eastern Kentucky.¹⁴

Figure C. Methamphetamine Laboratory Seizures in Kentucky, 2009



Source: Kentucky State Police Report¹⁴

A recent research letter described the correlation between PSE sales and the number of clandestine laboratories per county in Kentucky in 2010.¹⁵ The results showed Kentuckians purchased a mean of 24,664 grams of PSE per county and 1072 laboratories were reported in Kentucky in 2010.¹⁵ A great deal of variability existed in both the amount of PSE sold and laboratories reported among counties. Counties with a larger number of PSE sales were associated with a significantly greater number of reported laboratories. The research letter reports a 1.7% increase in laboratories for every 1 gram increase in PSE purchased per 100 people.¹⁵

Current and Proposed Regulation of Methamphetamine Precursors in Kentucky

In addition to the federal regulations controlling access to methamphetamine precursors, Kentucky has implemented additional methamphetamine precursor regulations. Kentucky requires electronic tracking and block of PSE sales exceeding the legal limit. Kentucky was the first state to implement electronic tracking with NPLeX in 2008.² Additionally, Kentucky has recently passed a stricter PSE quantity limit than the federal limit of 9 grams per month. As of July 2012, Kentucky law limits PSE monthly sales per individual to 7.2 grams.¹⁶ New legislation

also includes the creation of a methamphetamine registry for those convicted of a methamphetamine-related crime and blocking sales of PSE to individuals listed in the registry.¹⁷

Over the past year, a great deal of attention has been focused on the methamphetamine problem in Kentucky and new legislation regarding methamphetamine precursors has been proposed. Much controversy has been generated regarding the proposal to make PSE available by prescription-only.² Proponents of requiring a prescription to purchase PSE argue that data from Oregon and Mississippi indicate efficacy in reducing the number of laboratory incidents and associated hazards in states with a large number of clandestine laboratories.² Additional data show a decrease in methamphetamine-related crime, arrest and admission to substance abuse treatment facilities following implementation of prescription-only PSE mandates.² However, further data are needed to ensure the reduction in methamphetamine indicators is sustained. Additionally, proponents of a prescription-only mandate argue that a majority of OTC PSE purchased is used for methamphetamine production.² Proponents believe OTC PSE creates hazards for the public and law enforcement, which represents a large cost to society.

Opponents of requiring a prescription to obtain PSE reason that the mandate would place additional burdens on physicians, pharmacists, insurance companies and consumers.² Some believe consumers will face additional costs and inconveniences for repeat doctor visits to obtain prescriptions for PSE. The Asthma and Allergy Foundation of America (AAFA), which strongly opposes making PSE available by prescription-only, conducted an online survey in July 2010 of more than 2,000 adults suffering from asthma, allergies, cold, cough or flu in the preceding twelve months. According to the survey, 71% of respondents oppose a law that requires a prescription to obtain PSE, while 66% support a nationwide e-tracking system.¹⁸ Most respondents reported opposing a law that requires a prescription to obtain PSE due to increased

costs, inconvenience and the thought that the law would be ineffective in decreasing methamphetamine abuse and target honest citizens. According to the survey, respondents prefer e-tracking over a prescription requirement due to efficacy and the limited burden placed on law abiding citizens.¹⁸

An analysis of the prescription-only PSE requirement in Oregon was conducted by the Cascade Policy Institute and funded by a grant from the Consumer Healthcare Products Association (CHPA). CHPA is a not-for-profit organization which represents manufactures and distributors of OTC medications, and supports keeping PSE and associated products available OTC. Multiple studies have found methamphetamine precursor restrictions to be effective in reducing methamphetamine indicators, at least in the short-term.^{9,10} However, the analysis by the Cascade Policy Institute presents evidence of non-significant changes in methamphetamine lab incidents, similar decreases in treatment episodes when compared to similar states with no prescription requirement, and no decrease in methamphetamine-related deaths.¹⁹ The analysis also reports added time and expenses involved with additional doctor visits. Added costs could include the direct cost of the doctor visit, the increased cost of the drug, travel expenses and costs from lost time and productivity.¹⁹ Additionally, the article states that some patients may opt for less effective treatment or no treatment, which could result in a lower quality of life.

Importance of Studying Kentucky Pharmacist Opinions of the Potential

Reclassification of Pseudoephedrine as a Legend Drug

Data clearly indicate the notable problem of methamphetamine abuse and production in Kentucky. Methamphetamine production in clandestine laboratories appears to be increasing in Kentucky and represents a significant hazard and cost to society as a whole.^{13,14} While there appears to be consensus that something must be done to address the methamphetamine problem,

various solutions have been proposed with some generating a great deal of controversy; the most notable being the proposed prescription-only mandate for purchase of PSE. To date, quantitative and qualitative data are available regarding consumers' opinions of various methamphetamine precursor controls.^{18,19} However, there is very limited understanding of the opinions of healthcare providers, specifically pharmacists, regarding methamphetamine precursor controls.

A 2009 study interviewed twenty Australian community pharmacists-in-charge regarding their opinions of developments in the Australian OTC medication market, including PSE sales.²⁰ Project STOP is an electronic PSE tracking system in Australia, which consists of an online database that checks patient identification and recent OTC PSE purchases to support pharmacists' determination of the legitimacy of PSE requests. According to the study, Australian pharmacists deemed Project STOP to be very useful in preventing misuse and abuse of PSE.²⁰ However, some pharmacists reported concern over robberies due to illicit methamphetamine manufacturers being unable to obtain PSE through legal means. Other concerns about the program included challenges in pharmacists' workloads and strained relationships with patients.

Community/retail pharmacists and staff are often busy entering prescriptions into the computer system, clarifying prescriptions with physicians, verifying patient allergies, checking for potential drug interactions, processing insurance claims, calling insurance companies to resolve issues, ensuring the correct medication, dosage, strength and quantity is dispensed to the patient, and counseling patients on disease states and medications. The processing of OTC PSE purchases interrupts the pharmacy workflow and requires a pharmacy staff member to stop his or her current task, obtain customer identification, start the electronic tracking program, enter customer identification information and information about the product the customer is wishing to purchase, submit the information and wait for the tracking system to respond with the

recommendation to dispense or not dispense the PSE. If numerous PSE purchases are requested daily, a non-trivial amount of time can be spent dispensing PSE and result in a significant interruption in the pharmacy workflow. Thus, one might speculate integrating PSE into the usual prescription workflow by making PSE available by prescription-only might alleviate some of the burden associated with OTC PSE sales. However, concerns over cost and inconvenience will likely exist. The small sample size and limited geographical distribution of the study represents a limitation. Additionally, the study was performed via interview and pharmacist responder bias is a potential limitation.

Students and faculty at the State University of New York at Albany conducted a survey of New York pharmacists' opinions of PSE regulations and presented the results at the 2007 American Pharmacists Association Annual Meeting.²¹ *Drug Topics*, a non-peer reviewed trade journal, described the research in a 2008 article.²² One hundred ninety-three New York State pharmacists were surveyed regarding views on PSE regulations, which required logging of consumer information for PSE purchases. According to the article, pharmacists in New York felt the record-keeping for PSE was unduly burdensome and not reducing illicit methamphetamine production, despite 67% of pharmacists feeling there had been a dramatic decrease in PSE purchases.²² Additionally, average time spent logging information for PSE purchases was reported to be 30-38 minutes per week.²² Other pharmacist concerns over the PSE regulations included lack of a computerized system that could prevent purchases at multiple pharmacies and consumers switching to phenylephrine-based products (an alternative OTC nasal decongestant which is not utilized in illicit methamphetamine production) to avoid the inconvenience of purchasing PSE behind the pharmacy counter without understanding the difference between the two products.

The surveys of Australian and New York pharmacists provided a glimpse of the opinions of pharmacists regarding OTC PSE regulations requiring logging of PSE purchases. However, there are no known studies to date that have assessed healthcare providers', including pharmacists', opinions of the prescription-only PSE mandate. It is important to understand pharmacists' opinions regarding the proposed prescription-only PSE mandate because pharmacists are perceived to be significantly impacted by PSE distribution and appear knowledgeable regarding the burdens surrounding PSE distribution. Pharmacists have firsthand experience providing PSE to customers with legitimate needs. On-the-other-hand, it is likely that many pharmacists, unknowingly or with unsubstantiated suspicion, have provided PSE to customers involved in illicit methamphetamine production. Additionally, pharmacists are extremely familiar with medication barriers and the impact of disparities on patient care. Pharmacists and pharmacy staff are required to record PSE purchases, which takes time and leads to questions from patients. PSE regulations can create a strained relationship between patients and pharmacists, as patients sometimes view pharmacists as restricting access to PSE. Furthermore, pharmacists and pharmacy staff are put in the unique position to deny access to PSE, which can cause an uncomfortable situation. Thus, an understanding of pharmacists' opinions regarding methamphetamine precursor regulation is necessary to appreciate the current difficulties and perceived efficacy surrounding methamphetamine precursor control and implications of proposed legislation to make PSE available by prescription-only. By gaining a better understanding of the issues surrounding PSE sales, it is hoped that effective legislation may be enacted to reduce methamphetamine production, laboratory incidents and abuse while causing the least amount of inconvenience and cost to law abiding citizens.

Methods

This study uses survey methodology to investigate pharmacists' opinions on the effectiveness of current methamphetamine precursor controls, proposed legislation to make PSE a legend drug and the anticipated impact of making PSE a legend drug on Kentucky pharmacists' practice and patients. This research has been approved by the University of Kentucky Institutional Review Board. Survey questions included perceived efficacy of current methamphetamine precursor controls, anticipated impact of proposed legislation to make PSE available by prescription-only on individual pharmacy practice and patients, and current opinion regarding the proposed legislation (see Appendix A for copy of *2012 Pseudoephedrine Survey for Pharmacists*). The majority of the questions were fixed response questions. The survey utilized various types of response categories, including checklists, Likert-type scales, and multiple-choice. A few questions were partial open-ended with the option to select other and provide an alternative written answer. One contingency question that was purely open-ended asked why respondents were unsure of their support for or opposition to a law requiring a prescription to purchase PSE. Additionally, the survey asked open-ended questions about the average number of prescriptions filled per day, average number of PSE purchases per day, county of practice, description of practice site and year of professional degree.

