



THE STATE LEGISLATORS GUIDE TO

Prescription Drug Policy



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The American Legislative Exchange Council (ALEC) is the nation's largest nonpartisan, voluntary membership association of state legislators, with nearly 1,800 members across the nation. ALEC's mission is to promote free markets, limited government, individual liberty, and federalism through its model legislation in the states.

Guided by the principle that the best health care is patient-driven, not government-driven, ALEC's Health and Human Services Task Force has been a national leader in promoting free-market, pro-patient health care reform at the state level. Since 2005, 22 states have enacted model legislation developed by ALEC's Health and Human Services Task Force.

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ABOUT THIS GUIDE

With rising health care costs and declining tax revenues, state legislators are increasingly looking for ways to cut spending and reform our health care sector. And despite the fact that prescription drug spending has reached its lowest rate of growth in 45 years, some lawmakers view health “reform” through the lens of price controls on lifesaving prescription drugs; restrictions on pharmaceutical ads that help inform patients; and restrictive drug formularies that harm our most vulnerable citizens.

As an ALEC legislator, you know health reform legislation should mirror the same Hippocratic Oath that guides the practice of medicine—“First, do no harm.” And you also know the best health care is patient- and market-driven, not government-driven.

That’s what makes ALEC’s *State Legislators Guide to Prescription Drug Policy* an essential tool in navigating the complex world of prescription drug policy with an eye toward our common principles.

The *Guide* will provide “plain English” definitions of common prescription drug policy issues you’ll hear in your statehouse. It will identify the harmful, unintended consequences of these “reforms” to help you in floor debate. And most importantly, it will help you identify effective health reform solutions that curb rising health costs without restricting access to prescription drugs.

If you’d like to learn more about health care reform and prescription drug issues, or if you’d like access to any of ALEC’s model bills, please contact ALEC’s Director of the Health and Human Services Task Force, Christie Herrera, at (202) 742-8505 or christie@alec.org.



ABOUT THE AUTHOR

Christie Herrera is director of the Health and Human Services Task Force at the American Legislative Exchange Council (ALEC), the nation's largest nonpartisan voluntary membership association of state legislators.

Using her public policy and national campaign experience, Christie drives model legislation, conducts research, builds coalition support, and heightens media awareness in support of pro-patient health care policy. Since Christie joined ALEC in 2005, 22 states have enacted model legislation drafted by ALEC's Health and Human Services Task Force.

Christie has testified before the Arizona, Idaho, Kansas, Kentucky, Michigan, Oklahoma, Texas, Virginia, and Wisconsin legislatures, and she has been a keynote speaker to legislative caucuses, nonprofit organizations, trade associations, and business groups across the country. A contributing editor to *Health Care News*, her work has appeared in the *New York Times* and FoxNews.com, and has been featured on the Fox News Channel, MSNBC, and the Atlantic Politics Channel, among other local and national media outlets.

Christie holds a B.S. in communication studies and an M.S. in political science from Florida State University.



ALEC MODEL LEGISLATION ON PRESCRIPTION DRUG POLICY

The **Cancer Drug Donation Program Act** establishes a voluntary program through which cancer patients can donate their unused prescription drugs to indigent patients.

The **Clinical Trial and Results Registries Act** affirms that access to clinical trial information adds value to science and medicine, and that a state wishing to provide clinical trial information to citizens should link to the U.S. Food and Drug Administration (FDA)-established database, ensuring that clinical trial information is timely and consistent.

The **Drug Liability Act** declares that the lack of clear limitations on prescription drug liability creates disincentives for the research and development of new drugs, and provides those drug liability limitations in statutory form.

The **Drug Reimportation Liability Act** extends limited liability protections to physicians and pharmaceutical companies from damages caused by filling a prescription outside of the United States.

The **Good Samaritan Drug and Medical Supply Donation Act** encourages the donation of medical supplies and drugs by the private sector to nonprofit organizations for distribution to needy individuals without the threat of liability.

The **Prior Authorization Resolution** memorializes the state to eliminate prior authorization systems and preserve access to prescription drugs for America's indigent population.

The **Resolution Concerning the Prohibition of Imported Prescription Drugs** opposes the illegal importation of non-FDA-approved prescription drugs.

