
Managing Access to Pseudoephedrine /

Potential Impacts of a Prescription-Only Policy versus Real-Time Stop Sale Technology

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Table of Contents

Executive Summary	2
Introduction	5
Research Methodology and Data Sources	6
Policy Background	7
Government Authority to Determine Drug Access	7
Federal Regulation of PSE	8
State Regulation of PSE Products	9
Current Status of Fighting Methamphetamine	12
Policy Outlook	12
Impacts of Restricting Consumer Access to PSE Products	13
Market Response to Changes in Access to PSE Products	14
Consumer Utilization and Spending on PSE Products	14
Viability of PE Products as an Alternative to PSE	15
PSE Product Pricing	15
State Government Costs	16
Provider and Payer Utilization	18
Healthcare Provider Visits to Obtain Prescription for PSE Products	18
Provider Workforce, Work Load, and Reimbursement Issues	19
Commercial Health Plan Spending	21
Medicare and Other Federal Healthcare Program Spending	22
Medicaid Spending	23
Barriers for the Uninsured	24
Costs to Employers	25
Conclusions	26
Technical Appendix	28
Notes	34

Executive Summary

Over the last decade, federal and state initiatives have resulted in placement restrictions and retail sales limits on nonprescription medicines containing pseudoephedrine (PSE). PSE is an active ingredient in many Food and Drug Administration (FDA)-approved nasal decongestant products used by roughly 18 million American families¹ for relief from the symptoms caused by colds and allergies; however, it also can be used to manufacture methamphetamine, an abused and illegal psychostimulant. Under federal regulations, retailers must store nonprescription products containing PSE behind-the-counter (BTC) or in a locked cabinet; adhere to specific daily and monthly purchaser limits; and maintain a recordkeeping logbook of sales. Consumers, in turn, must show identification and sign a logbook when purchasing nonprescription PSE products.

Stakeholders acknowledge the devastating impact of methamphetamine in relation to law enforcement, safety, and health. In an effort to further curb the use of PSE in illegal methamphetamine production in small clandestine labs, many states have taken additional steps to prevent illegal PSE sales. In some states, products containing PSE are classified as Schedule V controlled substances, which must be kept behind the pharmacy counter (BTPC) and sold by a pharmacist. In addition, a number of states are implementing real-time statewide electronic tracking of PSE purchases to effectively enforce federal retail limits and deny illegal transactions. Using sales records that retailers are required to maintain by federal law, and which are made available to law enforcement, these systems verify whether the requested PSE purchase is within daily and monthly purchaser legal limits and block illegal sales in real time. Nineteen states had adopted real-time stop sale technology as of October 2011. Two states—Oregon in 2006 and in Mississippi in 2010—adopted stricter limitations on access to PSE-containing medicines by making PSE a Schedule III controlled substance, requiring a physician's prescription.

Stakeholders continue to debate the appropriate balance between maintaining consumer access to nonprescription drugs containing PSE and minimizing the risk of diversion of PSE-containing drugs for illicit production of methamphetamine. Proponents of a prescription-only policy believe a prescription requirement best thwarts diversion of PSE. Advocates of real-time stop sale technology contend this approach addresses illegal purchases without placing undue restrictions on consumers who appropriately use PSE products or imposing new costs on the healthcare system. Given the recent implementation of the state initiatives to prevent illegal PSE sales, very limited data exist on the relative benefits of a prescription-only policy for PSE versus real-time statewide electronic sales tracking in mitigating diversion of PSE-containing drugs.

This paper aims to identify the potential economic impacts of each approach to controlling consumer access to PSE-containing drugs on major stakeholders—the federal government, state governments, healthcare providers, commercial health insurance plans,

and consumers—and, where possible, to quantify those effects at a national level. We did not analyze the law enforcement, environmental clean-up, or social costs associated with the illegal diversion of PSE. Our perspective on the impact of policy changes on these stakeholder groups is informed primarily by our review of published research, data on PSE product sales, and data on healthcare service utilization. Figure 1 summarizes the impacts explored and our findings.

Figure 1: Potential Impacts on Key Stakeholders of Policies Aimed at Preventing Illegal PSE Sales

Stakeholder	Potential Impacts of Prescription-Only Policy	Potential Impacts of Real-Time Stop Sale Technology
Consumers	Higher out-of-pocket expenses due to additional provider visits	No impact to costs for provider visits
	Higher out-of-pocket expenses due to price increases for PSE products	No impact to prices for PSE products or consumer out-of-pocket costs
	Higher employee contributions to health insurance premiums	No impact to employee contributions for health insurance
	Delay in symptom relief while prescription is obtained and filled	Timely access to PSE products for appropriate use in treating symptoms
	Longer wait times at physician offices	No impact to wait times at physician offices
Employers	Increased employee absenteeism due to provider visits or untreated symptoms	No impact to current levels of employee absenteeism
	Reduced employee productivity due to waits for provider visits and untreated symptoms	No impact to current levels of employee productivity
	Increased costs of employer contributions to employee health insurance premiums	No impact to employer contributions for health insurance
Private health plans	Increased spending on prescription drugs	No impact on prescription drug spending
	Increased spending on provider visits	No impact on provider visit spending
	Increased premiums from higher spending on drugs and provider visits	No impact on premiums
Public payers (e.g., Medicare, Medicaid)	Increased spending on prescription drugs	No impact to current trends on drug spending
	Increased spending on provider visits	No impact on provider visit spending
Providers	Increased revenue opportunity from more visits	No impact to provider revenues
	Increased demand for uncompensated activities (use of phone, fax, email instead of visits)	No impact to demand for provider time on uncompensated activities
	Increased administrative burdens for scheduling visits and handling additional prescriptions	No impact to provider administrative activities
	Reduced time with patients from increased chance of overcrowding/unmet demand	No impact to demands for provider time with patients
State governments	Reduced sales tax revenue when moving PSE products to prescription-only status	Stable sales tax revenue from PSE-containing products

A prescription-only requirement will reduce PSE purchase for illicit use, thus potentially curbing methamphetamine production and related costs from a societal perspective. However, it also will create access restrictions for legitimate users of PSE, prolonging the

timeline to symptom relief for consumers waiting to get a prescription from their provider. While some patients would be able to request a prescription for PSE products while visiting their physician for other reasons, a subset of patients would need to schedule a separate visit to the physician just to obtain the prescription. Such an increase likely would present workload and administrative challenges for providers, especially in areas with primary care physician shortages. In addition, employers likely will see more employee absenteeism and less productivity while staff wait for physician visits. These challenges would be heightened during peak periods for cold, allergy, and sinus symptoms.

Our model indicates that a prescription-only policy would result in approximately 579,315 new physician visits for consumers in the first year. These new physician visits also would increase consumer costs by as much as \$26.6 million in the first year as a result of the associated out-of-pocket payments. Similarly, public and private payers would incur about \$23.9 million in additional spending associated with these new provider visits and an additional \$65.8 million due to coverage of PSE products. Higher payer spending typically results in higher health insurance premiums for consumers and employers, which reasonably could be expected to result from PSE prescription-only policies. Finally, state taxes on nonprescription medications would drop, and states would lose tax revenues of \$219.2 million over 10 years while simultaneously facing increased costs from Medicaid beneficiaries.

In part because of these additional costs, advocates of real-time stop sale technology for retail PSE purchases believe it is the better alternative to prescription-only status for PSE. They believe the technology enables retailers to effectively enforce federal retail limits, deny illegal transactions in real time, and provide timely access for consumers purchasing PSE for appropriate use. However, proponents of prescription-only status for PSE question the reliability of the real-time stop sale systems in preventing the variety of approaches taken by criminals to obtain PSE for illicit use, such as the practice of “smurfing,” whereby criminals use multiple or fraudulent identification or travel to neighboring states to make illegal PSE purchases.

As policymakers continue exploring options for preventing illegal sales of PSE, it would be prudent to fully vet the assumptions about the public health and economic benefits given the potential of unintended consequences on the overall healthcare system. It is possible that the expected benefits of both real-time stop sale technology and prescription-only PSE policies could be tested under the current framework without further compromising consumer access. Policymakers can pursue the implementation of interstate real-time stop sale systems as part of a comprehensive approach to addressing the illegal diversion of PSE for the manufacture of methamphetamine while exploring the potential benefits of a prescription-only policy for PSE by evaluating data from the Oregon and Mississippi initiatives. Ultimately, successfully addressing the methamphetamine problem requires a comprehensive strategy that incorporates the need for consumers to have appropriate access to PSE-containing medication, law enforcement concerns, demand reduction, and treatment.

Introduction

Over the last decade, federal and state initiatives have resulted in placement restrictions and retail sales limits on nonprescription medicines containing pseudoephedrine (PSE). PSE is an active ingredient in many Food and Drug Administration (FDA)-approved nasal decongestant products used by roughly 18 million American families² for relief from the symptoms caused by colds and allergies; however, it also can be used to manufacture methamphetamine, an abused and illegal psychostimulant. Currently, federal law requires retailers to store nonprescription PSE products behind-the-counter (BTC) or in a locked cabinet; adhere to specific daily and monthly purchaser limits; and maintain a recordkeeping logbook of sales. In some states, products containing PSE are classified as Schedule V controlled substances, which must be kept behind the pharmacy counter (BTPC) and sold by a pharmacist. When purchasing nonprescription PSE products at retail pharmacies nationwide, consumers must show identification and sign a logbook.

In an effort to further prevent the use of PSE in illegal methamphetamine production in small clandestine labs, a number of states are implementing a real-time statewide electronic tracking of PSE purchases to effectively enforce federal retail limits and deny illegal transactions. This approach is supported by manufacturers of nonprescription medicines containing PSE, who have committed to fund real-time stop sale systems in any state that mandates real-time, statewide electronic blocking of illegal PSE sales. In addition to verifying whether the requested purchase is within legal limits, these systems also assist state and federal enforcement authorities in identifying potential criminal activity.