A list of all licensed pharmacists from the Commonwealth of Kentucky was obtained from the Kentucky Board of Pharmacy for a nominal fee. Pharmacists with an out-of-state practice address were removed from the list prior to sampling. A simple random sample of pharmacists (n=2000) was drawn using Stata v11.0 software²³ from the list of all licensed pharmacists in the Commonwealth of Kentucky. For this project, all surveys were conducted anonymously with no identifying information collected. A cover letter, survey and paid business

reply envelope was mailed to the sample of pharmacists on June 11, 2012. A reminder postcard was mailed to non-responders on June 27, 2012. Survey collection ended October 5, 2012.

Returned surveys were entered and maintained in a Research Electronic Data Capture (REDCap) survey instrument hosted by the University of Kentucky.²⁴ A unique identification number was assigned to each responding pharmacist.

Stata v11.0 statistical software was utilized to analyze the data. Descriptive statistics were generated, including frequencies and proportions (See Appendix B). Bivariate analyses were conducted using the Chi-squared test and t-test. Multivariate logistic regression was performed to investigate the impact of independent variables on pharmacists' support of the legislation to make PSE available by prescription-only. Independent variables and related hypotheses are shown in Table 2.

Table 2. Independent Variables Utilized in Multivariate Regression and Hypotheses

Independent Variables	Hypotheses
Chain versus independent pharmacist status	Chain pharmacists will be more likely to support the legislation
Anticipated impact of legislation on time spent on PSE-related activities	Pharmacists anticipating a decrease in time spent on PSE-related activities will be more likely to support the legislation
Anticipated impact of legislation on pharmacy profits	Pharmacists anticipating an increase in profits will be more likely to support the legislation
Kentucky region of pharmacy practice	Pharmacists practicing in eastern, western and southern Kentucky will be more likely to support the legislation
Anticipated impact of legislation on methamphetamine abuse and laboratory incidents	Pharmacists anticipating the legislation to be effective in decreasing methamphetamine abuse and laboratory incidents will be more likely to support the legislation
Confidence in identifying patients utilizing PSE for a legitimate medical purpose	Pharmacists less confident in identifying patients utilizing PSE for legitimate medical purposes will be more likely to support the legislation
Grams of PSE sold per county resident	Pharmacists practicing in counties with more PSE sold per county resident will be more likely to support the legislation

The Kentucky regions were derived from the National Survey on Drug Use and Health (NSDUH), which is conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA).²⁵ The regions are depicted in Appendix C. The grams of PSE sold per county resident was obtained from NPLEX.²⁶ All other independent variables were derived directly from the survey responses.

Results

Descriptive Results

The 2012 *Pseudoephedrine Survey for Pharmacists* was returned by 608 pharmacists and 10 surveys were mailed back with an outdated address, yielding a 30.6% response rate.

Pharmacists reporting their practice site as “Hospital” or “Other”, as well as pharmacists not designating a practice site, were removed from analysis (n=177) because these pharmacists are not actively engaged with PSE dispensing. The final sample for analysis included the 431 pharmacists practicing in a community pharmacy, which included independent, chain, and supermarket/mass retailer pharmacy. Chain and supermarket/mass retailer practice sites were combined and are hereafter referred to as chain pharmacy for simplicity. Table 3 describes the characteristics of the responding community pharmacists and reported practice site characteristics.

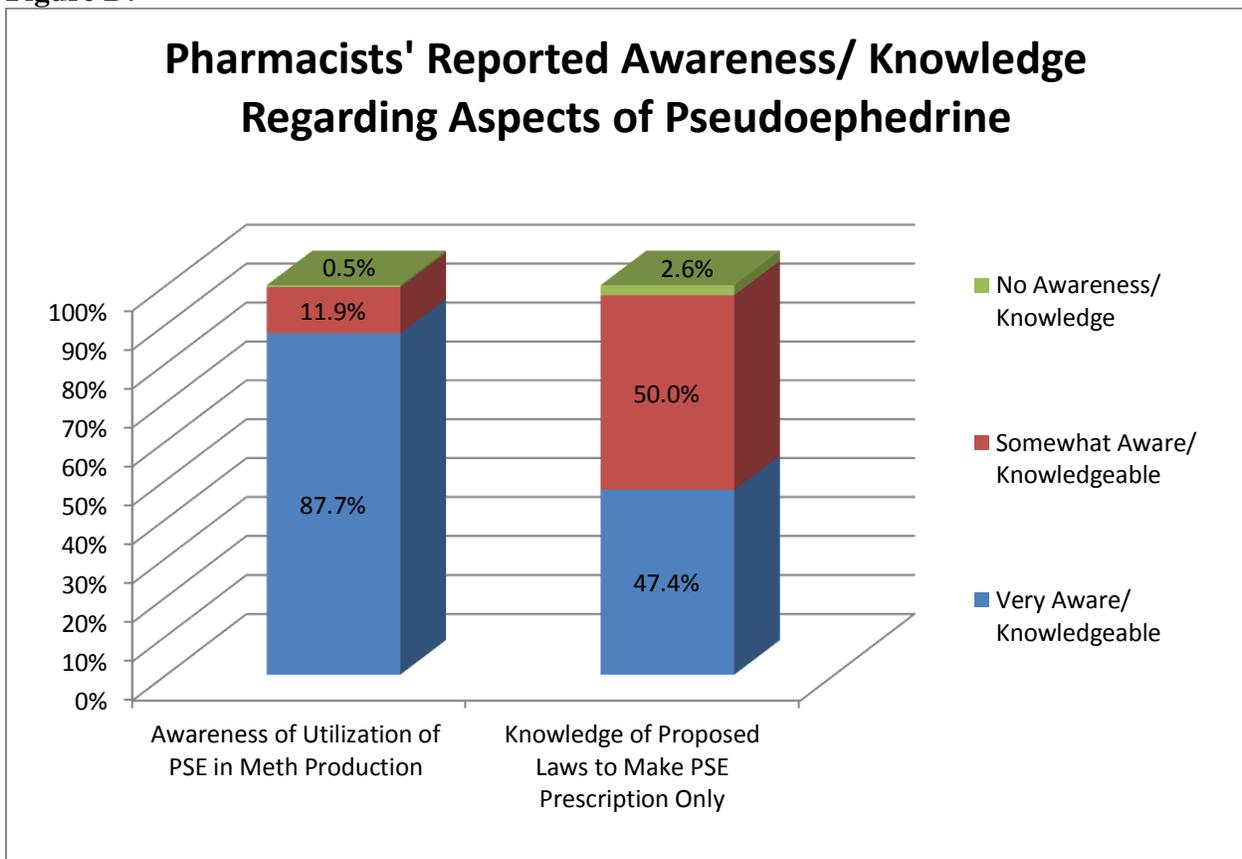
Table 3. Characteristics of Responding Pharmacists and Practice Sites

	Independent Pharmacists			Chain Pharmacists			All Community Pharmacists			P-value*
	Mean	Std. Dev.	Range	Mean	Std. Dev.	Range	Mean	Std. Dev.	Range	
Prescriptions/Day	277.0	148.5	70–1000	355.5	173.3	80–1000	325.5	168.3	70–1000	<0.001
PSE Purchases/Day	4.2	10.2	0–120	13.8	12.6	0–100	10.1	12.6	0–120	<0.001
Years in Practice	23.6	16.1	1–61	18.3	14.4	1–58	20.3	15.3	1–61	<0.001
N	169			262			431			
Percentage	39.2%			60.8%			100%			

* P-values for independent versus chain pharmacists

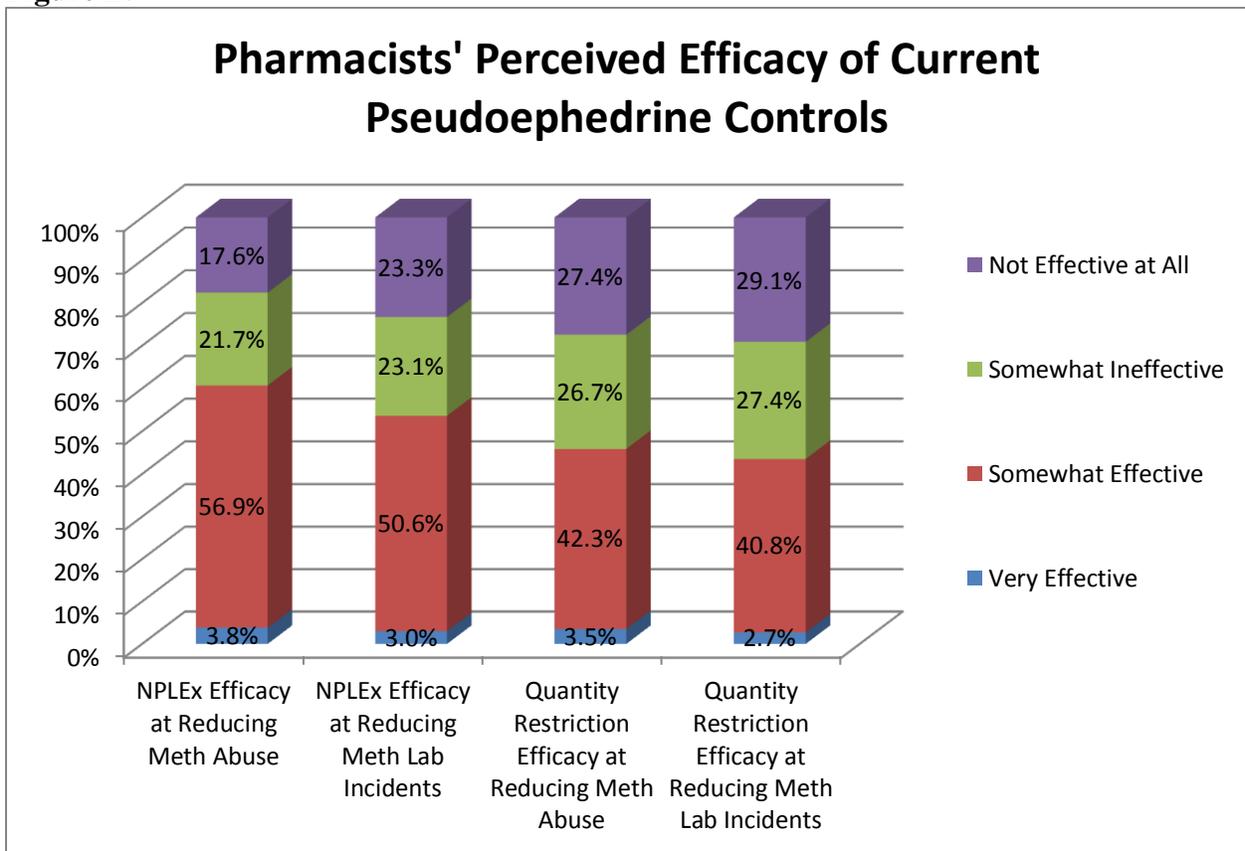
The vast majority, 99.5%, of pharmacists reported being at least somewhat knowledgeable regarding the use of PSE in the production of methamphetamine in clandestine laboratories. Additionally, a large majority, 97.5%, of pharmacists reported being at least somewhat knowledgeable regarding the recent proposals to make PSE available by prescription-only in the Commonwealth of Kentucky (See Figure D).

