2003

The State Legislators'

Desktop Reference to Prescription Drug Policy

American Legislative Exchange Council

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The State Legislators' Desktop Reference to Prescription Drug Policy

After nearly a decade of seeing their state revenues steadily grow, most states are facing a significant budget shortfall. State legislators are looking for places to cut their spending, and state purchases of pharmaceuticals have become one of the leading candidates.

But the prescription drug market is very complex and overrun with federal and state laws that can take years to fully understand. As a result, what might seem like a simple legislative change that would save the states money could lead to significant unintended consequences.

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We sympathize with legislators' need to be prudent stewards of taxpayer dollars. There are ways to get more bang for the prescription drug buck, but many states are paying scant attention to those options. This Desktop Reference will help state legislators identify effective actions that may save the states money without reducing access to needed medicines.

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Medicaid Restrictive Formularies

Explanation.

A restrictive formulary is a limited list of medications. Medications not on the list would not be covered by a state Medicaid program unless a physician specifically requested permission to prescribe it and the state granted that permission. Restrictive formularies seek to steer patients and their doctors toward lower-priced drugs in the hope of saving state money.

Issues.

Since the early 1990s, federal law has allowed states to “prior authorize” drugs in the Medicaid program, a process that requires doctors to get prior approval before dispensing drugs. But that option was intended to be very limited, primarily to prevent fraud and abuse. Recently, states have broadened the scope of their interpretation of the law in an effort to discourage doctors from using commonly prescribed drugs. The goal is to discourage doctors, who want to avoid additional government paperwork, from using expensive medications, even if they are the most appropriate.

Most of the increase in spending on drugs has come from increased utilization, not higher prices, and less than 10 percent of total health care spending is for prescription drugs. The fastest-growing component of health care spending — more than a third — is for hospitals. For Medicaid, it is long-term care services.

Spending on pharmaceuticals can save health care dollars while saving and improving the quality of lives. For example, it is estimated that every dollar shifted from older to newer drugs saves about $7 in other health care costs. And research has shown that restricting access to medications can increase overall health care costs by increasing the number of hospital, emergency room and physician visits. A survey by Project Patient Care and Harris Interactive estimates that in 2001 alone, formulary restrictions caused 1.1 million Americans to experience negative health outcomes and 1.9 million to experience side effects.

Restrictive formularies also can decrease patient access to appropriate care. In fact, a group of patients has filed a class action suit against the state of Florida, claiming that the state is denying them access to needed drugs as guaranteed under the federal agreement that created the Medicaid rebate program. Ironically, most states in the 1990s legislated against attempts by Health Maintenance Organizations (HMOs) to control costs by controlling access to care, yet states that impose restrictive formularies are doing the same thing.

Positive Steps.

States considering restrictive formularies are trying to save money, but there are better ways to save.

One way is to focus on outcomes. Disease management programs in which a health care professional educates patients and coordinates their care and support are promising. In several states, such programs are reducing costs by reducing emergency room visits and other pricey hospital services.

Another way is to focus on patients using multiple prescriptions and to carefully evaluate the treatment of these "high utilizers."

States also could consider implementing Maximum Allowable Cost (MAC) programs, which limit payments for brand-name drugs when generic copies are available. For example, a state can preclude Medicaid from paying more than 150 percent of the cost of the cheapest generic copy. This does not limit access to drugs and does lower costs.

States also should act to eliminate both intentional and unintentional Medicaid fraud. Some recipients leave the program, usually because their income increases, yet they remain on the rolls. If they are covered by an employer plan, the state Medicaid program can recover inappropriate payments from the new insurer. Reducing fraud is politically popular and saves money without reducing patients' access to needed drugs.

Finally, states could save significant monies under a nationwide Medicare prescription drug benefit for poor seniors on both Medicare and Medicaid. These so-called dual eligibles consume large parts of the states' Medicaid spending.

Drug Reimportation

Explanation.

In Canada and other countries, some brand-name prescription drugs cost less than in the United States — although many generics cost more. The reasons are clear: the other countries have government-imposed price controls, while we do not. To force drug prices down in the United States, some members of Congress propose allowing wholesalers, pharmacies and even consumers to reimport any drug manufactured in the U.S. and then sold abroad. Despite federal law prohibiting them from doing so, state legislatures in Maine and Vermont have proposed similar enabling statutes.

Issues.

The Prescription Drug Marketing Act of 1988 banned reimportation of drugs to protect American patients from adulterated or counterfeit drugs or drugs that might have lost their potency during foreign handling and shipping. The Food and Drug Administration opposes reimporting drugs, saying it does not have the ability to ensure their safety.

Eleven former FDA commissioners have sent a letter to Congress opposing reimportation, considering it a threat to public health. But a suggestion that drugs be reimported only from Canada does not solve the safety problems.

Of significant concern today is the threat of terrorist cells tainting prescription medicines that are illegally imported into the country with the intent of harming thousands of innocent Americans.

In addition, reimporting drugs into the U.S. is no guarantee that American consumers would see savings. Britain has found that the middlemen, the drug importers, reap most of the benefits.

So why don't drug companies simply refuse to sell their products to other countries at discounted prices? There are several reasons, including:

- *An ethical responsibility to provide life-saving medicines to all.*

- *Recognition that selling drugs even at lower prices to low-income countries helps offset fixed operations costs.*

- *Threats in some countries of compulsory licensing, which would allow the country to manufacturer a generic version of a drug if the drug company refuses the price the country offers.*

Positive Steps.