Of the 21 states that had enacted legislation to address illegal PSE sales as of October 2011, 19 adopted real-time stop sale technology, while only two adopted stricter limitations on access to PSE-containing medicines by requiring a doctor's prescription. In 2006, Oregon made PSE a Schedule III controlled substance, requiring a prescription. Mississippi also implemented prescription-only status for PSE products in 2010 by making all products containing PSE Schedule III controlled substances.

Limited data exist on the potential benefits and costs of each approach on major stakeholders, including the federal government, state governments, healthcare providers, commercial health insurance plans, and consumers. This paper aims to identify the potential economic impacts of each approach to control consumer access to PSE-containing drugs on these major stakeholders and, where possible, to quantify those effects at a national level. We do not examine the question of the effectiveness of the alternative access control measures on illegal diversion of PSE.

We begin with a brief discussion of the research and economic modeling that informed this analysis, present an overview of recent federal and state initiatives to further control consumer access to PSE, and discuss the current policy environment. In subsequent sections, we discuss the implications of a prescription-only policy for PSE versus real-time statewide stop sale systems and consequences for major stakeholders.

Research Methodology and Data Sources

We based the findings in this paper on a variety of research and analytical methods. We sought the opinion of healthcare policy experts and reviewed published research to identify the major stakeholders who could be affected by federal and state initiatives to control consumer access to products containing PSE and the potential consequences of such policy changes. We supplemented this qualitative research with data on PSE product sales and data on healthcare service utilization to conduct an economic impact analysis. We did not analyze the economic impact of PSE access control approaches on law enforcement, environmental clean-up, or social costs.

While many stakeholders may be directly and indirectly affected by changes in policy aimed at minimizing illegal purchases of PSE products, our analyses focus primarily on the major stakeholders we believe will be affected most directly by policy changes: the federal government, state governments, healthcare providers, commercial health insurance plans, and consumers.

Our secondary research consisted of a literature review of publicly available documents on:

- Federal and state policies on PSE access;
- Effectiveness of governmental policies on methamphetamine production and usage;
- Market impacts of federal and state policies on PSE product access;
- General information on PSE utilization, healthcare provider, and health plan trends; and
- Position statements on prescription-only policies and real-time stop sales technology mandates for PSE products.

To supplement our secondary research, we used public and private datasets to model the economic impacts of a PSE prescription-only policy. We examined the costs associated with the major stakeholders from two key perspectives: changes in the utilization and price of PSE-containing products, and the cost and access burdens associated with increased healthcare provider visits required to obtain a prescription for PSE-containing products. The model explores the direct costs related to the federal government, state governments, commercial health plans, and consumers; it does not include other indirect costs like worker productivity, which are examined qualitatively.

The effects of legislation requiring prescriptions for drug products containing PSE depend heavily on changes in consumer behavior. We based our model primarily on observable measures, such as changes in PSE sales following the enactment of the prescription-only policies in Oregon and Mississippi. However, consumer behavior also is influenced by coverage decisions by commercial health insurance plans and public programs, on which little data exist. Due to these limitations, much of our modeling on provider visit costs is based on assumptions informed by our analysis of survey data on healthcare service use by various populations.

Our methodology for estimating the economic impact of the policy on stakeholders at the national level builds off estimates at the state level and aggregates the costs across states for a total national estimate. This approach allowed us to forecast the state-level impacts and compare differences across states for various stakeholder groups. We used state-specific data for the model inputs when available and reliable; however, when the data were not available at the state level, we used national- or regional-level data indexed to the state. In very few cases when a state index could not be estimated reliably, we used the regional or national estimates applied to all states in that particular region or all states.

Our model also was designed to project a 10-year federal score. We accounted for changes in the overall U.S. population as well as changes in enrollment for commercial payers. Additionally, we accounted for the effect of enrollment into the federal and state health insurance exchanges beginning in 2014 as a part of the Affordable Care Act (ACA). For more information about our data and literature sources, key assumptions, methodology and data analysis, and limitations, see the Technical Appendix.

Policy Background

Governmental Authority to Determine Drug Access

A complex web of agencies and authorities at both the state and federal levels govern the distribution of, and access to, drugs. All of these authorities have a stake in determining current and future access to medicinal products containing PSE. The FDA acts as the initial gatekeeper. To legally market a drug in the United States, the manufacturer must prove to the FDA that the drug is safe and effective. The FDA also governs consumer access by determining whether a product requires the intervention of a medical professional such as a physician, and therefore should require a prescription, or if consumers should have the ability to purchase and administer a given product independently. Thus, the FDA determines consumer access by placing products into one of two categories: prescription or nonprescription.

Drugs with potential for abuse face additional access requirements. The Drug Enforcement Administration (DEA) administers the Controlled Substances Act (CSA), which includes a “schedule” of drugs with a high likelihood of abuse. The CSA Schedule categorizes drugs in five tiers based on their potential for abuse and establishes a corresponding set of access restrictions (e.g., Schedule I includes the most dangerous, and therefore most restricted products). The DEA also is responsible for monitoring chemicals “listed” in the Chemical Diversion and Trafficking Act of 1988 (CDTA), including PSE. Listed chemicals have legitimate commercial purposes but also can be used in the illicit manufacture of controlled substances. Both Congress and the DEA can schedule or list drugs, effectively creating more levels of control on access beyond the FDA’s two categories of prescription and nonprescription.

In addition to federal rules, states can enact their own access restrictions. States often use their authority over boards of pharmacy, which license pharmacists and pharmacies, to manage how and which drugs are sold in pharmacies and dispensed by pharmacists. State laws can place additional restrictions on consumer access to drugs beyond federal requirements, but they cannot eliminate federal restrictions.

Federal Regulation of PSE

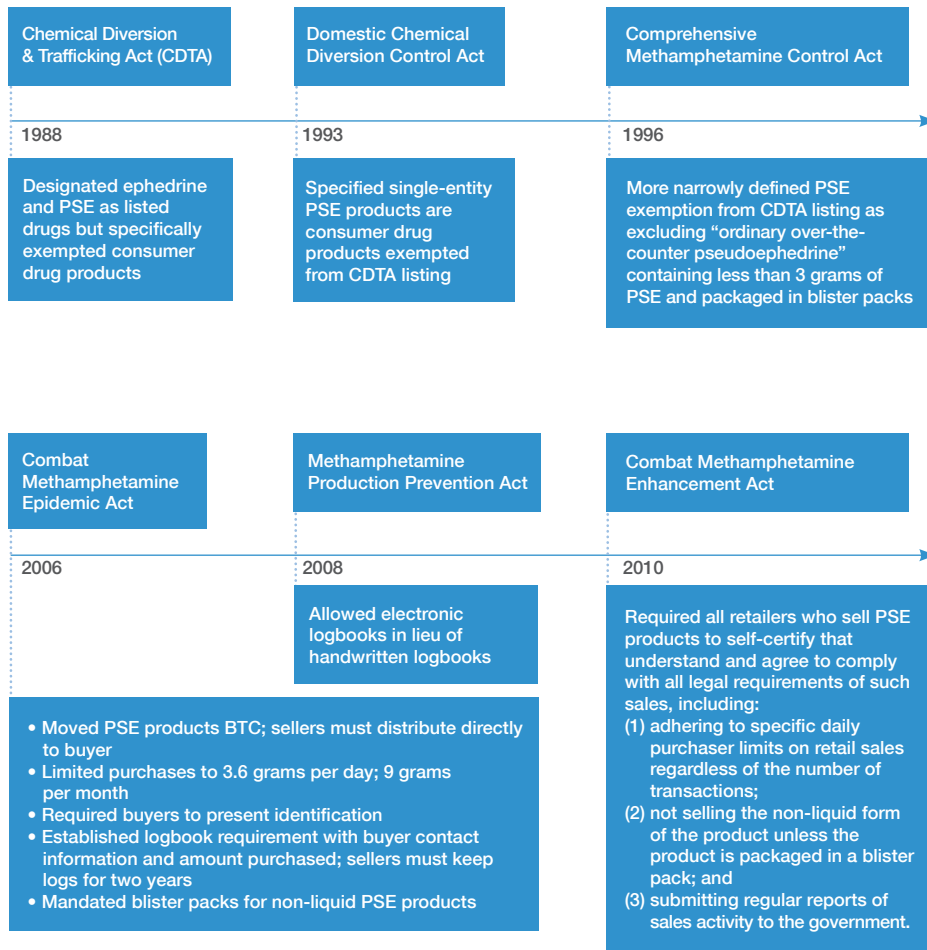
The CDTA designated ephedrine and PSE as listed substances; however, nonprescription drug products containing PSE were exempted from recordkeeping and reporting requirements. In 1993 and 1996, Congress revised this exemption to more clearly separate consumer products containing PSE from federal restrictions intended to control methamphetamine production.³ Other federal laws have focused on regulating importation and international shipment of consumer PSE products as a methamphetamine precursor.⁴

In 2006, the Combat Methamphetamine Epidemic Act (CMEA) initiated tougher regulation of consumer purchase of PSE-containing products. Under the law, consumers can buy no more than 3.6 grams per day or 9 grams per month; distributors must package non-liquid PSE products in thick plastic packaging that isolates two-tablet dosages into one unit called a blister pack; all sellers must store PSE products out of immediate customer access; and all sellers must directly distribute the product into the custody of the buyers. CMEA also requires that buyers present identification and enter contact information into a logbook, matched with the amount of product purchased, which the seller must keep for two years following the sale to aid law enforcement reviews as needed.⁵

Subsequent to the CMEA, the Methamphetamine Production Prevention Act of 2008 amended the registration requirements to specifically allow sellers of nonprescription PSE products to record such purchases using electronic logbooks rather than handwritten logbooks.⁶ Supporters argued that electronic logbooks were a more effective and efficient vehicle for law enforcement monitoring of PSE purchases.