The ***Resolution in Support of the PhRMA Code and Corporate Self-Regulation*** affirms the pharmaceutical industry's commitment to ethical patient and physician interactions without government interference.

The ***Resolution on Federalism in Recycling Narcotics*** memorializes the federal government to work with states in establishing recycling and redistribution programs for narcotics in health care facilities and other established state drug repositories.

The ***Resolution on Negative Impacts of Pharmaceutical Price Controls*** affirms that government-mandated price controls on pharmaceuticals negatively impact the quality of health care by increasing prices, curtailing competition, and stifling drug research and development.

The ***Resolution on Prescribing Data*** commends the American Medical Association for establishing the Physician Data Restriction Program and urges the state medical society to inform all licensed physicians about the program.

The ***Resolution on State Use Tax on Prescription Drug Samples*** recognizes that prescription drug samples allow patients new forms of therapy and provide much-needed subsidies for the uninsured, and memorializes the state to pass legislation providing a tax exemption on prescription drug samples.



To access ALEC's model legislation, visit www.alec.org.

Rx

PATIENT NAME:
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DIRECTIONS:

Price Controls

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THE ISSUE

“Price controls” refer to when the government sets a maximum or minimum price for a particular product.



How price controls affect the states

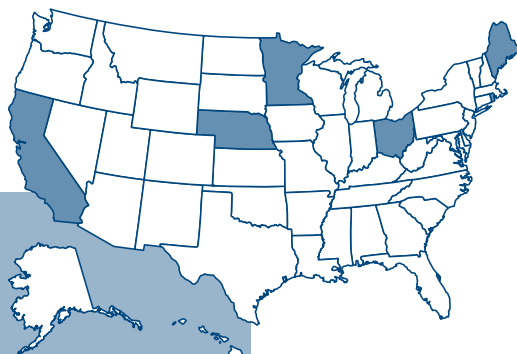
Faced with some consumers who are unable to afford prescription drugs, some state lawmakers are considering price controls to keep drug prices low.

Forced drug rebates are an implicit form of price controls. A 1990 federal law requires drug manufacturers to rebate as much as 35 percent of drug prices to the federal government so states can receive federal Medicaid funds for coverage of those drugs.

In 2000, Maine signed into law the Maine Rx program, which threatened drug manufacturers with prior authorization and preferred drug lists if they did not extend Medicaid rebates to a non-Medicaid population. In other words, if a drug manufacturer did not agree to Maine’s price controls, Maine’s Medicaid program would limit beneficiaries’ access to those drugs.

A lengthy legal battle ensued over whether Maine could extend Medicaid rebates to citizens who earn too much to qualify for the program, and whether Medicaid beneficiaries could be held hostage in favor of lower drug prices. Although Maine eventually backed down from implementing Maine Rx, some cash-strapped states are now requiring federally approved “supplemental” rebates to either force manufacturers to give the state extra cash or block those manufacturers’ drugs from the Medicaid formulary. Since 2004, six states have enacted Maine Rx or similar programs.

More explicit price controls also abound. In 2005, the District of Columbia passed the *Prescription Drugs Excessive Pricing Act*, which made it illegal to sell patented medications for an “excessive price”—defined as a wholesale price



6 Number of states that have enacted Maine Rx or similar programs.

30 percent higher than that same drug's price in Australia, Canada, Germany, or the United Kingdom. If a drug was found to be "excessively priced," D.C. residents could sue manufacturers for being overcharged, or the D.C. government could steal that drug's patent and give it to another manufacturer to sell for less. (The latter is called "compulsory licensing" and is often used by countries with single-payer health systems to similarly extort

price controls on drug manufacturers.)

The D.C. law was struck down by a federal court on grounds that it was unconstitutional and that it violated interstate commerce and patent laws. Despite this ruling, since 2004, 10 states—Colorado, Connecticut, Georgia, Hawaii, Maryland, New Jersey, New York, Oklahoma, Pennsylvania, and Vermont—have introduced similar price control measures.



Problems with price controls

Price controls interfere with the competitive marketplace and lead to rationing.