Figure D.



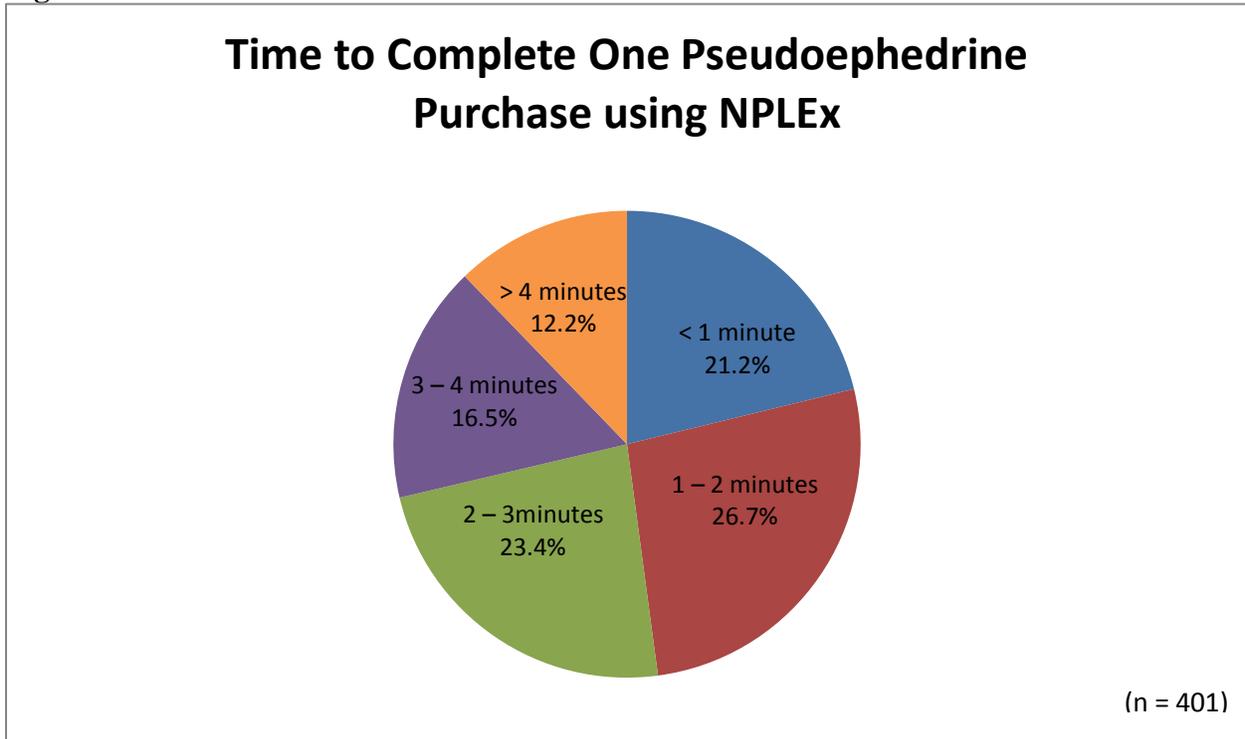
Pharmacists were questioned regarding perceived efficacy of current PSE controls, including the NPLEx electronic tracking system and current quantity limitations, in reducing methamphetamine abuse and laboratory incidents. As shown in Figure E, very few pharmacists reported that the current PSE controls were “very effective” in reducing methamphetamine abuse or laboratory incidents. However, the most frequently selected answer was “somewhat effective”. PSE controls were perceived to be more effective at reducing methamphetamine abuse than reducing methamphetamine laboratory incidents.

Figure E.



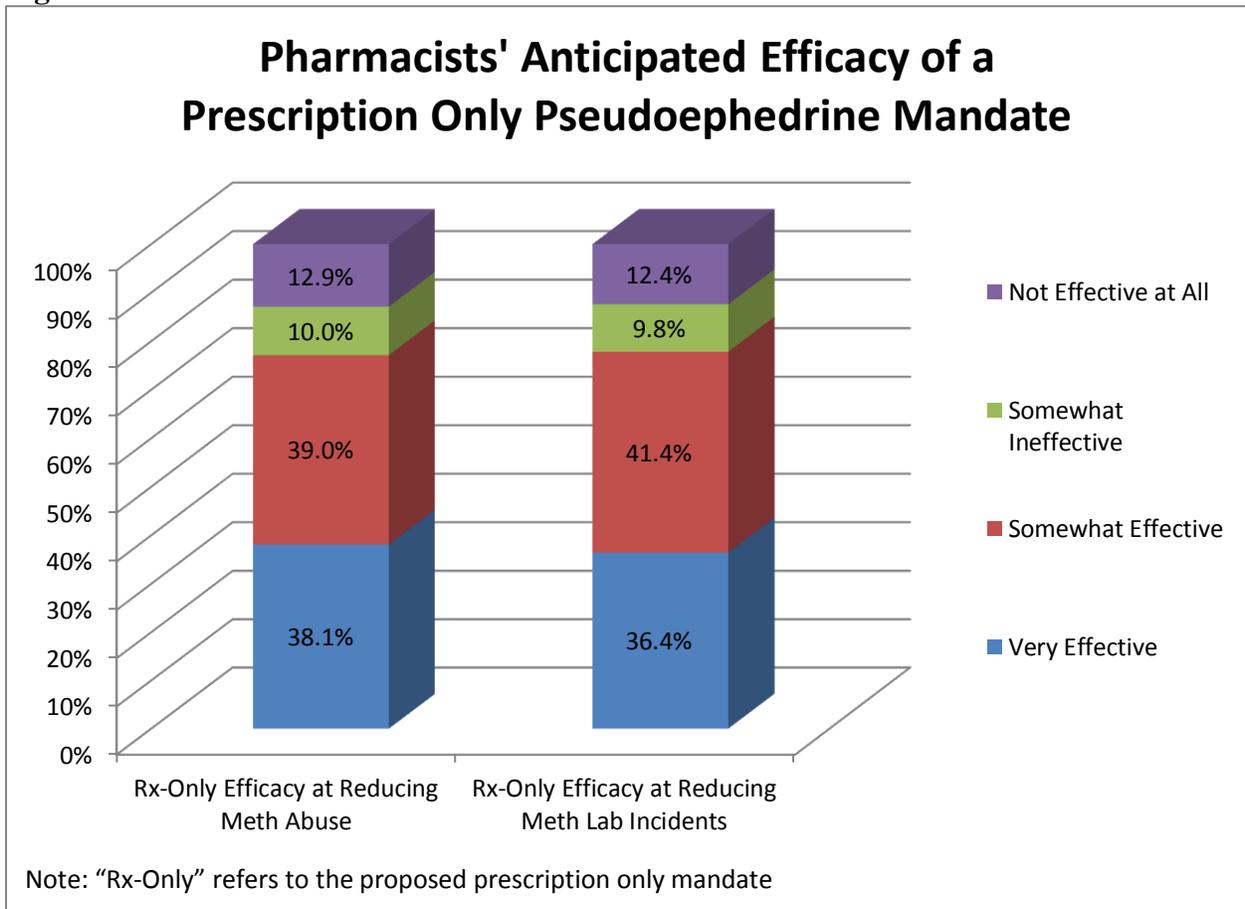
Pharmacists reported a large range in the amount of time required to complete one PSE purchase using NPLEx, as shown in Figure F. Answers were distributed among < 1 minute, 1 – 2 minutes, 2 – 3 minutes, 3 – 4 minutes and > 4 minutes.

Figure F.