The recent enactment of the Combat Methamphetamine Enhancement Act of 2010 (“Enhancement Act”) increases retailer self-certification requirements. The Enhancement Act amends the CSA by requiring all regulated retail sellers of products containing PSE to submit to the Department of Justice a self-certification with a statement that the seller understands and agrees to comply with the legal requirements associated with these products.⁷ Figure 2 summarizes these federal policies regulating consumer purchases of PSE.

Figure 2: Federal Legislation Restricting Consumer Access to Pseudoephedrine Products



Sources:

- Chemical Diversion and Trafficking Act. Pub. L. 100-690. November 18, 1988.
- Domestic Chemical Diversion Control Act. Pub. L. 103-200. December 17, 1993.
- Comprehensive Methamphetamine Control Act. Pub. L. 104-237. October 3, 1996.
- Combat Methamphetamine Epidemic Act. Pub. L. 109-177, Title VII. March 9, 2006.
- Methamphetamine Production Prevention Act. Pub. L. 110-415. October 14, 2008.
- Combat Methamphetamine Enhancement Act. Pub. L. 111-268. October 12, 2010.

State Regulation of PSE Products

Prior to the passage of CMEA in 2006, some state legislatures had enacted requirements to restrict access to PSE in order to curb diversion for local methamphetamine production. In the spring of 2004, Oklahoma passed a bill classifying PSE as a Schedule V controlled substance,⁸ thus requiring PSE-based products to be kept BTPC and sold by a licensed pharmacist. Although PSE purchases in Oklahoma did not require a prescription, the state required a minimum purchase age of 18, identification for purchase, and logging of all purchases. Oregon soon followed Oklahoma's example, with a 2004 Board of Pharmacy

temporary administrative rule requiring sellers to store PSE products BTC.⁹ This temporary rule developed into a permanent rule in April 2005, and also required purchasers to present photo identification and sellers to maintain logs of all PSE sales. By late 2006, 10 more states had classified PSE as a Schedule V controlled substance.¹⁰

In mid-2006, after passage of the CMEA, Oregon lawmakers approved legislation making PSE a Schedule III controlled substance, requiring a prescription. With this move, Oregon instituted the most restrictive policy for PSE access within the United States: consumers could obtain PSE products only with a healthcare provider's prescription. In 2010, Mississippi became the second state to impose a prescription-only requirement on all PSE products and reclassified all PSE products from Schedule V controlled substances to Schedule III controlled substances.¹¹

In recent months, a number of states have considered legislation that mimics the approach taken by Oregon and Mississippi; through December 2011, none of the states had adopted these additional restrictions on consumer access to PSE products. In 2011, Georgia, Illinois, Missouri, and Washington introduced PSE prescription-only bills that failed to emerge from committee. In their 2011 sessions, Hawaii, Indiana, Kentucky, Tennessee, and Virginia introduced legislation to make PSE-based products Schedule III controlled substances, which require a physician's prescription.¹²

In an effort to effectively enforce federal retail limits and deny illegal transactions, other states have pursued real-time statewide electronic sales tracking systems that allow sellers to verify whether the requested purchase is within legal limits and can also supply real-time information on PSE purchases to law enforcement authorities. Oklahoma, followed by Kentucky and Arkansas, were the first three states to implement such tracking systems. Kentucky implemented a pilot program in 2005 in several counties that linked electronic logs in a program called "MethCheck," and the initiative received positive feedback from law enforcement and pharmacists.¹³ The program was expanded in the spring of 2009 to allow Indiana counties on Kentucky's border to participate.¹⁴ The expansion aimed to improve cross-border monitoring and address illegal stockpiling of PSE products for the manufacture of methamphetamine by individuals who purchase their legal limit of PSE products at multiple retailers, a practice known as "smurfing." This technology has expanded to include the National Precursor Log Exchange (NPLEx), a multi-state electronic PSE stop sales system funded by the manufacturers of medicines containing PSE.

As of October 2011, 19 states had passed laws requiring the implementation of real-time stop sale technology in all retail and pharmacy locations statewide, and all of these states will have implemented their systems by January 1, 2012. With the exception of Arkansas and Oklahoma, all the states that have passed laws requiring real-time electronic sales tracking systems have adopted NPLEx.¹⁵ Other states rely on existing federal or state policies for PSE access. Figures 3 and 4 summarize state policies regulating consumer purchases of PSE.

Figure 3: State-by-State Policies for Regulating PSE Purchases

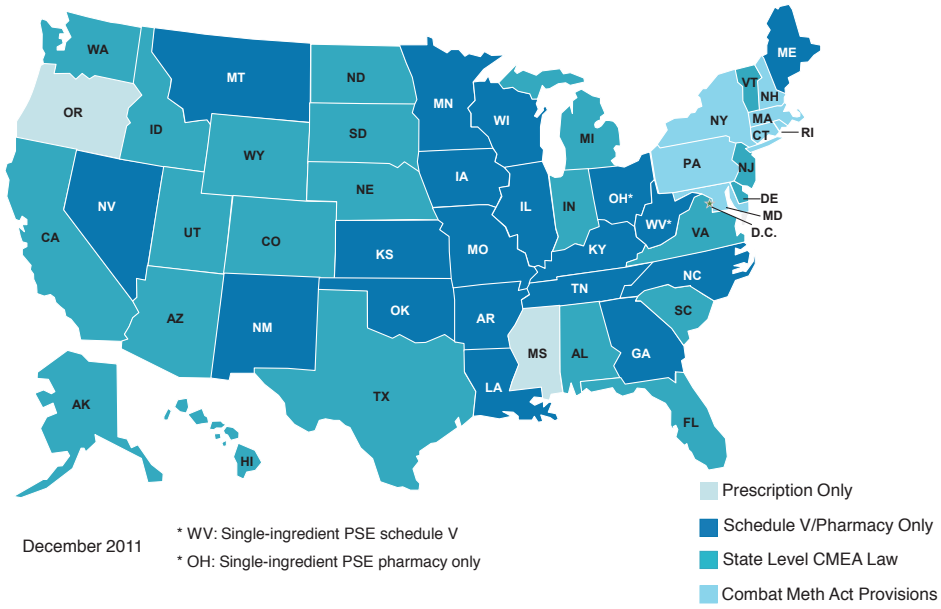
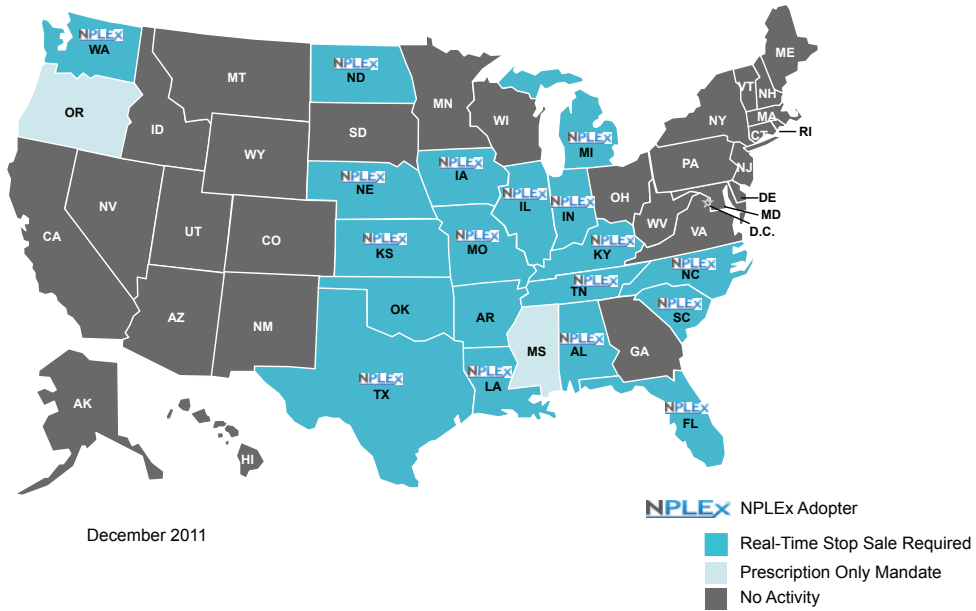


Figure 4: State-by-State Use of NPLeX for Regulating PSE-Containing Medicine Purchases



Current Status of Fighting Methamphetamine

While national rates of methamphetamine abuse are trending down,¹⁶ stakeholders acknowledge the devastating impact of methamphetamine that is manufactured in clandestine labs in relation to law enforcement, safety, and health. Law enforcement officials are concerned about time and budget allocated to fighting crime, prosecuting methamphetamine-related activities, and corrections. Concerns about hazardous materials and the costs and consequences to children, the surrounding community, and the environment are shared across stakeholders. Laboratory and dump-site clean-up can represent a significant cost.¹⁷ However, some states have recently employed more cost-efficient tactics to cleaning these laboratories. Tennessee, for example, has developed a regional container program that places specially designed containers throughout the state for labs to be taken and properly disposed. This change has resulted in a reduction in costs from \$2,000 per lab clean-up under the federal program to \$100.¹⁸

Restricting consumer access to PSE has resulted in a decrease in the number of small clandestine methamphetamine labs. However, the decrease in methamphetamine labs has not correlated with a reduction in methamphetamine usage because Mexican suppliers have more than filled the void. The DEA notes that production of methamphetamine by domestic clandestine laboratory operators is usually on a smaller scale, as Mexican drug trafficking organizations have become the primary manufacturers and distributors of methamphetamine in the United States.¹⁹ Stopping the cross-border trafficking of methamphetamine and its precursor chemicals therefore remains a priority.