Buyers and sellers, not the government, know the best price for any product. When bureaucrats artificially depress prices, buyers will hoard those products and sellers will leave the marketplace because of an inability to recoup profits. This results in shortages that not only lead to fewer product choices, but often result in the government rationing products and resources. Proponents of price controls rightly point out that rationing based on price already exists—indeed, rationing is a fact of life since most consumers can't purchase everything they desire. But price controls ensure that the government, rather than individuals, will do the rationing.

Price controls hinder new drug development.

The most damaging effect of price controls on pharmaceuticals is that they will discourage manufacturers from develop-

ing additional lifesaving drugs because they will not be able to recoup the costs of the research and development (R&D) process. Price controls encourage manufacturers to shift resources from R&D to the marketing of existing drugs because investing money in experimental drugs would not be cost-effective. The result is not only harmful for patients, but inevitably leads to devastating cuts in R&D-related jobs.

Price controls lead to increased drug prices.

Simple economics reveal price controls almost always increase prices in the long run. That's because every company engages in what's called "differential pricing"—charging different prices for the same product based on how much is purchased, when it is purchased, etc. (For example, differential pricing is responsible for the deep discounts customers receive at Costco or Sam's Club.) Differential pricing means a manufacturer can sell a product at a lower rate and still turn a profit. In the case of price controls, if

a manufacturer is forced to sell its product at the bulk rate to everyone, then it's rational for the company to raise its lowest price for everyone. While the intention of price controls is to reduce the price of prescription drugs, it will inevitably result in higher prices for all consumers.

Price controls raise overall health care costs.

Profits allow the private sector to invest in the medicines of tomorrow. Price controls limit profits, which means some drugs will never be invented, or that some new drugs will never enter the marketplace. The shortage of cost-effective, innovative drugs will mean some patients must continue to rely on more taxing, and more expensive, forms of treatment. Similarly, price controls in public programs mean government purchasers of prescription drugs will pay less than market value—resulting in a “cost shift” to those with private coverage to make up those funds. In

other words, Medicaid drug price controls will likely result in higher prices and increased premiums for those with private insurance.

Price controls may crowd out the private sector and result in a single-buyer system for prescription drugs.

In the case of Maine Rx, government would have eventually become the only purchaser of prescription drugs in the state. This is called “crowd out,” which means that when the government begins to provide a service, it crowds out private-sector alternatives already in the marketplace. In Maine, government officials would have threatened compulsory licensing to force below-market prices for prescription drugs. This would have given those with private drug purchasing arrangements incentives to instead buy drugs through the state. Eventually, private drug procurement would be squeezed out in favor of the Maine Rx program.

“Simple economics reveal that price controls lead to higher drug prices. If a company is required to sell its product at the lowest rate to everyone, then it’s rational for the company to raise its lowest price for everyone.”



Effective solutions for state legislators

State legislators can't regulate or extort low drug prices into existence. Instead, they should work to protect a free and competitive marketplace that results in lower drug prices and increased innovation.

The private sector is already meeting this challenge. The Partnership for Prescription Assistance (PPA) is an industry-funded effort that serves as a single point of contact for more than 475 patient assistance programs, including nearly 200 offered by pharmaceutical companies. Since its inception in 2005, PPA has helped nearly six million Americans access free or discounted medications. More information about PPA can be found at www.pparx.org.

Together Rx Access is a privately funded, free prescription savings program for those without drug coverage. Under the program, otherwise-eligible families earning up to \$105,000 per year can save 25 to 40 percent on brand-name medicines, and can save thousands on generic products. Nationwide, Together Rx Access boasts more than 1.8 million cardholders

who have saved over \$81 million in prescription drug costs. State legislators may get more information for their constituents at www.togetherrxaccess.com.

Policymakers should work toward a deregulated, competitive marketplace for prescription drugs and insurance coverage. State legislators can also promote price transparency by helping consumers shop for the best drug prices in their state. For example, Florida has established MyFloridaRx.com, a website that provides retail prices for the 100 most commonly used prescription drugs statewide. More information can be found at www.myfloridarx.com.

To counter price control proposals in the statehouse, legislators may also introduce ALEC's *Resolution on Negative Impacts of Pharmaceutical Price Controls*, which affirms that government-mandated price controls on pharmaceuticals negatively impact the quality of health care by increasing prices, curtailing competition, and stifling drug research and development.