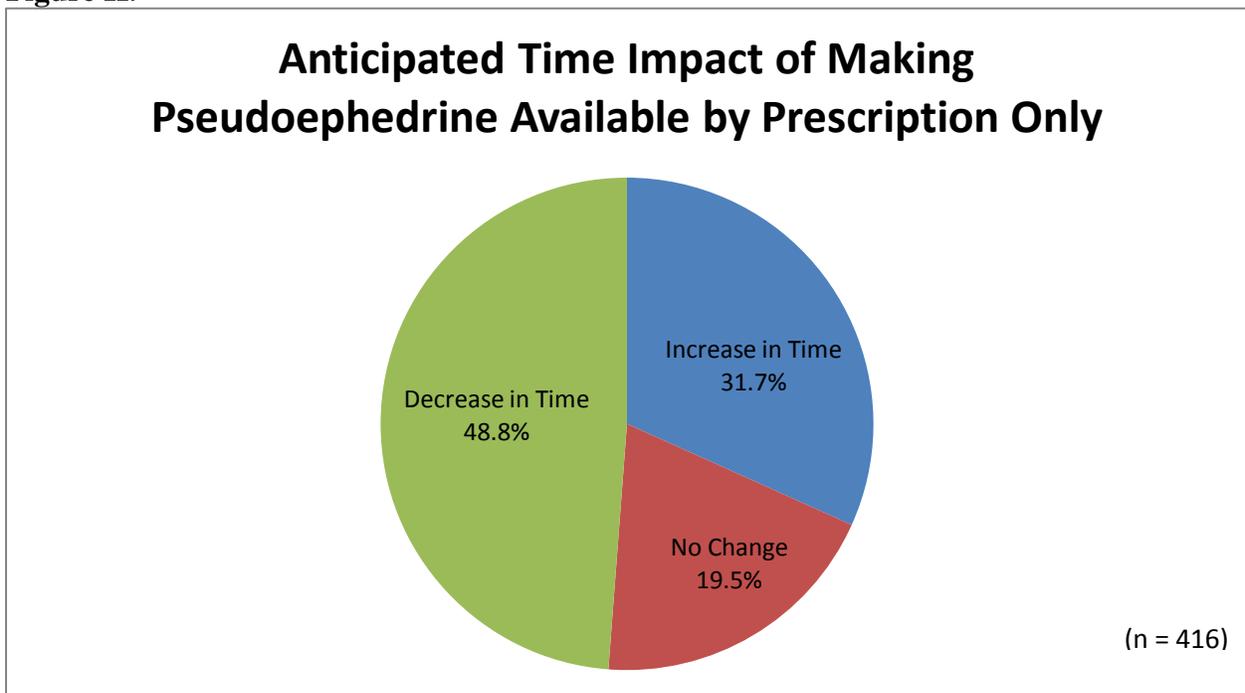
When questioned about the anticipated efficacy of making PSE a legend drug (i.e. requiring a prescription for purchase), approximately 77% of pharmacists reported that the legislation would be at least somewhat effective at reducing methamphetamine abuse and laboratory incidents, as shown in Figure G.

Figure G.



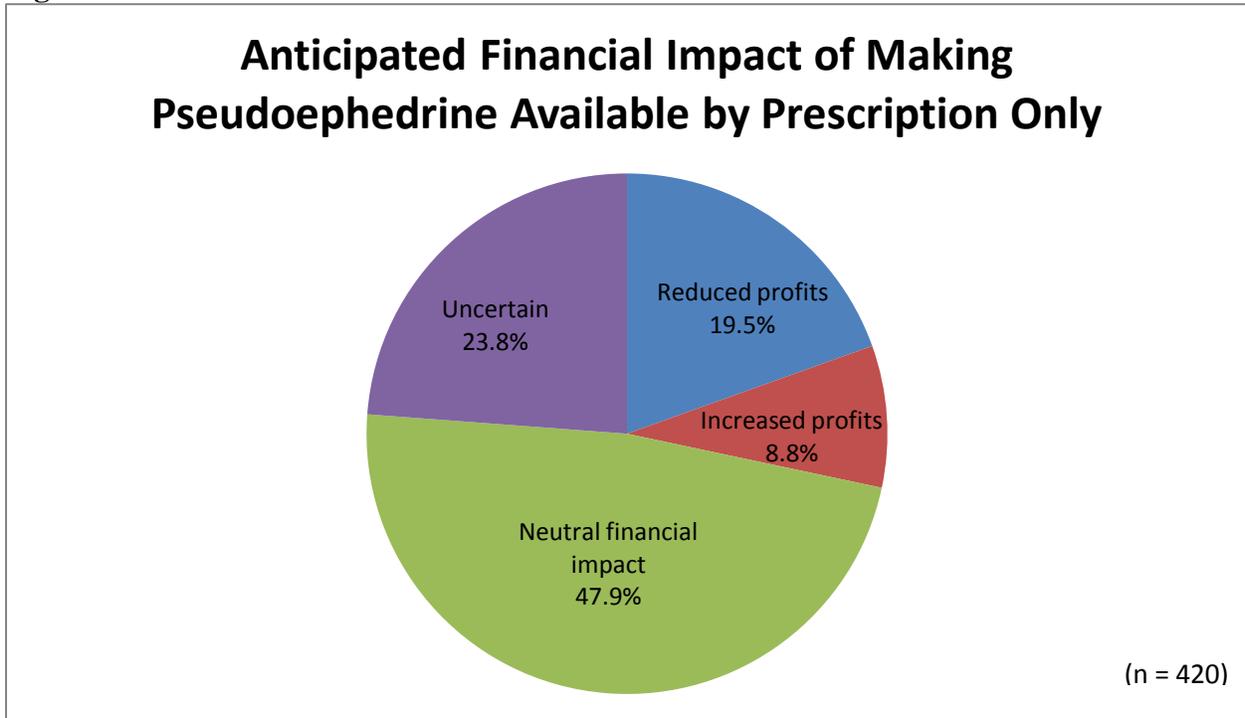
Pharmacists were questioned regarding the anticipated impact of making PSE available by prescription-only on their own pharmacy practice and patients. Nearly half, 48.8%, of pharmacists reported an anticipated decrease in time spent on PSE-related activities if PSE were to be made available by prescription-only, while 31.7% of pharmacists reported an anticipated increase in time spent on PSE-related activities, as shown in Figure H.

Figure H.



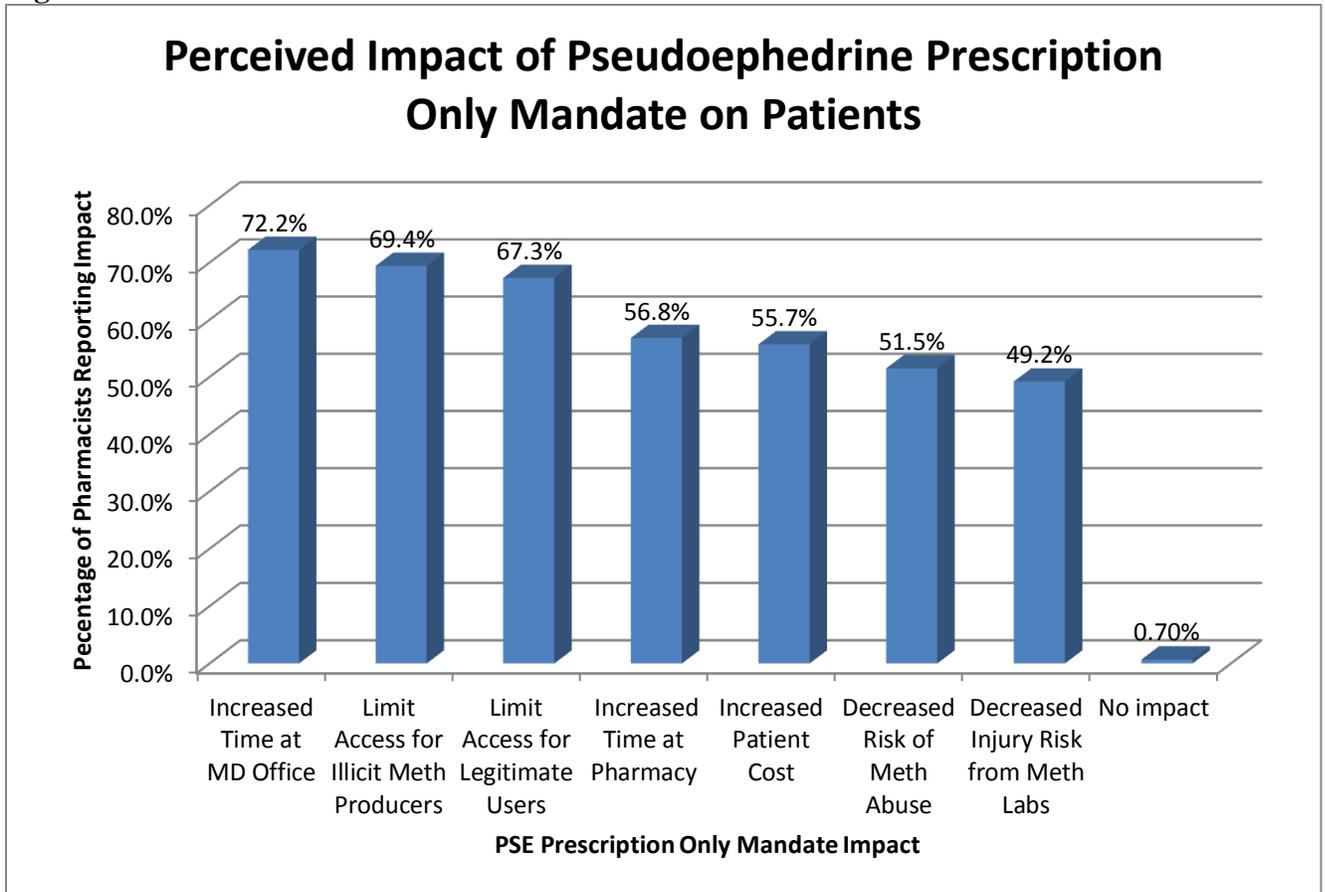
Most pharmacists, 47.9%, reported an anticipated neutral financial impact if PSE were to be made available by prescription-only. However, a large percentage, 23.8%, reported being uncertain of the financial impact on their pharmacy if a prescription were required to obtain PSE (see Figure I).

Figure I.