While the number of labs is one measure, other factors, like overall methamphetamine production and the various costs noted above, indicate growing challenges in managing the drug's trade. As a result, some stakeholders are calling for a multi-faceted approach to building safe and healthy communities, focusing equally on prevention, enforcement, and treatment. For example, Oklahoma's Methamphetamine Abuse Prevention Initiative is a state-sponsored effort focusing on community-based prevention of methamphetamine abuse. This approach expands the state's focus beyond just law enforcement to also include tools, training, and education for a variety of stakeholders, such as parents, educators, anti-drug coalitions, and government officials.²⁰ Tennessee also promotes similar multi-faceted approaches to combating methamphetamine.²¹ Other states, like Oregon, supplement law enforcement with prevention and treatment efforts; however law enforcement remains the primary focus for those states.²²

Policy Outlook

Consumer access to PSE continues to evolve at multiple levels of government. Congress, federal agencies, state legislatures, and boards of pharmacy all have the ability to restrict access to drugs containing PSE, and to date many of these entities have taken action. As a

result, a patchwork of state and federal policies determine PSE access, which does not allow for a unified, national approach to combating the methamphetamine problem.

While acknowledging the need for a national strategy to address methamphetamine production and abuse, stakeholders continue to debate the appropriate balance between maintaining consumer access to nonprescription drugs containing PSE and minimizing the risk of diversion of PSE-containing drugs for illicit production of methamphetamine.

Proponents of a prescription-only policy believe real-time stop sale systems cannot accurately detect criminal drug activity and that further access restrictions in the form of a prescription requirement are needed to thwart diversion of PSE. Advocates of real-time stop sale technology contend these systems address the illegal sale of PSE-containing medicines without placing undue restrictions on consumers who appropriately use PSE products or imposing new costs on the healthcare system.

Given the recent implementation of these state initiatives, very limited data exist on the relative benefits of a prescription-only policy for PSE versus real-time statewide electronic sales tracking in mitigating diversion of PSE-containing. If policymakers are interested in adopting a national policy to prevent diversion of PSE for the manufacture of methamphetamine, it would be prudent to fully vet the assumptions about the public health and economic benefits given the potential of unintended consequences on the overall healthcare system.

Impacts of Restricting Consumer Access to PSE Products

States continue to explore alternatives to help fight the incidence of methamphetamine laboratories while also ensuring access for appropriate use by patients. Three distinct approaches have emerged:

- Establishing real-time stop sale technology for tracking purchases of PSE products stored BTC using electronic, inter-connected patient logging to block illegal sales. This approach builds on initiatives underway in several states and helps align efforts to existing systems and efforts that have proven successful.
- Making PSE a Schedule III controlled substance, requiring a physician's prescription. In most states, while this approach requires a prescription, an in-person encounter with a healthcare provider is not necessary to obtain the prescription. Oregon and Mississippi adopted this approach in 2006 and 2010, respectively.
- Making PSE a Schedule II controlled substance. This policy requires consumers to have an in-person visit with a healthcare provider to obtain a prescription.

These options compose the foundation of our evaluation. It is important to note that the economic model focuses primarily on real-time stop sale technology and the approach of making PSE a Schedule III controlled substance, requiring a physician's prescription but not

an in-person encounter with a physician. We do not assess the economic impact of the more restrictive approach of making PSE a Schedule II controlled substance, which requires consumers to have an in-person visit with a healthcare provider to obtain a prescription. However, the impacts of all three options are explored qualitatively.

Each of these alternatives would place varying levels of restrictions on consumer access to PSE. However, the economic and behavioral implications from each of these approaches yield results beyond just limiting access for methamphetamine production and must be considered. Policymakers at all levels of government must consider carefully the downstream impacts or ripple effects of PSE restrictions on other aspects of the healthcare system.

Market Response to Changes in Access to PSE Products

Consumer Utilization and Spending on PSE Products

Any attempt at controlling PSE access for illegitimate purposes ultimately results in limiting access to PSE products for legitimate purposes as well. In addition to the reduction of symptoms many consumers experience as a result of using PSE products, the relative low cost of PSE products resulting from over-the-counter (OTC) status has created strong demand for these remedies to nasal congestion. In 2007, retailers sold more than 67 million units of nonprescription PSE products nationwide, with consumers spending approximately \$666 million for such products.²³

The three initiatives identified to address the illegitimate purchases of PSE yield very different implications to the ultimate availability of PSE products. Use of real-time stop sale technology to manage access to PSE products would build on federal requirements that all PSE products be placed BTC and each consumer sign a record of purchase maintained by the retailer. In addition, real-time stop sale technology would require entry of purchase registration requirements in an electronic system, enabling real-time status checks on each purchaser to assess if daily and/or monthly limits have already been met. Such a system would allow the retailer to reduce the illegitimate purchase of the PSE products directly and further support law enforcement efforts by sharing the data.

Both prescription-only initiatives increase access restrictions for both legal and illegal purchases of PSE. PSE products no longer would be available BTC without a prescription, essentially eliminating the OTC PSE market. While clearly curtailing illegitimate purchase of PSE, such initiatives also have dramatic impact on legitimate uses for relieving nasal congestion. For example, Oregon has seen an almost 78 percent decline, and Mississippi an 88 percent drop, in the use of PSE-containing products, some of which is attributable to consumers trying other OTC options, such as products that contain phenylephrine (PE).²⁴

Viability of PE Products as an Alternative to PSE

PSE and PE are the only two oral decongestants approved by the FDA for OTC use to relieve nasal or sinus congestion caused by the common cold, sinusitis, and respiratory allergies. While both ingredients have a similar mechanism of action, PSE has a longer duration of action.²⁵

Increasing federal and state restrictions on PSE products have prompted many OTC manufacturers to offer alternative product formulations, such as substituting PE for PSE; PE does not have a BTC or prescription requirement. Manufacturers of products such as Sudafed® and Robitussin® have reformulated their products with PE as “on the shelf” alternatives to their PSE variants.²⁶ But while PSE access can be reduced this way, the OTC PE products do not represent a viable substitute for PSE products for all consumers.

Individuals respond differently to medications, with some getting more benefit from a specific ingredient than others. Similarly, findings from PE and PSE comparisons have varied, with some individuals demonstrating that PE products can be less effective than their PSE alternatives in controlling nasal congestion and other allergies.²⁷ Further investigation has also revealed that consumers prefer the longer lasting effects, less frequent dosing of PSE products compared to PE products.²⁸ Additional research and comparative studies are warranted to determine the efficacy of PE products as substitutes for PSE products. But a clear conclusion can be drawn that having access to both PSE and PE without the need for obtaining a prescription from a healthcare professional allows consumers to obtain the medication quickly and without prolonging suffering.

PSE Product Pricing

Prescription drugs typically face more labeling, handling, storage, and dispensing requirements relative to OTC products. Each of these supplemental requirements results in additional activities and costs for manufacturers and pharmacies, driving the price of the product upward and resulting in higher costs to consumers and their health plans. While the FDA has increasingly expanded access to prescription drugs by switching to OTC status, little precedent exists for the change of a nonprescription drug to prescription-only status. This absence is even more glaring for products when the prescription requirements are not based on the drug’s safety and efficacy when used as directed, as would be the case for PSE products. Therefore, it is difficult to judge the exact requirements and associated costs in a transition from OTC to prescription-only status for PSE products.

Oregon attempted to mitigate some of these prescription status costs by waiving certain storage requirements for PSE products.²⁹ In addition, stakeholders have not incurred a level of costs that warrant broad pricing action in meeting the requirements for Oregon, which was the only state with such requirements for several years. However, if more states implement prescription-only status, the costs associated with prescription status will grow, making pricing increases necessary. In addition, states that make PSE a Schedule II controlled substance are less likely to waive storage requirements and are in fact likely to have even more costly rules.

Little evidence exists from the Oregon and Mississippi experiences to assess the impact to PSE product pricing. However, PSE product pricing dropped when moving from prescription-only to OTC status, a common trend when prescription products become available OTC. For example, prices for Claritin-D[®], Zyrtec-D[®], and Allegra-D[®] fell approximately 26 percent when these products switched from prescription to OTC status.³⁰ Following these trends, we estimate that per unit costs are likely to increase about 35 percent from the current lower levels in the reverse situation when PSE products move from OTC to prescription-only.

Interestingly, corresponding price increases are non-existent when pursuing real-time stop sale technology. Because this option maintains OTC status for PSE products, manufacturers and pharmacies do not face the same additional costs that they do under either prescription-only approach.

State Government Costs

Access to PSE products also has significant financial considerations for state governments. Any of the three approaches to restrict consumer access to PSE may yield government savings if the policy reduces both the manufacturing and uses of methamphetamine. States currently face a range of activities and associated costs related to methamphetamine. For example, state and local law enforcement play an active part in fighting methamphetamine. In addition, the manufacturing process of methamphetamine includes a mix of toxic chemicals that can lead to lab explosions, fires, or severe chemical burns,³¹ and it also creates toxic by-products that can cause environmental damage.³² Clean-up efforts for a single methamphetamine laboratory site average \$5,000 nationwide, though some clean-ups can reach up to \$100,000 or more.³³ As noted earlier, some states, like Tennessee, are implementing efforts to cut these clean-up costs.

Besides law enforcement and environmental clean-up, social costs, such as foster care for children with parents arrested for using or manufacturing the drug, also impact states.³⁴ A 2005 study estimates that methamphetamine use cost the U.S. economy \$23 billion, of which \$4.2 billion per year were associated with the criminal justice system.³⁵ We would note that a significant portion of costs to the judicial system or from social costs would remain in any scenario, given the prevalence of methamphetamine and precursor chemicals from drug trafficking organizations.