For further reading

Hugh Rockoff, "Price Controls," Concise Encyclopedia of Economics, The Liberty Fund: www.econlib.org.



Rx

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Purchasing Coalitions

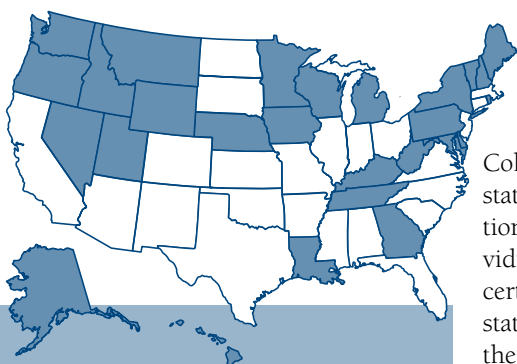
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THE ISSUE

Some states are pooling their collective purchasing power to get bulk prescription drug discounts for either Medicaid beneficiaries or state employees, or a combination of the two populations. Lower-cost drugs are negotiated and those savings are passed along to taxpayers.



How purchasing coalitions affect the states



27 Number of states (and the District of Columbia) that participate in multi-state drug purchasing coalitions.

Twenty-seven states and the District of Columbia participate in one of five multi-state Medicaid drug purchasing coalitions. Nearly all of these states have individual Medicaid formularies in which certain medications are covered by the state Medicaid program, and those not on the list require permission from the state (called “prior authorization”) in order to be covered. And many states have coercive “supplemental” rebate laws that force manufacturers to hand over extra cash, or risk exclusion from that state’s Medicaid formulary.

“It makes sense for states to take advantage of economies of scale in an attempt to negotiate discounts. However, state legislators must consider the tradeoffs before joining a purchasing coalition.”

“Legislators should work to ensure that drug purchasing coalitions aggregate purchasing preferences rather than dictate them.”



Problems with purchasing coalitions

It makes sense for states to take advantage of economies of scale in an attempt to negotiate discounts. However, state legislators must consider the tradeoffs before joining a purchasing coalition.

Purchasing coalitions may give participating states incentives to limit access to certain prescription drugs.

A 2005 Texas Health and Human Services Commission (HHSC) study explained that under the TOP\$ purchasing pool, discounts are based on the number of states that include a particular drug in their formularies. For example, the study says, a discount might be \$0.20 per unit if two TOP\$ states include an identical drug on their formularies, but a discount on the same drug might increase to \$0.30 per unit if four TOP\$ states include that drug on their preferred drug lists. While this does allow states to retain administrative control over their formularies, it also gives them incentives to favor certain drugs over others in order to realize additional savings. Clinical effectiveness, rather than cost, should be the basis for Medicaid drug coverage.

Purchasing coalitions may result in paltry savings.

The Texas HHSC study also determined the cost benefits and feasibility of either establishing a multi-state purchasing pool or joining TOP\$, an existing purchasing pool. The study concluded Texas would miss out on significant savings because 20 percent of its Medicaid-covered drugs were not included in TOP\$. As a result, Texas has not joined TOP\$ or any other purchasing coalition. Similarly, any purchasing coalition that combines the needs of Medicaid and non-Medicaid populations may not produce additional savings, because federally mandated rebates already dictate the “Medicaid best price” for drugs—or the fact that the “Medicaid best price” doesn’t apply to individuals not on the Medicaid program. And despite the fact that a purchasing coalition may initially save money by centralizing drug preferences, an individual state must still pay for additional doctor visits or hospitalizations that may result from changes in medication.



Effective solutions for state legislators

State legislators should ensure any purchasing coalitions are free from coercion, and do not force manufacturers to extend federal Medicaid drug price controls on a non-Medicaid population. Legislators should also work to ensure that drug pur-

chasing coalitions aggregate individual states' purchasing preferences rather than dictate them. Such coalitions should not become de facto central committees that make decisions on which drugs are available to Medicaid beneficiaries.



For further reading

The American Legislative Exchange Council and the Institute for Policy Innovation, "Purchasing Coalitions," *The State Legislators Desktop Reference to Prescription Drug Policy*, January 2005.