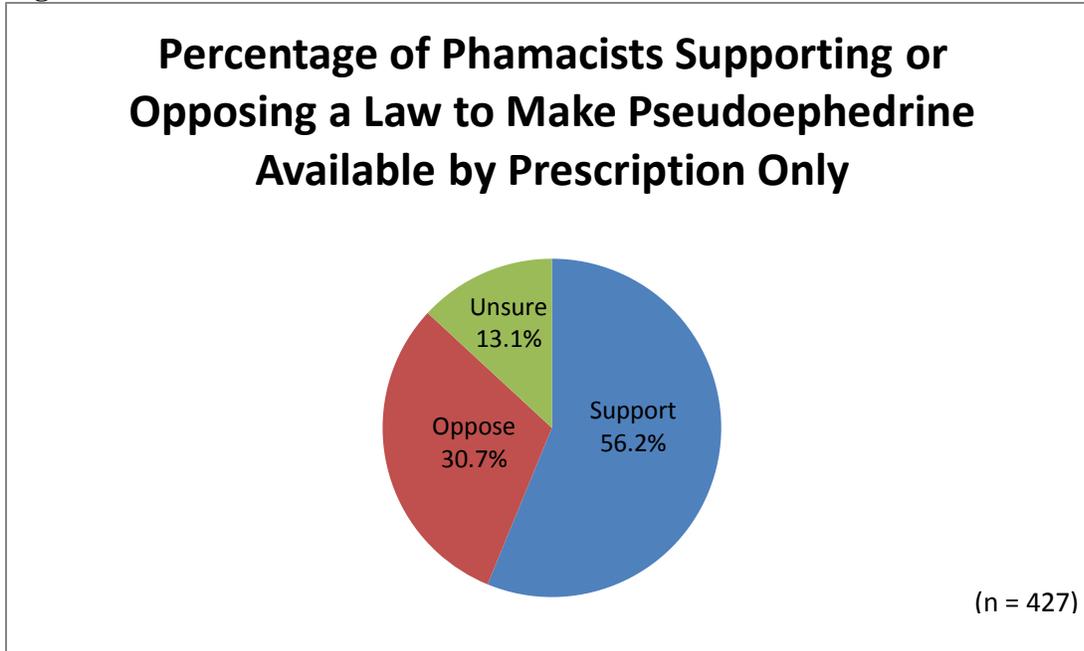
Pharmacists reported that patients would be impacted in a variety of ways if PSE were to be made available by prescription-only. A majority, 72.2%, of pharmacists reported patients would experience increased time at physicians' offices obtaining a prescription for PSE. Additionally, 69.4% and 67.3% of pharmacists reported limited access to PSE for illicit and legitimate users, respectively. Over half of pharmacists reported an anticipated increase in patient time spent at the pharmacy obtaining a prescription for PSE and an increase in patient costs (see Figure J).

Figure J.



As shown in Figure K, 56.2% of pharmacists support a law to make PSE available by prescription-only, while 30.7% of pharmacists oppose the law.

Figure K.



Pharmacists reported the primary reason that they support or oppose a law to make PSE available by prescription-only, as shown in Figures L and M. Additionally, space was provide for respondents to provide a description of the reason for their stance on the proposed legislation if they felt their reasoning was not captured by available answers. The vast majority of comments described why the respondent opposed or was unsure regarding the proposed legislation. Comments appeared to fall into two major categories. Approximately 35% of the comments indicated that methamphetamine abusers/manufactures will always find a way around laws and cited opiates and benzodiazepines as examples of continued abuse and diversion problems despite a prescription requirement. An additional 35% of the comments reported that the government would be punishing law-abiding citizens if a prescription-only requirement were to be implemented. A less common theme was that it is not enough to make PSE prescription-only; PSE should be made a controlled substance and tracked by the Kentucky All Schedule

Prescription Electronic Reporting (KASPER) system. Additionally, several comments stated that pharmacists should use better professional judgment and deny PSE to those who are thought to be using PSE illicitly. Comments reasoned that pharmacists asking more questions and using better professional judgment would ultimately result in fewer illicit producers coming to the pharmacy to purchase PSE. Finally, concern over increased criminal activity (robberies and threatening behavior towards pharmacy staff) if PSE were made prescription-only was discussed in several comments.

Figure L.

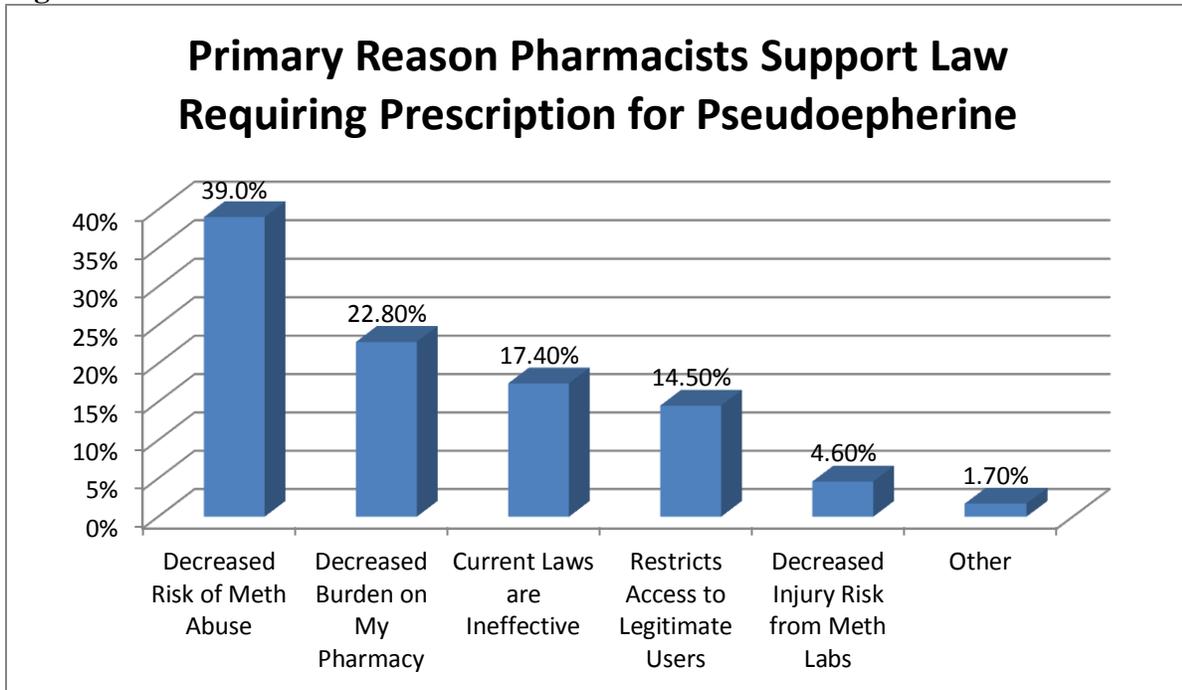


Figure M.

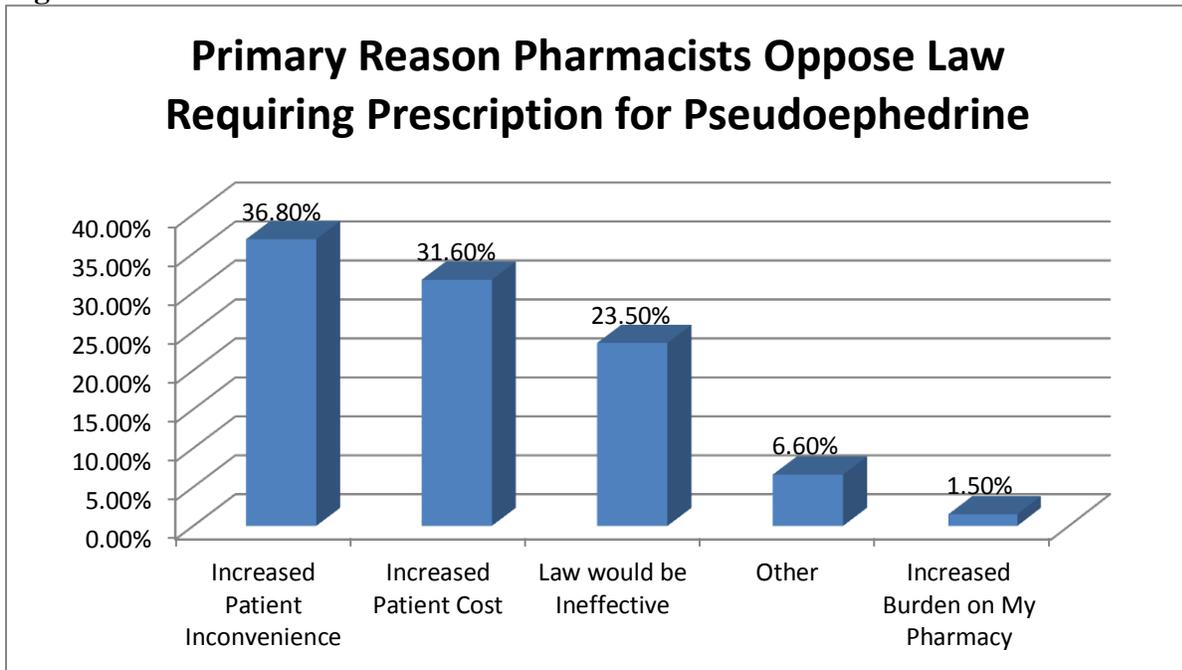


Table 4 breaks down pharmacists’ support or opposition of the legislation by region. Regions 1 and 3, which include northern Kentucky, Lexington and Louisville, remain split on the legislation. However, the remaining regions, which include western, eastern and southern Kentucky, largely support the legislation. The vast majority, 86.0%, of pharmacists in southern Kentucky (region 6) support the legislation.