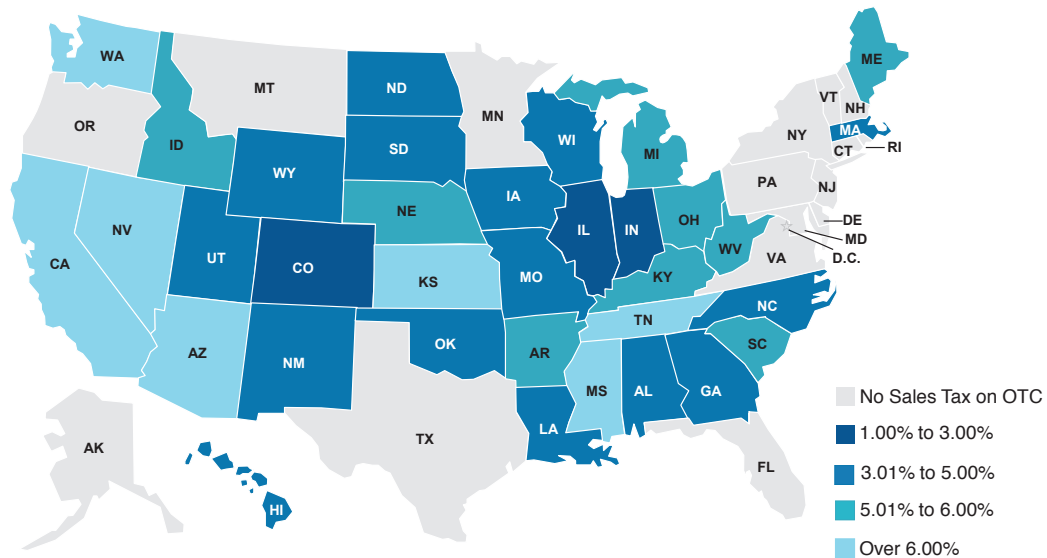
Many states saw a reduction in small methamphetamine labs following the implementation of federal and state policies restricting PSE access. In Oregon, the number of labs fell from 192 in 2005 to 12 in 2010,³⁶ while surrounding states saw similar lab decreases without a prescription-only limitation. Similarly, Mississippi, a state with prescription-only status, and Alabama, a state with real-time stop sale technology, experienced similar declines in labs, falling 66 percent and 69 percent, respectively, in the period June 2010 to June 2011.³⁷ These statistics make it difficult to determine which specific actions, such as a

prescription-only policy or federal requirements to place PSE products BTC, directly impact the number of small-scale methamphetamine labs. In addition, some law enforcement officials have noted that reductions in home-based labs have coincided with an increase of methamphetamine manufactured in larger “super labs”—labs capable of producing at least 10 pounds of methamphetamine per production cycle—or imported from Mexico.³⁸

Because of these alternate sources of supply, the overall impact of specific state actions to limit PSE access on methamphetamine production and abuse is unknown. As a result, any potential savings by states from a prescription-only policy are also not quantifiable.

State tax revenues, however, are quantifiable, and restricting OTC access to PSE products will result in the loss of sales tax revenue. States that collect a sales tax on OTC products currently benefit from such revenues and would continue to do so with real-time stop sale technology approaches for PSE (Figure 5). Under either prescription-only requirement, however, most states would lose this source of tax revenue, as prescription drugs are exempt from sales tax in all states except Illinois.³⁹ This loss of revenue would result in almost a 100 percent decline in PSE-related sales tax collections nationally, from current levels of \$18.2 million to only \$107,000 annually. Over a 10-year period, states would lose \$219.2 million, a significant impact to states facing ever-tighter budgets.

Figure 5: State Sales Tax Rates for Over-the-Counter Medicines



Note: Additional local taxes apply in some states.
 Source: Federation of Tax Administrators website. “State Sales Tax Rates.” Federation of Tax Administrators.
<http://www.taxadmin.org/fta/rate/sales.pdf> (accessed October 10, 2011)

Provider and Payer Utilization

Beyond market responses, the broader healthcare system also will incur additional utilization and associated cost implications with any changes in PSE status. The U.S. healthcare system continues to face significant challenges, including provider shortages⁴⁰ and rapidly increasing healthcare spending.⁴¹ In fact, the ACA, enacted in 2010 and more broadly known as “health reform,” attempts to address some of these challenges around the access and cost of healthcare. Specifically, health reform aims to make healthcare more affordable, expand coverage to more Americans, and make the broader health system sustainable. Some of the actions the ACA mandates include expanded coverage of specific services, more individuals with insurance under public and private payers, new approaches to address insurer premiums, and the creation of new tools like insurance exchanges and Accountable Care Organizations. This analysis is affected by the introduction of insurance exchanges in 2014 and the subsequent change in enrollment across public and private payers.

Each of the three potential options identified to address the illegal purchase of PSE products affects key stakeholders in the healthcare system—consumers, providers, health plans, and government payers—differently.

Healthcare Provider Visits to Obtain Prescription for PSE Products

A provider visit requirement is a key component of each of the three options identified to restrict illegal use of PSE products.

- Under the real-time stop sale technology approach, qualified retailers can store PSE products BTPC and sell the products to consumers without a prescription, thus negating the need for additional visits to providers for a prescription.
- By making PSE products Schedule III controlled substances, consumers must obtain a prescription but are not required to do so with an in-person healthcare provider visit. While this may have limited impact on the number of provider visits, it does increase provider workload.
- By making PSE products Schedule II controlled substances, consumers are required to have an in-person visit with a healthcare provider to obtain a prescription before purchasing a PSE product, an approach that will increase provider visits and workload.

The economic model further explores the direct impact of prescription-only status on provider utilization and associated costs, and incorporates several assumptions for consumers’ projected use of healthcare provider visits. Using publicly available sources, we examined data on physician visits, emergency room use, and other comparable outpatient setting utilization for patients likely to continue using PSE products. To estimate the number of potential new visits required to satisfy a prescription-only mandate for a controlled substance, we assumed an 83 percent decline in use of prescribed PSE products based

on the experience in Oregon and Mississippi. For the remaining 17 percent of prescribed PSE products, we assumed one of three individuals would require a new provider visit to obtain a prescription based on a prior Avalere economic model.⁴²

In Oregon's experience, where a prescription is required but a provider visit is not, the number of healthcare provider visits did not grow significantly,⁴³ as consumers have noted obtaining a prescription via telephone or fax request. Provider workload to handle such telephone and fax requests must increase to enable the prescription to be processed. Despite Oregon's initial experience, some consumers will need to see providers to obtain an initial PSE prescription, as outlined above. Our model estimates that the number of healthcare visits rises by 579,315 nationwide in the first year with the Schedule III controlled substance classification, which requires a prescription. These additional provider visits represent an increase to provider workload and subsequent decrease in provider accessibility to consumers. In addition, each of these additional healthcare provider visits comes at a cost to both consumers and the payers that cover such benefits. Figure 6 summarizes the increase in healthcare visits and the associated costs for payers and consumers.

Figure 6: Increased Provider Utilization and Associated Payer and Consumer Out-of-Pocket Costs

Measure/ Stakeholder	Assumption	Payer	Increase in Number of New Visits	Payer Spending on New Visits (thousands)	Consumer Out-of- Pocket for New Visits (thousands)
New visits to and spending on providers for acquiring PSE prescription	33% of users will add one more PSE- related provider visit ^{44,45}	Medicare	9,853	\$604	\$151
		Medicaid	64,370	\$5,220	\$0
		Other Public	46,573	\$2,731	\$806
		Private Insurance	324,025	\$23,855	\$6,729
		Uninsured	134,494	-	\$18,961

While data currently do not exist to measure the effects of making PSE a Schedule II controlled substance, requiring an in-person provider visit to obtain the prescription could have a more significant impact on provider visits and associated costs. Real-time stop sale technology, however, will not have a direct impact on provider visits or workload.

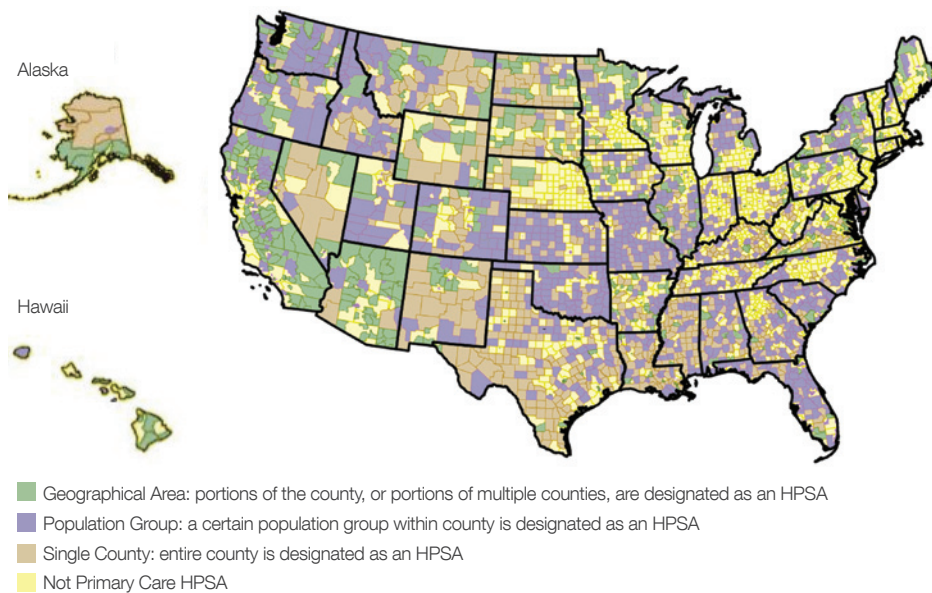
Provider Workforce, Work Load, and Reimbursement Issues

We assume that primary care providers (PCPs) are, and will remain, the main source of care for people with cold, allergy, and sinus symptoms. Therefore, they are more likely to experience the impact of a prescription-only requirement for PSE than specialists. These PCPs would be the first contact for most people looking to receive treatment for their symptoms. However, for the uninsured or those living in areas with PCP shortages, hospital emergency rooms often serve as the primary source of care.⁴⁶ Thus, increased demand and utilization of both primary care and emergency care providers will likely occur with a prescription-only requirement for PSE.