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Sales & Marketing Restrictions

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THE ISSUE

In 1997 the U.S. Food and Drug Administration relaxed its rules regarding pharmaceutical broadcast advertising. The new rules spurred an increase in new television and radio ads featuring prescription drugs. Also controversial are promotional efforts directed at physicians who prescribe those drugs.

According to IMS Health, in 2007—the last year for which data are available—drugmakers spent \$4.8 billion on direct-to-consumer advertising and \$6.3 billion on direct-to-physician marketing, which includes the employment of sales reps and their related activities.

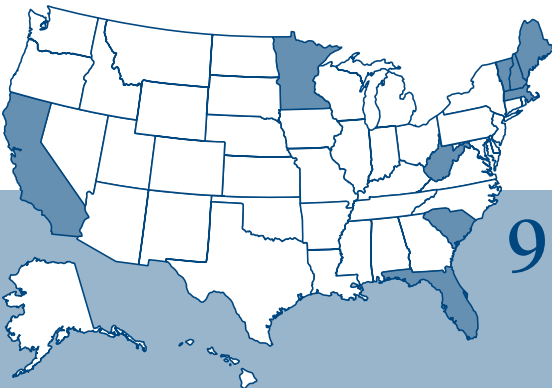
Critics claim pharmaceutical marketing drives up drug prices; spurs unnecessary drug usage; and causes a conflict of interest between manufacturers who make prescription drugs, doctors who prescribe them, and patients who use them.



How sales and marketing restrictions affect the states

At issue for state legislators is whether pharmaceutical sales and marketing tactics lead to increased state spending on prescription drugs for Medicaid recipients and state employees. Nine states and the District of Columbia have enacted laws or resolutions restricting pharmaceutical marketing.

Legislative restrictions on pharmaceutical sales and marketing can take many forms, including restrictions on direct-to-consumer advertising for prescription drugs; licensure of sales representatives; limits on, or reporting of, gifts to doctors over a certain value; bans on prescriber-identifiable data used for commercial purposes; or the mandatory reporting of trade secrets such as marketing or direct-to-consumer advertising disclosures.



9 Number of states (and the District of Columbia) that have enacted laws or resolutions restricting pharmaceutical marketing.



Problems with sales and marketing restrictions

Sales and marketing restrictions are anti-competitive.

Sales and marketing are essential parts of our free-market economy, and restrictions on them amount to an assault on free speech. Sales and marketing spur competition among drug manufacturers, which results in more choices, better consumer information, and lower prices. In contrast, mandatory sales and marketing disclosures could give competitors proprietary information about each other—thus decreasing competition and innovation, and increasing overall health costs.

Sales and marketing restrictions lead to bigger government.

State-level sales and marketing restrictions would introduce more government interference into an already-overregulated industry. Drugmakers' business practices are already subject to myriad federal laws enforced by the U.S. Department of Justice and guided by the U.S. Department of Health and Human Services. What's more, any state-level sales and marketing restrictions would require additional bureaucracies and state taxpayer dollars to enforce those provisions.

Sales and marketing restrictions keep drug prices high.

Critics claim advertising keeps drug prices high, but the National Institute for Health Care Management estimates half of what manufacturers call "promotion" is actually spent on free samples, which benefit patients. And there is no correlation

between marketing expenses and drug pricing. Advertising spurs sales, increasing the incentive for drugmakers to bring new products to market, thus spurring competition and lowering prices.

Sales and marketing restrictions contribute to worsening health outcomes.

Direct-to-consumer advertising raises patient awareness and spurs the diagnosis and treatment of previously undisclosed conditions. Researcher Jacob Arfwedson cites surveys that indicate between 33 and 40 percent of patients say ads prompt them to discuss health issues with a doctor. Early disease detection, coupled with prescription drug treatment and lifestyle changes, may lead to better health outcomes and can help patients avoid costlier interventions (such as hospital stays) later on.

"Sales and marketing are essential parts of our free-market economy."

Sales and marketing restrictions harm industry-physician collaboration, an essential part of medical research and development.

Promotional items from drug manufacturers, such as notepads or a free lunch, are unlikely to have a significant impact

on prescribing behavior. Critics also condemn the fact that drugmakers fund academic research programs and pay physicians to participate in clinical trials. But attempts to squash industry-physician collaboration through burdensome disclosure requirements will produce a chilling effect on doctor participation and, by extension, medical progress.