Table 4. Pharmacists Support or Opposition of Legislation Broken Down by Region

	Regions						Total
	1	2	3	4	5	6	
Oppose Legislation	50	13	32	11	12	8	126
Support Legislation	60	32	35	27	27	49	230
Total	110	45	67	38	39	57	356
Percentage Pharmacists Supporting	54.5%	71.1%	52.2%	71.1%	71.1%	86.0%	64.6%

Bivariate and Multivariate Analyses

An independent group t-test was performed to compare the means of independent versus chain pharmacist reported PSE sales per day (see Table 4). Chain pharmacists sell significantly more PSE per day than independent pharmacists ($t(406) = -8.0569, p = <0.001$). Additionally,

the t-test was repeated to control for size of the pharmacy by dividing reported PSE sales per day by the reported number of prescriptions per day times 100% ($t(398) = -7.5016, p = <0.001$). Thus, chain pharmacies are selling significantly more PSE than independent pharmacies when controlling for pharmacy size. Furthermore the independent group t-test was performed to compare the means of independent versus chain pharmacist reported prescriptions per day ($t(411) = -4.7077, p = <0.001$) and to compare the mean number of years in practice ($t(423) = 3.5356, p = <0.001$).

A 2x2 chi-squared test was performed to compare the anticipated impact on time spent on PSE-related activities if PSE were available by prescription-only (increase or decrease in time spent on PSE-related activities, see Figure H) between independent and chain pharmacists. There was no significant difference between independent and chain pharmacists' anticipated impact on time spent on PSE-related activities if PSE were available by prescription-only, $p = 0.336$. A 2x2 chi-squared test was also performed to compare the anticipated impact on profits if PSE were available by prescription-only (increase or decrease in profit, see Figure I) between independent and chain pharmacists. There was no significant difference between independent and chain pharmacists' anticipated impact on profit if PSE were available by prescription-only, $p = 0.744$.

Logistic regression was conducted to determine the impact of selected independent variables on pharmacists' support of the proposed legislation to make PSE available by prescription-only. Regression results are shown in Table 5.

Table 5. Logistic Regression Model for Pharmacists Supporting the Legislation to Make PSE Available by Prescription-only

Support Legislation to Make PSE Available by Prescription-only	Odds Ratio	Robust Std. Error	95% Confidence Interval
Chain Pharmacists	2.90*	1.22	1.27 – 6.60
Anticipated PSE Rx Only Impact on Time Spent on PSE Activities – Increase in Time			
No Change in Time	5.09*	2.75	1.77 – 14.65
Decrease in Time	10.57*	4.71	4.42 – 25.30
Not Applicable	1.02e7*	1.37e7	7.24e5 – 1.43e8
Anticipated PSE Rx Only Impact on Pharmacy Profits – Reduced Profits			
Increased Profits	9.45*	7.98	1.80 – 49.5
Neutral Financial Impact	4.53*	2.34	1.64 – 12.45
Uncertain	3.78*	2.11	1.27 – 11.26
Not Applicable	3.86e-6*	6.02e-6	1.82e-7 – 8.2e-5
Regions – Bluegrass, Comprehend, North Key			
Kentucky River, Mountain, Pathways	4.57*	2.86	1.34 – 15.59
Seven Counties	1.89	1.02	0.66 – 5.44
Communicare and River Valley	8.17*	6.52	1.71 – 39.03
Four Rivers and Pennyroyal	4.04*	2.53	1.19 – 13.79
Adanta, Cumberland River, Lifeskills	7.99*	5.01	2.34 – 27.30
Perceived Efficacy of Making PSE Rx Only on Reducing Methamphetamine Abuse – Not Effective			
Somewhat ineffective	1.52	1.38	0.26 – 9.02
Somewhat effective	8.22*	6.07	1.94 – 34.93
Very effective	34.05*	30.49	5.89 – 196.97
Perceived Efficacy of Making PSE Rx Only on Reducing Methamphetamine Lab Incidents – Not Effective			
Somewhat ineffective	2.26	2.07	0.38 – 13.55
Somewhat effective	2.56	1.69	0.70 – 9.32
Very effective	8.47*	6.98	1.68 – 42.60
No opinion	4.92	5.47	0.56 – 43.54
Confidence in Identifying Patients Using PSE for a Legitimate Purpose – Extremely Confident			
Somewhat confident	0.67	0.28	0.30 – 1.54
Not confident	0.81	0.72	0.14 – 4.58
Not applicable	0.81	1.16	0.05 – 13.54
Grams PSE per County Resident Sold	0.51	0.36	0.13 – 1.99

Note: * P-value <0.05; “Rx-only” refers to the proposed prescription-only mandate

The logistic regression results showed that chain pharmacists were 2.9 times more likely to support the legislation to make PSE available by prescription-only versus independent pharmacists. Pharmacists that anticipated no change in time related to PSE activities or a decrease in time related to PSE activities if PSE were to be available by prescription-only were 5.09 and 10.57 times more likely to support the legislation, respectively. Anticipated impact on pharmacy profits was also significantly related to pharmacists' support of the legislation requiring a prescription to purchase PSE. Pharmacists reporting an anticipated increase in profits were 9.45 times more likely to support the legislation and pharmacists reporting a neutral financial impact were 4.53 times more likely to support the legislation versus pharmacists reporting an anticipated decrease in profits. The region of pharmacy practice significantly impacted pharmacists' support of the legislation. Compared to pharmacists practicing in region 1, which includes northern Kentucky and Lexington (see Appendix C for map), pharmacists practicing in regions 2, 4, 5, and 6 were 4.57, 8.17, 4.04, 7.99 times more likely to support the legislation, respectively. Region 3, which includes Louisville, was not significant and reported results more similar to region 1.

Pharmacists anticipating the legislation to be somewhat effective or very effective at reducing methamphetamine related abuse were 8.22 and 34.05 times more likely to support the legislation versus pharmacists reporting that the legislation would not be effective at all. The results were not significant for anticipated reduction in methamphetamine lab incidents, except when pharmacists reported the legislation to be very effective in reducing lab incidents. Pharmacists anticipating the new legislation to be very effective at reducing lab incidents were 8.47 times more likely to support the legislation versus pharmacists anticipating the legislation to not be effective at all. Interestingly, pharmacists' reported confidence in identifying patients

utilizing PSE for a legitimate medical purpose is not significantly related to support of the legislation. Furthermore, grams of PSE sold per county resident is not significantly related to support of the legislation.

Discussion

There is currently very little data available about the opinions of healthcare providers, specifically pharmacists, regarding methamphetamine precursor chemical controls. The only available studies investigated the opinions of Australian and New York pharmacists regarding OTC PSE regulations requiring logging of PSE purchases.^{20,22} Furthermore, studies funded by the Asthma and Allergy Foundation of America (AAFA) and the Consumer Health Products Association (CHPA), which are organizations that largely oppose the proposed prescription-only PSE legislation, have shown that a majority of consumers oppose legislation requiring a prescription to purchase PSE and that the legislation would unduly burden law-abiding citizens.^{18,19} This study aims to gain a better understanding of Kentucky pharmacists' opinions of current precursor controls and proposed legislation to make PSE available by prescription-only.

Hospital and specialty pharmacists were excluded from the analysis in order to focus on pharmacists practicing in a community pharmacy setting, including independent and chain pharmacies. Community pharmacists are more visibly impacted by PSE controls. There were significant differences between independent and chain pharmacists in terms of the reported number of prescriptions filled per day, number of PSE purchases per day and the number of years in practice. Significantly more PSE was reported to be sold on a daily basis in chain pharmacies, 13.8 purchases per day versus 4.2 purchases per day. A potential reasoning could be the sheer difference in store size and the number of customers entering the pharmacy per day;

independent pharmacists reported filling an average of 277 prescriptions per day versus 355.5 prescriptions per day in chain pharmacies. On-the-other-hand, several written comments referenced the push from chain pharmacy management to sell PSE, “Independent pharmacists are more reserved in selling PSE to patients - chain pharmacists are impacted by store managers/profit”. It is possible that independent pharmacists feel more empowered to develop their own store policies in the best interest of patients regarding PSE purchases, while chain pharmacists are required to follow corporate policies aimed at increasing profits. Additionally, chain pharmacists were 2.90 times more likely to support the legislation to make PSE available by prescription-only versus independent pharmacists.

The anticipated efficacy of the proposed legislation to require a prescription in order to purchase PSE was reported by approximately 77% of pharmacists to be at least somewhat effective in reducing methamphetamine abuse and laboratory incidents. Despite the large number of pharmacists reporting at least some anticipated efficacy of the proposed legislation requiring a prescription to purchase PSE, 56.2% of pharmacists reported supporting a law to make PSE available by prescription-only and 30.7% of pharmacists reported opposition to the law. The survey results showed that the majority of pharmacists, approximately 68%, opposing the proposed legislation reported doing so based on patient specific factors, including increased patient inconvenience and cost. Only 23.5% of the pharmacists opposing the legislation selected anticipated inefficacy of the law as the primary reason for opposing the law. On-the-other-hand, the primary reason pharmacists reported supporting a law requiring a prescription for PSE was decreased risk of methamphetamine abuse and the second most common reason was the anticipated decreased burden on the pharmacy. Additionally, the logistic regression model showed that pharmacists’ anticipated efficacy of making PSE available by prescription-only in

reducing methamphetamine abuse is significantly related to supporting the legislation.

Pharmacists reporting the legislation to be effective in reducing methamphetamine abuse are more likely to support the legislation.