Under the approach requiring a prescription but not a healthcare provider visit, providers likely will see more requests from consumers to obtain PSE prescriptions “virtually,” either over the phone or via email, for example. Following this request, providers may call or fax a prescription to the patient’s pharmacy, an approach that likely gained in popularity since the implementation of Oregon’s regulations.⁴⁷ However, providers typically receive no reimbursement for such virtual interactions with patients. This unpaid time spent with the patient and the pharmacy may place administrative as well as financial burdens on providers, particularly because that time may represent a lost office visit or other reimbursable activity.

This approach, as well as the one that requires a healthcare provider visit to obtain a PSE prescription, also will result in increased visits to healthcare providers, a consequence likely to create both positive and negative effects for these providers. If a provider has the capacity for additional patient visits for PSE prescriptions, the visit will generate additional revenue for that individual provider. However, not all providers have that capacity, and a required healthcare visit to obtain a PSE prescription would place additional burden on a care delivery system that in many parts of the country already lacks the provider supply to meet the current demand for PCPs (Figure 7).⁴⁸ In these areas, such a requirement would create more administrative and overcrowding issues for providers. It also would create potential adverse impacts for consumers on both their ability to access care and the quality of care they receive. As patients request office visits for services not previously needed, wait times to access such care will likely increase, and overwhelmed providers may struggle to provide patients the appropriate time and treatment.

Figure 7: Health Professional Shortage Areas – Primary Care



Commercial Health Plan Spending

Consumers with commercial health insurance will incur co-pays or coinsurance for each provider visit depending on the design of their benefit plans, and the health plan will pay the balance of the negotiated rate to the provider. The average cost of a provider visit under commercial plans is \$94,⁴⁹ of which members pay 22 percent on average.⁵⁰ Under a prescription-only mandate, our model shows that health plans will incur an additional \$23.9 million in provider visits in the first year, and consumers with commercial insurance will pay an additional \$6.7 million in out-of-pocket costs for those same provider visits. These provider visit costs reach as much as \$29.8 million to plans and \$8.1 million to consumers in the tenth year.

In addition to healthcare provider visits, both of the prescription-only options will lead to increased costs in payment for PSE products by commercial insurers. Actual coverage and tier placement for PSE products will vary among payers. While not all health plans will initially cover PSE products, we assume that about 50 percent of payers will include them on formularies initially based on regional needs and consumer demand. As those needs and demand grow, we anticipate that 95 percent of plans will eventually add PSE products to their formularies.

PSE products are available in generic form, which will likely fall under Tier 1 on formularies, and the brand-name PSE products will likely fall on higher tiers (typically Tier 3 or higher). Because of the cost of PSE products, those covered under the higher tiers of plan formularies will not likely impact cost to the plan because the cost of the PSE product is likely less than the co-pay or coinsurance associated with that higher tier. For example, the average co-pay for lifestyle drugs used for indications such as erectile dysfunction and hair loss, which are typically Tier 3 or higher, was \$72 per script in 2010,⁵¹ which is significantly higher than the cost of the PSE product, even with the estimated 35 percent price increase under prescription-only status noted earlier. In these situations, the consumer will be forced to pay for the PSE product completely out-of-pocket.

Given the discrepancy between the cost of PSE products and the out-of-pocket payments for higher tiers, consumers are likely to purchase generic PSE products under a prescription-only scenario. With an average generic co-pay of \$10,⁵² commercial insurers will see additional drug costs for PSE products of \$33.4 million in the first year, an amount that will reach \$67.6 million in the tenth year with the increased uptake by plans for their formularies. These costs include both the drug itself and the dispensing fees paid to pharmacies. For consumers with commercial insurance, out-of-pocket costs for purchases of prescription PSE will total \$56.2 million in the first year and fall to \$55.7 million in the tenth year due to the growth in payers including PSE on formularies.

Commercial insurers include costs for all medical services and drugs in their premium calculations, and they will take the same approach with any additional spending for PSE products and provider visits to obtain a prescription. Health plans use a per member per month (PMPM) measure, based on the amount of money paid or received on a monthly basis for each individual enrolled in the plan, to assess the impact of costs and premiums. With prescription-only status for PSE products as a non-scheduled drug, our model shows that health plans will see \$0.03 PMPM in additional expenses, which in turn will result in a rise in premium levels across plans. Additional expenses may be even higher under the approach that requires in-person visit with a healthcare provider to obtain a PSE prescription due to the inclusion of costs from more provider visits.

Though the amount may appear small, such growth in expenses and premiums are in direct conflict with the current environment of health reform that aims to make insurance more available and affordable to consumers. Real-time stop sale technology is more aligned with this focus on access to healthcare and cost containment.

Medicare and Other Federal Healthcare Program Spending

Medicare, which covers individuals age 65 and over as well as those who qualify due to disability or end stage renal disease diagnosis, offers different types of programs for beneficiaries. Some focus on coverage for medical services such as office visits (e.g., Medicare Part B); others on coverage of outpatient prescription drugs not covered under Part B (e.g., Medicare Part D plans); and still others include coverage for both medical services and outpatient prescription drugs (e.g., Medicare Advantage).

As with commercial plans, the already strapped Medicare program will face higher costs from additional spending on PSE products and physician visits under either prescription-only option. Medicare programs that cover office visits have an average provider visit cost of \$76,⁵³ of which members pay 20 percent. By making PSE a Schedule III controlled substance, requiring a prescription but not an in-person healthcare visit to obtain a prescription, Medicare will face \$603,952 in additional costs for office visits in the first year, and Medicare beneficiaries will pay an additional \$150,988 in out-of-pocket costs for provider visits.

Medicare programs that cover outpatient prescription drugs will also face additional costs from spending on PSE products, the primary impact to Medicare Part D. With similar formulary tier placement (Tier 1 for generics and Tier 3 or higher for brand) and generic utilization to commercial plans, our model estimates the Medicare program will see additional spending on PSE products rise from \$18.4 million in the first year to \$29.1 million in 10 years. PSE product out-of-pocket costs for Medicare beneficiaries will total \$6.8 million in the first year and reach \$10.8 million in the tenth year.

While Medicare is often broadly noted as facing fiscal issues, the 2011 Medicare Trustees Report finds the specific programs that fund provider and product costs from PSE prescription status are projected to remain adequately financed because current law automatically provides funding each year to meet the next year's expected costs. These funding sources include about three-quarters from general revenues and one-quarter from premiums paid by beneficiaries.⁵⁵ Existing projected costs are already slated to grow rapidly, and adding even greater growth on top of current projections will thus yield even steeper premiums for Medicare beneficiaries.

In addition to the costs to Medicare, our analysis shows that the federal government also will incur expenses for other federal programs, such as contributions to Medicaid, TRICARE (the military health program), the Veterans Health Administration, and the pending implementation of health insurance exchanges as part of ACA. The combined impact of these programs to the federal government yield a 10-year federal score of a \$420.3 million cost if the policy were implemented in 2012. Under Congress' pay-as-you-go ("Paygo") rules, these costs must be offset with other revenues or savings in order for Congress to enact them. Again, both prescription-only options exacerbate these challenges, while real-time stop sale technology does not.

Medicaid Spending

Medicaid is a joint state-federal healthcare program for the indigent. Similar to Medicare and commercial payers, state Medicaid programs will also face increased costs with either prescription-only option; however the amount would vary state-to-state based on their specific coverage of PSE products and provider visits.

Unique to Medicaid programs, some states currently cover OTC PSE products, requiring beneficiaries to present a prescription before Medicaid will pay for any drug.⁵⁶ Limited available data on the costs of this benefit suggests that many Medicaid beneficiaries pay out-of-pocket for PSE products, avoiding the need to get a prescription. Therefore, Medicaid payment for physician visits could potentially rise even in states that currently cover these products. With a weighted average cost of \$70 for provider visits under Medicaid,⁵⁷ our model shows additional Medicaid provider costs on federal and state levels would total \$5.2 million in the first year and rise to \$7.8 million in the tenth year.

The impact to state Medicaid programs from covering the cost of PSE drugs is even greater. Medicaid rules require states to cover any prescription drug offered by a manufacturer that has a rebate agreement with the federal government.⁵⁸ By making PSE a Schedule III controlled substance, requiring a prescription but not an in-person healthcare visit to obtain a prescription, we estimate that federal and state Medicaid drug costs could rise by as much as \$12.7 million nationwide in the first year and \$19 million in the tenth year. These costs may shift downward, depending on states' ability to secure additional rebates beyond the statutorily required ones. Medicaid beneficiaries purchasing PSE products could face out-of-pocket costs of \$1.1 million in the first year and \$1.6 million in year 10.

Just as the Medicare program faces solvency issues, increased federal contributions to Medicaid are also a concern in the current economic environment. In addition, state Medicaid programs are facing severe budgetary challenges, as many states are in financial crises with cumulative state budget shortfalls for 2010 and 2011 estimated at \$350 billion.⁵⁹ These deficits have prompted cuts to Medicaid programs averaging 12 percent since 2008.⁶⁰ States are also concerned about increasing Medicaid enrollment from both the soft economy and implementation of health reform. Nationally, the number of Medicaid beneficiaries has risen by 8 percent a year from 2008 to 2010.⁶¹ Following a similar trend seen with other payers, a prescription-only approach adds to each state Medicaid program's burden, while the real-time stop sale technology once again does not.