Sales and marketing restrictions may harm the state economy.

Currently, more than 42,000 clinical trials are underway in the United States. These clinical trials not only offer access to innovative drug therapies—they also create jobs. States that threaten exposure of proprietary information related to clinical trials would encourage companies to move those jobs to a less-regulated state.



Effective solutions for state legislators

State legislators should affirm that any business has the right to communicate with its potential customers—and recognize that pharmaceutical sales and marketing yield societal benefits such as improved health, more choices, and lower prices.

The private sector, not government bureaucrats, should decide how, when, and if to market products to potential customers. To that end, state legislators may introduce ALEC's *Resolution in Support of the PhRMA Code and Corporate Self-Regulation*, which affirms the pharmaceutical industry's commitment to ethical patient and physician interactions without government interference.

And instead of legislating blanket bans on prescribing data, state legislators

should recognize the societal benefits of sharing non-patient-identifiable prescribing data while affirming the rights of individual doctors to restrict access to their personal prescribing data. The American Medical Association (AMA) has established a voluntary solution, the Physician Data Restriction Program, which allows doctors to withhold their prescribing data from pharmaceutical sales reps while still making that information available for medical research purposes.

To that end, state legislators may also introduce ALEC's *Resolution on Prescribing Data*, which commends the AMA for establishing its program and urges the state medical society to inform all licensed physicians about the program.

“The private sector, not government bureaucrats, should decide how, when, and if to market products to potential customers.”



For further reading

Doug Bandow, “Answering the Critics: Five Reasons Why Pharmaceutical Marketing Helps, Not Hurts, Patients,” *ALEC State Factor*, July 2009.



Rx

PATIENT NAME:
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DIRECTIONS:

Reimportation

THE ISSUE

Some consumers are clamoring to purchase lower-priced prescription drugs in countries that have government-imposed price controls, like Canada. “Reimportation” refers to drugs that are made by American manufacturers, sold to other countries, and then shipped back to American consumers.

Passage of the 1987 *Prescription Drug Marketing Act* banned reimportation to “ensure the safety and efficacy of the prescription drug supply of the United States.” Despite the federal ban, Internet and mail-order sales of reimported prescription drugs are on the rise. That’s because it’s virtually impossible for the U.S. Food and Drug Administration to monitor all of the prescription drugs entering the country. Recent federal laws have authorized imported drugs from Canada, so long as the U.S. Secretary of Health and Human Services (HHS) can vouch for their safety. Thus far, however, HHS has not been able to make that claim.

In March 2009, U.S. Senator Byron Dorgan introduced S. 525, the *Pharmaceutical Market Access and Drug Safety Act*, which would allow American consumers, pharmacies, and wholesalers to reimport FDA-approved drugs from Australia, Canada, Europe, Japan, and New Zealand.



How reimportation affects the states

In 2004, Illinois launched its “I-SaveRx” program, through which residents can purchase 120 common name-brand medications from state-approved pharmacies and wholesalers in Canada, the United Kingdom, and other countries.

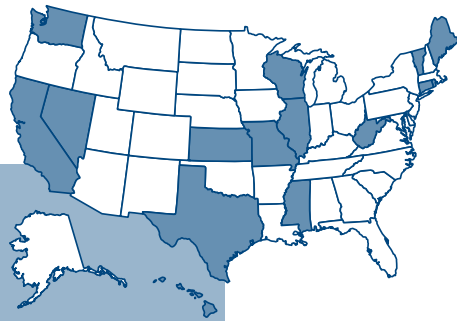
Since then, four other states—Kansas, Missouri, Vermont, and Wisconsin—have also established the I-SaveRx model. But last January, the program’s Canadian supplier dropped out of the program, citing poor participation. In the five participat-

ing I-SaveRx states, only about 6,000 individuals actually enrolled in the program.

Despite the administrative problems with I-SaveRx—and even with the federal reimportation ban in place—some cash-strapped states still view reimportation as a way to cut drug spending despite the fact that existing programs are nonoperational.