An additional interesting result of the survey involves the time requirements for PSE controls. Pharmacists reported a large range in the time requirements to complete one PSE purchase using the electronic tracking system, NPLEx. Answers varied from less than one minute to greater than four minutes to complete one purchase. A potential reason for the wide variation in reported time to complete one PSE purchase is that pharmacists are not actually completing PSE purchases and are not fully aware of the time requirement. It is likely that pharmacy technicians and interns perform the majority of the PSE purchases. An alternative reason for the wide variation is differing time saving technology among pharmacies. Some pharmacies are able to simply scan identification cards versus manually entering in patient information into the NPLEx website. Additionally, pharmacists were asked to report the anticipated time impact of making PSE available by prescription-only. The majority of pharmacists, 48.8%, reported an anticipated decrease in time spent on PSE-related activities if PSE were to be available by prescription-only and 31.7% of pharmacists reported an anticipated increase in time spent on PSE related activities. However, it has been estimated that the average prescription takes approximately eight minutes to be filled, yet approximately 88% of pharmacist reported that one PSE purchase took less than four minutes.²⁷ It appears that a significant portion of pharmacists either view prescriptions as taking less time to fill than the true time to fill a prescription or pharmacists perceive PSE purchases to take a more significant amount of time than reported according to the survey results as shown in figure H. One potential reasoning for the disconnect is that PSE purchases represent an interruption in the normal workflow of the

pharmacy, which predominately involves filling prescriptions. None-the-less pharmacists were more likely to support the legislation if they anticipated a decrease in time spent on PSE-related activities.

The logistic regression analysis of pharmacists' support of the legislation to make PSE available by prescription showed a significant impact of pharmacy practice region on support for the legislation. Pharmacists practicing in western, eastern and southern Kentucky were significantly more likely to support the proposed legislation. The odds ratios for these regions ranged from approximately 4 to 8 when comparing to the northern Kentucky and Lexington region. Additionally, the descriptive statistics showed that roughly 53% of pharmacists in the northern Kentucky, Lexington and Louisville regions support the legislation while approximately 71% of pharmacists in eastern and western Kentucky support the legislation. Finally, 86% of pharmacists in southern Kentucky support the legislation. Traditionally, methamphetamine production has been associated with western and south central Kentucky, and indicators of methamphetamine are increasing in eastern Kentucky.¹⁴ The pharmacists practicing in areas most strongly associated with methamphetamine appear to be more likely to support the legislation to make PSE available by prescription-only.

Finally, two independent variables were surprisingly not found to have significant impact on pharmacists' support of the proposed legislation to make PSE available by prescription-only. Whether or not a pharmacist is confident in identifying patients utilizing PSE for a legitimate medical purpose was not found to be significantly related to the support of the legislation. The hypothesis that pharmacists not confident in identifying patients utilizing PSE for a legitimate medical purpose would be more likely to support the legislation was not supported by the logistic regression model. Additionally, pharmacists' support of the legislation was not found to be

significantly related to the amount of PSE (grams) sold per county resident. Again, the hypothesis that pharmacists practicing in counties selling more PSE per county resident would be more likely to support the legislation was not supported by the logistic regression model. It is possible that pharmacists are simply not aware of how much PSE is sold per county resident in comparison to other counties.

Limitations

Several limitations exist in regards to this capstone project. The survey response rate, while respectable, only represents 30.6% of the total pharmacist sample surveyed. Additionally, the sample size is relatively small (n=608) and was further reduced to n=431 when hospital pharmacists and pharmacists practicing in “other” settings were excluded from analysis. The sample for analysis, while representing strong internal validity, lacks external validity as only Kentucky pharmacists practicing in a community pharmacy setting were included.

Some of the capstone limitations are simply due to the research survey methodology. The researcher developed the survey questions and it is possible that important response categories might have been missing from fixed-choice questions. Additionally, responses are mostly inflexible and require respondents to select one answer and do not provide much opportunity for discussion or additional details. Another potential issue with survey methodology is response bias and self-selection bias. Pharmacists choosing to respond to the survey may be inherently different from pharmacists not choosing to respond. Unfortunately, given the design of the study, it is not possible to explore potential differences between responders and non-responders.

Conclusion and Implications

In conclusion, the results of the *2012 Pseudoephedrine Survey for Pharmacists* have shed some light on the controversial proposed legislation to make PSE available by prescription-only. Despite current federal legislation and increased Kentucky quantity restrictions and NPLEX tracking, methamphetamine abuse remains a significant problem in Kentucky. This survey was conducted in order to gain a better understanding of the issues surrounding the sale of PSE from the health care provider at the frontline – the pharmacist. By gaining a better understanding of the issues surrounding the sale of PSE it is hoped that effective, future legislation may be enacted to reduce methamphetamine production, laboratory incidents and abuse yet result in the least amount of inconvenience and cost to law abiding citizens.

The survey results showed that 56.2% of Kentucky pharmacists practicing in a community pharmacy support the proposed legislation to make PSE available by prescription-only, 30.7% of pharmacists oppose the legislation and 13.1% of pharmacists are unsure. Furthermore, independent and chain pharmacists significantly differ in the average number of prescriptions filled per day, number of PSE purchases per day and the number of years in practice. Practice site significantly impacts support for the proposed legislation with chain pharmacists being 2.90 times more likely to support the legislation to make PSE prescription-only. One possible explanation for this difference is that independent pharmacists may exhibit more autonomy in the decision making process to sell or not sell PSE to potential customers. Additional factors that influence pharmacist support of the legislation include: anticipated impact of making PSE prescription-only on time spent on PSE-related activities and pharmacy profits, Kentucky region of pharmacy practice, and anticipated impact of making PSE prescription-only on methamphetamine abuse and laboratory incidents. Kentucky region of pharmacy practice

appears to have a large impact on pharmacist support of the legislation. Regions associated more strongly with methamphetamine such as western, eastern, and southern Kentucky appear to more strongly support the proposed legislation.

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Appendix A: 2012 Pseudoephedrine Survey for Pharmacists

2012 Pseudoephedrine Survey for Pharmacists

The survey is for the pharmacist whose name is on the envelope. You may skip any question that you do not want to answer and may write comments next to any question or on a separate page. Your answers are anonymous and your name will not be used in any report.

Please return the survey using the postage paid envelope within the next two weeks

If you have any questions about the survey please call the University of Kentucky survey team at 855-642-0053. If you have any questions about your rights as a volunteer in the research, contact the Office of Research Integrity at the University of Kentucky at 1-866-400-9428. Thank you for your assistance.

Section I: Questions about Your Prior Knowledge of Methamphetamine and Pseudoephedrine (PSE)

1. How aware are you regarding the use of PSE in the production of methamphetamine in clandestine labs?

<input type="checkbox"/> Very aware
<input type="checkbox"/> Somewhat aware
<input type="checkbox"/> I am not aware of the production of methamphetamine in clandestine labs

2. How knowledgeable are you regarding the recent proposals to make PSE a legend (unscheduled) drug available by prescription only in the Commonwealth of Kentucky?

<input type="checkbox"/> Very knowledgeable
<input type="checkbox"/> Somewhat knowledgeable
<input type="checkbox"/> I have no knowledge of the recent proposals

Section II: Impact of Restrictions on PSE

An estimated 35% of methamphetamine is produced illegally in the United States in small clandestine labs. The remaining 65% is imported to the United States from other countries. The production of methamphetamine in clandestine labs poses significant health hazards. There have been recent efforts aimed at controlling access to precursors used in the production of methamphetamine in clandestine labs. One such precursor is pseudoephedrine (PSE).

Effectiveness is often defined as producing a desired result.

3. To what extent do you believe the current National Precursor Log Exchange (NPLEx), formerly MethCheck, is effective at reducing:

A.) Methamphetamine-related abuse?	B.) Methamphetamine-related lab incidents?
<input type="checkbox"/> Not effective at all	<input type="checkbox"/> Not effective at all
<input type="checkbox"/> Somewhat ineffective	<input type="checkbox"/> Somewhat ineffective
<input type="checkbox"/> Somewhat effective	<input type="checkbox"/> Somewhat effective
<input type="checkbox"/> Very effective	<input type="checkbox"/> Very effective
<input type="checkbox"/> I have no opinion	<input type="checkbox"/> I have no opinion

4. On average, how long does it currently take your pharmacy to use NPLEx to complete one PSE purchase?

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
< 30 seconds	30 seconds – 1 minute	1 – 2 minutes	2 – 3 minutes	3 – 4 minutes	> 4 minutes	N/A

5. To what extent do you believe the current retail sales quantity restriction of PSE (9 grams per month) is effective at reducing:

A.) Methamphetamine-related abuse?	B.) Methamphetamine-related lab incidents?
<input type="checkbox"/> Not effective at all	<input type="checkbox"/> Not effective at all
<input type="checkbox"/> Somewhat ineffective	<input type="checkbox"/> Somewhat ineffective
<input type="checkbox"/> Somewhat effective	<input type="checkbox"/> Somewhat effective
<input type="checkbox"/> Very effective	<input type="checkbox"/> Very effective
<input type="checkbox"/> I have no opinion	<input type="checkbox"/> I have no opinion

6. To what extent do you believe making PSE a legend drug (unscheduled) available by prescription only would be effective at reducing:

A.) Methamphetamine-related abuse?	B.) Methamphetamine-related lab incidents?
<input type="checkbox"/> Not effective at all	<input type="checkbox"/> Not effective at all
<input type="checkbox"/> Somewhat ineffective	<input type="checkbox"/> Somewhat ineffective
<input type="checkbox"/> Somewhat effective	<input type="checkbox"/> Somewhat effective
<input type="checkbox"/> Very effective	<input type="checkbox"/> Very effective
<input type="checkbox"/> I have no opinion	<input type="checkbox"/> I have no opinion

Section III: Impact of Making PSE a Legend Drug (Unscheduled) Available by Prescription Only on Your Pharmacy

7. If PSE were to be available by prescription only, how significant of an impact on your pharmacy would you anticipate?

<input type="checkbox"/> Increase in time spent on PSE related activities
<input type="checkbox"/> No change in time spent on PSE related activities
<input type="checkbox"/> Decrease in time spent on PSE related activities
<input type="checkbox"/> Not applicable for my practice setting

8. If PSE were to be available by prescription only, what financial impact would you anticipate to your pharmacy?

<input type="checkbox"/> Reduced profits
<input type="checkbox"/> Increased profits
<input type="checkbox"/> Neutral financial impact
<input type="checkbox"/> Uncertain
<input type="checkbox"/> Not applicable for my practice setting

9. How confident do you feel in your ability to identify your patients who are using PSE for a legitimate medical purpose?