Barriers for the Uninsured

Consumers without commercial insurance, Medicare, or Medicaid coverage will face even greater barriers to accessing care and PSE products. In a September 2011 report, the U.S. Census Bureau reported that the number of uninsured citizens reached 50.7 million lives,⁶² the highest level ever. Even with coverage expansions due to federal health reform over the next decade, the number of uninsured lives by 2019 is estimated at 20 million lives.⁶³

The uninsured are adversely affected under either option that mandates a prescription. The uninsured often have more difficulty accessing a healthcare provider who can furnish a prescription, either in person or in a virtual capacity. Many providers will not see uninsured patients and certainly will not provide virtual prescriptions to non-patients. Providers who do see uninsured patients typically require full payment at the office visit, an amount that is often higher than what is paid by commercial health plans and the associated consumer co-pay. These economic barriers often result in the uninsured population receiving treatment for their medical needs by emergency care centers at costs that far exceed the cost of preventive measures.⁶⁴ We estimate either prescription-only approach will cost the uninsured \$19 million in provider visits to obtain a prescription in the first year, though this amount is anticipated to fall considerably as the number of uninsured declines with ACA implementation over the next decade.

Because of the economic factors that contribute to those who are uninsured, the cost of the PSE product remains a concern under the real-time stop sale technology or either prescription-only option. However, the expected rising cost of PSE products and a lack of insurance to help pay that cost make the prescription-only approaches more cost prohibitive, with uninsured consumers facing \$6 million in out-of-pocket costs for PSE products. Thus, the uninsured will face sizable barriers to appropriate use of PSE products under any kind of prescription-only mandate. Real-time stop sale technology, however, does not disproportionately disadvantage the uninsured from accessing PSE products.

Figure 8 summarizes payer and consumer spending resulting from a prescription-only PSE policy.

Figure 8: Payer and Consumer Out-of-Pocket Spending on Prescription PSE Products

Measure/ Stakeholder	Assumptions	Payer	Payer Spending on Prescription PSE Products (millions)	New Consumer Out-of-Pocket Spending for Prescription PSE (millions)
Spending on prescription PSE	17% of PSE utilization is under a prescription ⁶⁶ ; Providers begin to cover PSE products ⁶⁶ ; Price increase of 35% ⁶⁷	Medicare	\$18.4	\$6.8
		Medicaid	\$12.7	\$1.1
		Other Public	\$1.4	\$0.75
		Private Insurance	\$33.3	\$56.2
		Uninsured	-	\$24.7

Costs to Employers

Employers are the principal source of health insurance in the United States, providing health benefits for about 150 million people.⁶⁸ With the rise in commercial health insurance premiums noted under prescription-only status, employers will be forced to make larger contributions or pass the higher costs on to employees. In fact, while employee contributions to health insurance premiums have grown 131 percent since 2001 (from \$1,787 in 2001 to \$4,129 in 2011), employers still pay for more than 75 percent of total premium costs.⁶⁹

In addition to costs from increased health insurance premiums, employers are likely to experience adverse changes in employee absenteeism and productivity, particularly during cold and allergy seasons, with either prescription-only option. Absenteeism and lost productivity have a significant financial impact on employers, with colds already costing employers \$25 billion each year, including an estimated \$16.6 billion in lost productivity.⁷⁰ These numbers will only expand, as employees who use less effective OTC products or go without treatment may miss more work or be less productive while at work. With a prescription mandate for PSE products, employers can expect more absenteeism from employees who need to visit their healthcare provider to obtain such a prescription.

While either prescription-only mandate will further increase costs to employers, making PSE products available without a prescription using real-time stop sale technology allows employees to more readily treat their symptoms and thus may actually benefit employers with higher levels of productivity and reduced absenteeism.

Conclusions

Currently, very limited data exist on the relative benefits of a prescription-only policy for PSE versus real-time stop sale technology in mitigating diversion of PSE-containing drugs for use in the illegal manufacture of methamphetamine. As of October 2011, only two states had adopted a PSE prescription-only policy while 19 states had chosen to adopt or implement a real-time stop sale technology.

Requiring a prescription for PSE-containing products, like any policy change, is likely to have intended and unintended consequences on key stakeholders, including the federal government, state governments, healthcare providers, commercial health insurance plans, and consumers. A prescription requirement will reduce PSE access for criminals, hence reducing methamphetamine production in small clandestine labs and related costs from a societal perspective. However, the decline in sales and any possible impact on illicit production of methamphetamine from a prescription-only policy should be weighed against the estimated costs on key stakeholders.

A prescription requirement for PSE products would create access restrictions for legitimate users of PSE, prolonging the timeline to symptom relief for consumers waiting to get a prescription from their provider. While some patients would be able to request a prescription for PSE products while visiting their physician for other reasons, others would need to schedule a separate visit just to obtain the prescription. An increase in the number of physician visits likely would present workload and administrative challenges, especially in areas with PCP shortages. These challenges would be amplified during peak periods for cold, allergy, and sinus symptoms.

A prescription-only model for PSE products also could boost consumer costs as a result of more provider visits and additional contributions toward higher health insurance premiums resulting from increased spending on provider visits and prescription medicines. Employers also would face higher health insurance premiums as well as more employee absenteeism and decreased employee productivity due to provider visits or untreated symptoms. Public and private payers would see higher spending on provider visits and PSE products, which in turn would flow through to consumers through costlier premiums when possible. States would lose tax revenues while simultaneously face increasing costs from Medicaid beneficiaries.

Advocates of electronic tracking of retail PSE purchases believe the real-time stop sale technology is the better alternative because the technology enables retailers to enforce federal retail limits and deny illegal transactions in real time. However, proponents of a prescription-only model for PSE question the reliability of the real-time stop sale systems in preventing smurfing or accurately detecting multiple or fraudulent identification used by criminals, especially in the absence of similar laws in neighboring states.

As policymakers debate options for further curbing diversion of PSE for the illicit manufacture of methamphetamine, it would be prudent to fully vet the assumptions about the various approaches on the public health and economic benefits given the unintended consequences on the overall healthcare system. It is possible that the expected benefits of both real-time stop sale technology and prescription-only PSE policies could be tested under the current framework without further compromising consumer access.

Policymakers can pursue the implementation of interstate real-time stop sale systems as part of a comprehensive approach to addressing the illegal diversion of PSE for the manufacturing of methamphetamine while exploring the potential benefits of a prescription-only policy for PSE by evaluating data from the Oregon and Mississippi initiatives. Successfully addressing the methamphetamine problem requires a wide-ranging strategy that incorporates the need for consumers to have appropriate access to medication, law enforcement concerns, demand reduction, and treatment.

Technical Appendix

Measuring Implications for PSE Purchases

To establish a baseline level of use for PSE-containing products, we used data from Information Resources, Inc. (IRI) Infoscan®, a retail tracking service with information from food, drug, and mass merchandisers (FDM) nationwide. The Infoscan data include unit and dollar sales of nonprescription PSE products for FDM in FY2011 (July 1, 2010 to June 30, 2011). Seven states and the District of Columbia (DC) are not represented in the IRI data. As a result, we imputed PSE product sales for these states and DC by using the per-person national average based on the 43 states and applied it to the missing states' populations using 2010 U.S. Census data. To estimate the average cost to consumers of PSE-containing products, we multiplied the state's unit sales by the state's average price of PSE products. We used the national unit average price for the seven states missing from IRI data. Also, it is important to note that "unit" in this case refers to the packaged item that a consumer purchases in a BTC setting, such as one bottle of liquid, a box of tablets, or other package type.

To estimate the average level of PSE utilization per user, we used our previous research in this area to guide our assumptions about the patient population using PSE-containing products.⁷¹ The methodology used in our previous research accessed the National Ambulatory Medical Care Survey (NAMCS), a national survey of office-based physicians published by the National Center for Health Statistics. Our research profiled patients for whom prescribers recommend use of a drug containing PSE. In addition to information about prescribed and OTC medicines, NAMCS includes patient symptoms, diagnoses, services provided, and demographic characteristics. NAMCS data, along with market research on PSE containing products from AC Nielsen Homescan & Spectra Product Library and IRI Household Panel data, were used to build assumptions around the number of households purchasing PSE products and the number of purchases per household.

To determine the potential change in the utilization of PSE products and project the impact of prescription-only status on other states, we analyzed the experience of Oregon and Mississippi. Specifically, we reviewed trends in PSE product sales in Oregon before and after the July 2006 effective date for the state law requiring a prescription for the sale of all PSE products as well as the trends in sales of PSE-containing products in Mississippi before and after the July 2010 effective date for the state law placing PSE-containing products on the controlled substance list.

Because the IRI data are limited to nonprescription products, we obtained data from IMS Health's Xponent® on prescription PSE products dispensed by retail pharmacies to estimate total sales of PSE-containing products in Oregon after 2006 and Mississippi after 2010, as well as all other states. IMS Health compiles drug transaction information

from sources including retail pharmacies, hospitals, and healthcare providers whenever a claim is filed to a payer. One important note is that the IMS data included utilization of nonprescription (“non-legend”) PSE sales that were purchased from a retail pharmacy with a prescription; however, since these units are already being purchased through a plan or by Medicaid, we assumed these types of users would continue to purchase PSE products despite the new prescription policy, and consequently will have no effect on utilization of units picked up through IMS. The only impact to these users relates to the increase in the price of the PSE product.

No precedent exists for measuring the price effect of moving products from nonprescription to prescription status. To evaluate the potential change in average prices for PSE products, we tracked the change in price observed when allergy products containing PSE were moved from prescription-only to OTC. These products include Claritin-D®, Zyrtec-D®, and Allegra-D®. We reverse-engineered the price impact of these products moving from prescription-only to OTC, applying the inverse of that price change to each state’s PSE price. Another option we discussed was to use the price change observed in Oregon and Mississippi and apply that change to all products nationally. However, we concluded that manufacturers, distributors, and retailers would react much differently to a broader scale nationwide policy versus that of a two-state switch, and therefore the Oregon and Mississippi experiences would not serve as good proxies for measuring the potential price effect of the return to prescription status.