15

Number of states (and the District of Columbia) that have enacted laws or resolutions that allow or encourage drug reimportation.





Problems with reimportation

Of course, the safety of reimported drugs—and the liability of states that assist in reimporting them—is of serious concern. But the free-market implications of imposing foreign price controls on the American market are much more severe.

Reimportation allows Canadian-style health care regulation to dominate the American drug market.

Proponents claim reimporting pharmaceuticals from Canada means promoting “free trade.” There are a few libertarian-minded advocates who view reimportation as a way to “right” the market, but the majority of its supporters are anti-free-traders who want drug companies to become charitable institutions rather than profit-making businesses. They know the Canadian drug market is the antithesis of “free trade,” because Canadian drug prices are set by government bureaucrats rather than by the marketplace. And they see a similar opportunity for government intervention here at home.

Reimportation may lead to higher drug prices.

Price controls do keep foreign drug prices low. But widespread importation would mean large American demand for prescription drugs will meet Canada’s limited supply—and force prices to rise.

Reimportation forces American pharmaceutical companies to either participate in foreign price fixing or risk being exploited for their intellectual property.

Legalizing drug reimportation would put American drug manufacturers in a tough position. In order to enter the market in another country, they would be forced either to sell their products at the lowest regulated price there or face “compulsory licensing” that would allow the foreign country to steal the patent and manufacture the drug itself.

Reimportation hinders research and development of lifesaving new drugs.

When price controls—foreign or domestic—are imposed on any new industry, they reduce returns on investments, as well as hinder manufacturers’ ability to develop new drugs, fund innovative research, or increase production.

Reimportation will negatively impact jobs and the economy.

David Tuerck of the Beacon Hill Institute estimates that reduced R&D spending attributable to reimportation would be devastating to state economies. In Massachusetts, the home of numerous biotech and pharmaceutical companies, reimportation would destroy nearly 4,000 jobs and would result in the loss of \$247 million in economic activity.

“When foreign price controls are imposed via reimportation, they hinder manufacturers’ ability to develop new drugs, fund innovative research, or increase production.”



Effective solutions for state legislators

State legislators looking for lower-priced prescription drugs should look to competition and innovation in the private sector—not “free trade” between the U.S. and price-fixing countries—to produce high-quality, affordable prescription drugs.

Competition has already spurred into existence private-sector patient assistance programs, like the Partnership for Prescription Assistance (www.pparx.org) and Together Rx Access (www.together-rxaccess.org).

State legislators can also ensure consumers have the ability to shop for prescription drugs and other health care services

based on price. Florida has already established a website, www.myfloridarx.com, which provides retail prices for the 100 most commonly used prescription drugs in the state.

To counter reimportation proposals in the statehouse, state legislators may also introduce ALEC’s *Drug Reimportation Liability Act*, which extends limited liability protections to physicians and pharmaceutical companies from damages caused by filling a prescription outside of the U.S., or ALEC’s *Resolution Concerning the Prohibition of Imported Prescription Drugs*, which opposes the illegal importation of non-FDA-approved prescription drugs.



For further reading

Mary Katherine Stout, “Drug Importation: A Solution to the Cost of Prescription Drugs?,” Texas Public Policy Foundation Policy Perspective, December 2005.

Rx

PATIENT NAME:
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DIRECTIONS:

Medicaid Formularies

THE ISSUE

A Medicaid formulary (otherwise known as a “preferred drug list”) is a limited list of prescription drugs that are paid for by Medicaid. A beneficiary can petition the state Medicaid program to cover a non-formulary drug as long as his doctor first asks permission from the state to prescribe it (called “prior authorization”).

Formularies exist to create a list of “efficient” drugs that combine clinical effectiveness and cost savings, and to curb the use of “marginally effective” drugs. States with Medicaid formularies have a Pharmacy and Therapeutics (P&T) Committee—made up of physicians and pharmacists—to decide which drugs make the list. The P&T Committee typically evaluates drugs based on clinical trials data, evidence-based treatment guidelines, and cost to the state.