<input type="checkbox"/> Extremely confident
<input type="checkbox"/> Somewhat confident
<input type="checkbox"/> Not confident
<input type="checkbox"/> Unknown
<input type="checkbox"/> Not applicable for my practice setting

10. How would making PSE available by prescription only impact your patients? *Check all that apply.*

<input type="checkbox"/> Increase in patient time spent at physician's office obtaining prescription for PSE
<input type="checkbox"/> Increase in patient time spent in the pharmacy getting a prescription for PSE filled
<input type="checkbox"/> Increase in financial costs for patients
<input type="checkbox"/> Limit access to PSE for those with legitimate needs
<input type="checkbox"/> Limit access to PSE for those attempting to illegally produce methamphetamine
<input type="checkbox"/> Reduce risk of methamphetamine abuse
<input type="checkbox"/> Reduce risk of injury sustained from unsafe methamphetamine clandestine labs
<input type="checkbox"/> No impact

11. At this time, do you support or oppose a law that would require a prescription in order to obtain PSE?

<input type="checkbox"/> Support	→	Please go to question # 12
<input type="checkbox"/> Oppose	→	Please go to question # 13
<input type="checkbox"/> Unsure	→	Please go to question # 14

12. Please indicate the primary reason why you support a law that would require a prescription in order to obtain PSE? *Select one.*

<input type="checkbox"/> Reduces risk of methamphetamine abuse
<input type="checkbox"/> Reduces risk of injury from clandestine lab
<input type="checkbox"/> Decreased burden on my pharmacy dealing with people trying to purchase PSE behind the counter
<input type="checkbox"/> Current laws requiring electronic tracking of PSE are ineffective
<input type="checkbox"/> Restricts access to only those who need the medication
<input type="checkbox"/> Other _____

13. Please indicate the primary reason why you would oppose a law that would require a prescription in order to purchase PSE? *Select one.*

<input type="checkbox"/> Increased cost to patients
<input type="checkbox"/> Increased inconvenience to patients
<input type="checkbox"/> Law would be ineffective
<input type="checkbox"/> Increased burden on my pharmacy to fill additional prescriptions
<input type="checkbox"/> Other _____

14. Please explain why you are currently unsure of your support or opposition of a law that would require a prescription in order to obtain PSE.

Section IV: Practice Information

15. On average, how many prescriptions does your pharmacy fill each day? _____ (# prescriptions)

16. On average, how many PSE purchases are made at your pharmacy each day? _____ (# PSE purchases)

17. In what city/county do you currently practice? _____
(If you practice in more than one city/county, please report the one that you spend the majority of your time in.)

18. What best describes your practice site? *Select one.*

<input type="checkbox"/> Independent Pharmacy
<input type="checkbox"/> Chain Pharmacy
<input type="checkbox"/> Supermarket/ Mass Retailer Pharmacy
<input type="checkbox"/> Hospital Pharmacy
<input type="checkbox"/> Other _____

19. In what year did you receive your professional degree? _____

**THANK YOU FOR COMPLETING THE SURVEY.
PLEASE RETURN IT USING THE ENCLOSED ENVELOPE AS SOON AS POSSIBLE.**

Appendix B: Descriptive Survey Results

How aware are you regarding the use of PSE in the production of methamphetamine in clandestine labs?		
	Frequency	Percentage (%)
Very aware	377	87.7
Somewhat aware	51	11.9
I am not aware	2	0.5
Total Respondents	430	

How knowledgeable are you regarding the recent proposals to make PSE a legend (unscheduled) drug available by prescription-only in the Commonwealth of Kentucky?		
	Frequency	Percentage (%)
Very knowledgeable	204	47.4
Somewhat knowledgeable	215	50.0
I have no knowledge	11	2.6
Total Respondents	430	

To what extent do you believe the current National Precursor Log Exchange (NPLEx), formerly MethCheck, is effective at reducing methamphetamine-related abuse?		
	Frequency	Percentage (%)
Not effective at all	74	17.2
Somewhat ineffective	91	21.2
Somewhat effective	239	55.6
Very effective	16	3.7
I have no opinion	10	2.3
Total Respondents	430	

To what extent do you believe the current National Precursor Log Exchange (NPLEx), formerly MethCheck, is effective at reducing methamphetamine-related lab incidents?		
	Frequency	Percentage (%)
Not effective at all	94	22.2
Somewhat ineffective	93	22.0
Somewhat effective	204	48.2
Very effective	12	2.8
I have no opinion	20	4.7
Total Respondents	423	

On average, how long does it currently take your pharmacy to use NPLeX to complete one PSE purchase?		
	Frequency	Percentage (%)
< 30 seconds	26	6.1
30 seconds – 1 minute	59	13.8
1 – 2 minutes	107	25.1
2 – 3minutes	94	22.0
3 – 4 minutes	66	15.5
> 4 minutes	49	11.5
N/A	26	6.1
Total Respondents	427	

To what extent do you believe the current retail sales quantity restriction of PSE (9 grams per month) is effective at reducing methamphetamine-related abuse?		
	Frequency	Percentage (%)
Not effective at all	116	27.0
Somewhat ineffective	113	26.3
Somewhat effective	179	41.6
Very effective	15	3.5
I have no opinion	7	1.6
Total Respondents	430	

To what extent do you believe the current retail sales quantity restriction of PSE (9 grams per month) is effective at reducing methamphetamine-related lab incidents?		
	Frequency	Percentage (%)
Not effective at all	119	28.1
Somewhat ineffective	112	26.4
Somewhat effective	167	39.4
Very effective	11	2.6
I have no opinion	15	3.5
Total Respondents	424	

To what extent do you believe making PSE a legend drug (unscheduled) available by prescription-only would be effective at reducing methamphetamine-related abuse?		
	Frequency	Percentage (%)
Not effective at all	55	12.8
Somewhat ineffective	43	10.0
Somewhat effective	167	38.9
Very effective	163	38.0
I have no opinion	1	0.2
Total Respondents	429	

To what extent do you believe making PSE a legend drug (unscheduled) available by prescription-only would be effective at reducing methamphetamine-related lab incidents?		
	Frequency	Percentage (%)
Not effective at all	52	12.2
Somewhat ineffective	41	9.6
Somewhat effective	174	40.9
Very effective	153	35.9
I have no opinion	6	1.4
Total Respondents	426	

If PSE were to be available by prescription-only, how significant of an impact on your pharmacy would you anticipate?		
	Frequency	Percentage (%)
Increase in time spent on PSE related activities	132	30.9
No change in time spent on PSE related activities	81	19.0
Decrease in time spent on PSE related activities	203	47.5
Not applicable for my practice setting	11	2.6
Total Respondents	427	

If PSE were to be available by prescription-only, what financial impact would you anticipate to your pharmacy?		
	Frequency	Percentage (%)
Reduced profits	82	19.1
Increased profits	37	8.6
Neutral financial impact	201	46.7
Uncertain	100	23.3
Not applicable for my practice setting	10	2.3
Total Respondents	430	

How confident do you feel in your ability to identify your patients who are using PSE for a legitimate medical purpose?		
	Frequency	Percentage (%)
Extremely confident	132	31.1
Somewhat confident	256	60.2
Not confident	28	6.6
Unknown	4	0.9
Not applicable for my practice setting	5	1.2
Total Respondents	425	

How would making PSE available by prescription-only impact your patients? <i>Check all that apply.</i>		
	Frequency	Percentage (%)
Increase in patient time spent at physician's office obtaining prescription for PSE	311	72.2
Increase in patient time spent in the pharmacy getting a prescription for PSE filled	245	56.8
Increase in financial costs for patients	240	55.7
Limit access to PSE for those with legitimate needs	290	67.3
Limit access to PSE for those attempting to illegally produce methamphetamine	299	69.4
Reduce risk of methamphetamine abuse	222	51.5
Reduce risk of injury sustained from unsafe methamphetamine clandestine labs	212	49.2
No impact	3	0.7

At this time, do you support or oppose a law that would require a prescription in order to obtain PSE?		
	Frequency	Percentage (%)
Support	240	56.2
Oppose	131	30.7
Unsure	56	13.1
Total Respondents	427	

Please indicate the primary reason why you support a law that would require a prescription in order to obtain PSE? <i>Select one.</i>		
	Frequency	Percentage (%)
Reduces risk of methamphetamine abuse	94	39.0
Reduces risk of injury from clandestine lab	11	4.6
Decreased burden on my pharmacy dealing with people trying to purchase PSE behind the counter	55	22.8
Current laws requiring electronic tracking of PSE are ineffective	42	17.4
Restricts access to only those who need the medication	35	14.5
Other	4	1.7
Total Respondents	241	

Please indicate the primary reason why you would oppose a law that would require a prescription in order to purchase PSE? <i>Select one.</i>		
	Frequency	Percentage (%)
Increased cost to patients	43	31.6
Increased inconvenience to patients	50	36.8
Law would be ineffective	32	23.5
Increased burden on my pharmacy to fill additional prescriptions	2	1.5
Other	9	6.6
Total Respondents	136	

On average, how many prescriptions does your pharmacy fill each day?			
Mean	Std. Dev.	Median	Range
325.5	168.3	300	70 - 1000
Total Respondents			411

On average, how many PSE purchases are made at your pharmacy each day?			
Mean	Std. Dev.	Median	Range
10.1	12.6	5	0 - 120
Total Respondents			408

What best describes your practice site? <i>Select one.</i>		
	Frequency	Percentage (%)
Independent Pharmacy	169	39.2
Chain/ Supermarket/ Mass Retailer Pharmacy	262	60.8
Total Respondents	431	

Number of Years in Practice. (Derived from “In what year did you receive your professional degree?”)			
Mean	Std. Dev.	Median	Range
20.3	15.3	18	1 - 61
		Total Respondents	423

Appendix C: Kentucky Regions²⁵