Measuring Changes in Provider Utilization

We assumed a prescription requirement for PSE products would increase the number of healthcare provider visits because some patients would continue to prefer to use PSE products rather than alternative therapies and would have to add a provider visit in order to obtain that prescription or refill.

To determine the increased level of provider utilization resulting from PSE users seeking prescriptions, we compared physician visit, emergency room use, and other comparable outpatient setting utilization for patients likely to continue using PSE products. Data sources for this analysis include the Medicare 5 percent Standard Analytical Files (SAFs) and the Medicare Expenditure Panel Survey (MEPS). Published by the federal Agency for Healthcare Research and Quality (AHRQ), MEPS is a national survey of individuals, providers, and employers that profiles utilization and expenditures of medical services for all health insurance payers.

We used the SAFs and MEPS to assess current utilization of hospital and physician visits by PSE users. By matching their records to specific International Classification of Diseases, Ninth Revision (ICD-9), codes for conditions that are treated with PSE (e.g., allergies, cold, and sinus conditions), we were able to identify visits relating to PSE-related conditions. To estimate the number of potential new visits required after a move to prescription-only

status, we made the assumption that only a portion of consumers with PSE-related conditions would add another visit. Based on the experience in Oregon and Mississippi, we assumed an 83 percent decline in use of PSE products. For the remaining 17 percent of prescribed PSE products, we assumed one in three individuals would require a new provider visit to obtain a PSE prescription. This estimate was supported by our previous research on the likelihood of PSE users to add a physician visit.⁷²

Unlike the Medicare SAFs, MEPS does not contain data at the state level, and instead aggregates the data to the regional level: Northeast, South, Midwest, and West. Due to the potential disparity within a region, we refined our MEPS values to estimate newly added visits at the state level. In order to do so, we used the Medicare SAFs to create a state-specific index of state-to-region newly added visits. This state-specific index reduced by the one-third user estimate was then applied to each state to calculate a state-specific new visit estimate for each insurance category (Medicaid, private insurance, other public coverage, and uninsured).

To allow for variation in the mix of insurance coverage across states, we used data from Avalere Health Inc.'s Healthcare Enrollment Model to assign PSE users to various insurance categories (private insurance, Medicare, Medicaid, other public coverage, and uninsured). We assumed no difference in the utilization rate of PSE products between insurance categories. This allowed us to estimate PSE units and users by their respective percent enrollment by state.

We calculated costs to payers and patient typical out-of-pocket (OOP) costs for physician visits using the Medicare SAFs for Medicare beneficiaries, the Kaiser Family Foundation's 2011 Employer health Benefits Survey for commercial health plans, The Centers for Medicare & Medicaid Services (CMS) data for Medicaid, and Veterans Health Administration/TRICARE data for our "other public" data. We derived other assumptions about third-party coverage of, and patient cost sharing for, PSE-containing drugs from various sources, including our CY2009 stakeholder interviews, the Pharmacy Benefit Management Institute's Prescription Drug Benefit Cost and Plan Design Report: 2010-11 Edition, and the 2010 Kaiser/HRET Employer Health Benefits Survey.

Measuring Other Effects on Stakeholders

This model explores cost impacts to four major stakeholders: the federal government, state governments, commercial health insurance plans, and consumers. Spending by the five payer groups was cross-walked to one of the four stakeholders. For example, Medicaid spending was split between federal and state government using each state's federal medical assistance percentage (FMAP) rates. This allocation of spending to stakeholders was done for both PSE spending and the cost of new provider visits. For commercial health insurance plans we assumed an initial 50 percent placement of PSE products onto formulary, a number that grows to 95 percent by the tenth year.

We also addressed state governments' loss of sales tax revenue because prescription PSE products are ineligible for state sales taxing in all states, with the exception of Illinois that levies a 1 percent sales tax on prescription drugs. However, our estimate of reduced sales tax does not include the increase in sales tax revenues for PSE-alternative OTC products. We obtained current sales tax information from the Federation of Tax Administrators, dated February 2011.

10-Year Score

The 10-year federal score to determine the potential costs from moving PSE to prescription-only status includes the following: (1) decreased utilization of PSE products, (2) increased physician visit costs, (3) higher price of PSE products, and (4) changes among payer populations. Regarding utilization of PSE-containing products, we have forecast a large one-time drop of 83 percent upon effective date of the change. This drop is a combination of the effects observed in Oregon and Mississippi. However, after the one-time drop we assume stagnant utilization of PSE products.

We used the Congressional Budget Office's (CBO) 2011 Medicare baseline to estimate the average growth in PSE product price between 2012 and 2021. CBO uses the Consumer Price Index for All Urban Consumers (CPI-U) for Medicinal Drugs, Prescription Drugs to adjust prescription drug prices. This inflation rate is applied to all prescription drug spending for the projected years.

To account for the ever-changing distribution of people among payers, we adjusted each spending amount by payer by their respective change in enrollment. These enrollment estimates were derived from the Avalere Health Enrollment Model. Once the changes in enrollment were made, we allocated costs to the stakeholders using the methodology outlined above. The CBO and Avalere estimates do not extend to 2021, so three-year running averages were used to estimate the last year for CPI-U and last two years for enrollment estimates.

The Affordable Care Act (ACA) aims to expand access to healthcare while also containing costs. One aspect of this is the forecast shift of uninsured persons into Medicaid and the state and federal health insurance exchanges beginning in 2014. The Avalere Health Enrollment Model estimates these enrollment changes. To adjust spending by stakeholders from these changes, we shifted newly-added provider visits as well as PSE units from the uninsured population to Medicaid and the exchanges. Also, just as with private insurance companies before the policy was implemented, we assumed a 50 percent uptake of PSE onto formulary in the first year (2012), growing at a constant rate so that by 2021, 95 percent of private plans, including exchange plans, would include PSE products on formularies.

The allocation of PSE units into the exchanges was done using the same method listed above. We applied units based on each insurance category's percent of total enrollment. However, since our provider visits are not distributed proportionately, we reallocated visits from the uninsured to the exchanges (subsidized and unsubsidized) using a different approach. We summed up new Medicaid and exchange enrollment between 2013 and 2014. We compared this number to the change in projected uninsured enrollment between 2013 and 2014 and found the numbers to be very similar indicating that the majority of uninsured persons would enroll into Medicaid and exchanges. By taking both subsidized and unsubsidized relative percentages of the Medicaid and exchange total, and applying it the estimated change in uninsured provider visits, we were able to create estimates for exchange newly added provider visits.

The ACA also mandates changes to the average FMAP rate beginning in 2014; specifically that the federal government will reimburse states at a rate of 100 percent for all new Medicaid enrollees. We used the Kaiser Family Foundation's estimate for the net effect of the FMAP rate changes.

Core Assumptions and Sensitivity of Results

Throughout this analysis, we present findings based on a core set of assumptions pertaining to how consumers, providers, insurers, and other stakeholders will respond if nonprescription PSE-containing products become available only with a prescription. Due to uncertainties inherent in this type of modeling exercise, limitations of our data sources, and a lack of real-life experience with prescription-only requirements for PSE outside Oregon and Mississippi, we recognize that our assumptions could potentially take on a range of values.

Figure 9: Sensitivity of Additional Assumptions in the Avalere Health Model

Stakeholder	Baseline Assumption	Baseline Measure/ Insurance Category	Avalere Assumption if Prescription-Only Adopted	Result of Policy Change	Change from Baseline
Use of Nonprescription PSE Products by Consumers	Observed Spending on BTC PSE products ⁷³	11.8M Medicare	Use of PSE decreases by 83% ⁷⁴	1.2M	-10.56M
		10.1M Medicaid		1.1M	-9.00M
		1.20M Other Public		0.11M	-1.09M
		40.8M Private		4.44M	-36.4M
		10.2M Uninsured		1.2M	-9.00M
Use of Nonprescription PSE Products by Consumers	Average PSE user purchases 4.6 units/year ⁷⁵	2.5M Medicare	Use of PSE decreases by 83%	0.270M	-2.23M
		2.2M Medicaid		0.239M	-1.96M
		0.3M Other Public		0.023M	-0.28M
		8.9M Private		0.965M	-7.94M
		2.2M Uninsured		0.260M	-1.94M
Total Spending on Nonprescription PSE	Observed Spending on BTC PSE products	\$0.0M Medicare	Use of PSE decreases by 83%; Providers begin to cover PSE products ⁷⁶ ; Price increase of 35% ⁷⁷	\$18.4M	+\$18.4M
		\$4.4M Medicaid		\$17.1M	+\$12.7M
		\$0.0M Other Public		\$1.4M	+\$1.4M
		\$0.0M Private		\$33.3M	+\$33.3M
		\$531.6M Consumer OOP		\$89.6M	-442.0M
State Government Tax Revenue	Many states charge sales tax for OTC drugs ⁷⁸	\$18.3M	One state (Illinois) taxes prescription PSE purchases	0.107M	-\$18.2M
Average Price of PSE Products	Average unit cost ⁷⁹	\$11.35	Price increase of 35%	\$15.32	+\$3.97

Notes

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²2009 SymphonyIRI consumer household panel.

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⁵Combat Methamphetamine Epidemic Act. Pub. L. 109-177, Title VII. March 9, 2006.

⁶Methamphetamine Production Prevention Act. Pub. L. 110-415. October 14, 2008.

⁷Combat Methamphetamine Enhancement Act. Pub. L. 111- 268. October 12, 2010.

⁸Oklahoma House Bill 2176.6 April 2004.

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¹⁶SAMHSA's National Survey of Drug Use and Health, 2010.

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