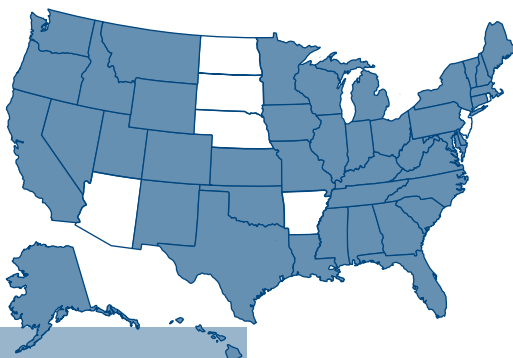
States limit access to Medicaid prescription drugs in a number of ways. In addition to formularies and prior authorization, state Medicaid programs may place arbitrary caps on the number of prescriptions a beneficiary may have at one time or require “step therapy” programs in which patients must first use low-cost drugs before moving to costlier and riskier therapies.

“What is best for patients overall might not work for an individual patient.”



How Medicaid formularies affect the states

A 1990 federal law allows states to engage in prior authorization for particular drugs, and in 1993 the law was amended to allow states to exclude certain drugs from their formularies if the drug lacks “significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome.”



43 Number of states that have Medicaid formularies.



Problems with Medicaid formularies

Medicaid formularies can increase overall health care costs.

Prescription drugs help patients manage chronic diseases and avoid costlier procedures. Some formularies may discourage overall prescription drug use and limit access to new, but costly, treatments. More restrictive formularies shift spending to other high-cost health care interventions, such as office visits, invasive medical procedures, or hospitalization.

Medicaid formularies put a bureaucratic barrier between doctors and patients.

Formularies place bureaucratic limits on the prescribing habits of doctors, which interfere with the doctor-patient relationship. With the availability of treatment options indirectly controlled by the government, doctors will make fewer and fewer decisions without bureaucratic approval.

Medicaid formularies politicize medicine.

Nearly half the states exempt (or “carve out”) certain classes of drugs, or certain beneficiary groups, from Medicaid formulary restrictions. Writes Independence Institute Senior Fellow Linda Gorman, “Now that formulary laws have begun to specifically exempt diseases that affect patients with well-organized lobbying groups, the people most likely to be harmed by the arbitrary drug denials common to Medicaid drug lists are often poor, debilitated, and ill-equipped to protest poor treatment.”

Medicaid formularies cater to the needs of the group, not to the needs of individual patients.

Medicaid formularies decide which drugs are covered based on population-level data. In other words, a drug might be placed on a formulary because it’s effective for a large group of people. But what is best for patients overall might not work for an individual patient.

Medicaid formularies can be based on questionable “evidence.”

Evidence-based data should be used to inform treatment decisions made by patients and physicians. But because Medicaid formularies use evidence-based data to mandate which treatments are available, policymakers should ensure such data meet high research and ethical standards. However, not all “evidence” is equal. Some drug decisions are based solely on randomized clinical trials, a method that excludes vital medical information. Other problems with “evidence” might include researcher or selection bias. Twila Brase of the Citizens’ Council on Health Care points out that each study on a prospective medical treatment is a contribution to an evolving body of evidence. What is known is known only until another study proves differently—and the results of a study may be biased or may not be transferable to all patients everywhere.



Effective solutions for state legislators

State legislators should build a wall around expanding Medicaid eligibility, rather than limiting access to effective medical treatments. The Cato Institute found 21 percent of Medicaid-eligible adults and 27 percent of Medicaid-eligible children actually had private insurance, but dropped their private coverage to join Medicaid. New Jersey extends Medicaid coverage to families earning 350 percent of the federal poverty level—that’s a family of four making over \$77,000 per year. Lawmakers looking to reduce Medicaid spending can do so by preserving the Medicaid program for the truly needy, not extending government health coverage to the middle class.

State legislators should also ensure that limiting Medicaid prescription drug spending does not lead to increased spending in other areas of the program—and this may be accomplished by an annual legislative study. Policymakers should also ensure that the evidence-based decision-making process is transparent and includes quality data from a number of sources.

State legislators may also introduce ALEC’s *Prior Authorization Resolution*, which memorializes the state to eliminate prior authorization systems and preserve access to prescription drugs for America’s indigent population.

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For further reading

Twila Brase, “Evidence-Based Medicine: Rationing Care, Hurting Patients,” ALEC State Factor, December 2008.



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