Reimporting drugs from Canada or elsewhere will not allay the concerns of individual states about drug prices that are high and getting higher. FDA officials and drug manufacturers both have pointed out that individual states considering the reimportation of prescription drugs face the same safety problems as the federal government. The real problem in terms of state budgets is the lack of drug coverage for many seniors in Medicare.

Since seniors' well-being is of paramount concern, states could request that their state medical society or department of health and human services study the health risks of widely practiced reimportation.

Purchasing Coalitions

Explanation.

Several states are considering joining together to get group discounts when buying drugs.

Issues.

In their effort to get lower prices for brand-name prescription drugs, some states are creating purchasing cooperatives. For example, the Minnesota Multi-State Purchasing Initiative includes 26 states that purchase prescription drugs for specific populations. The states control the transfer and dispensing of the drugs and so must follow state and federal pharmacy laws.

Three states — Vermont, New Hampshire and Maine —tried to develop a coalition that would work through a single pharmaceutical benefit management company (PBM). However, the three states have now gone in separate directions.

The notion of groups or states joining together to negotiate discounts in voluntary agreements encourages market mechanisms. However, some states are threatening to impose restrictive formularies that limit access

for Medicaid patients in order to gain lower prices in private markets. Using such threats as leverage is neither ethical nor appropriate. Government has no business trying to collectively organize all private markets.

Positive Steps.

States that want to establish purchasing cooperatives should use numbers, not coercion, to obtain lower pharmaceutical prices. States also should inventory their government pharmaceutical purchases to make certain that they are purchasing in the most cost-effective way.

Drug Price Controls

Explanation.

Under federal law, pharmaceutical companies participating in Medicaid rebate 11 percent for generic companies to between 15 percent and 25 percent for branded companies. Some states — most prominently, Maine — are attempting to force the pharmaceutical companies to give discounts equal to the Medicaid rebates to all state residents who lack drug coverage. If companies do not agree, Maine threatens to put their products on a “prior authorization” list, which means that most patients get the drugs only if a doctor specifically requests permission from the state. A number of states are considering similar programs. A challenge to the Maine program is before the U.S. Supreme Court.

Issues.

Maine and other states are attempting to use the federal statute authorizing special Medicaid drug pricing to justify a state requirement that pharmaceutical companies offer deep discounts to persons not in the federal program.

The Maine program also would give the state health department authority to impose statewide maximum retail price levels for prescription drugs if it deemed pharmaceutical company discounts to be unsatisfactory.

What Maine is doing is creating a system of price controls. But price controls never work in the long run. They always increase prices and decrease access, especially for low-income people. The reason is that all companies, not just those in the pharmaceutical industry, sell their products at different prices to different groups, depending on such factors as time, place and quantity. When price controls are implemented, the company does not settle on the lowest price, but somewhere between its lowest and highest prices. As a result, low-income people looking for the lowest price may pay more, while higher-income people may get the product for less. It is virtually certain that if Maine is successful in establishing price controls, the poor will face higher prices for their drugs.

Finally, imposing price controls in one area usually shifts costs to another. In this case, government-mandated price controls for Medicaid patients could impose higher costs for others, primarily those in the private sector.

Positive Steps.

Instead of quick, shortsighted and ultimately unsuccessful attempts to control prescription drug prices, states could expand disease and case management programs that promote effective drug use to reduce other health care costs, and consider further constructive approaches to improve patients' health outcomes.

States also can purvey information. Most states have drug assistance programs, and pharmaceutical manufacturers have numerous plans for seniors and the poor. Often, however, eligible patients do not know what is available or how to enroll. Each state can and should serve as a clearinghouse for information that connects the needy with the programs that can meet their needs. To this end, the National Council on Aging recently introduced a Web site, www.benefitscheckup.com, which acts as a clearinghouse for state, federal and manufacturer programs available to U.S. citizens.

Tort Reform

Explanation.

The United States has become the most litigious society in history. The tort system cost U.S. businesses, and ultimately consumers, about 2 percent of U.S. gross domestic product in 1998 — more than double the average cost for other industrialized nations — and the cost is growing. Some efforts at reforming the tort system have been successful. Building on these reforms could produce billions in savings throughout the health care system.

Issues.

The tort system costs the health care system $180 billion to $220 billion per year. About $60 billion to $100 billion of that amount is for “defensive medicine” — the cost of extra tests and other measures intended to discourage litigation. This “litigation tax” on every American is estimated at $650 to $1,200 each year. Ironically, about 60 cents of every litigation dollar goes to cover the costs of litigation, including attorneys’ fees.

These costs do not include benefits lost to individuals and society because of the liability concerns that keep valuable products off the market. These losses are most acute in medical research and development. Companies are wary of developing vaccines, and the number of companies doing research on contraceptive devices has declined from 13 to 2 because of the fear of liability.

States that have adopted the appropriate malpractice reforms have experienced substantial savings. Laws that directly limit liability cut hospital expenditures between 5 percent and 9 percent within three to five years, with no differences in mortality and no serious complications.

A Stanford University study estimated that uniform adoption of such legal reforms would reduce health care costs by $50 billion with no serious adverse consequences to the nation's health.

Reforming state liability laws also slows the rate at which malpractice insurance premiums increase. Premium increases from 2001 to 2002 averaged 15 percent in states with punitive damage caps of less than $250,000, compared with a 44 percent increase in states without caps.

Positive Steps.

State legislators should consider capping punitive damages (not economic damages). California's model of a $250,000 cap on non-economic damages for medical malpractice claims has also worked very well. While the issue may deserve more study, another alternative might be to follow the example of Nebraska, where all punitive damage awards are directed to that state's education fund. Monies could also be directed to a state's high risk pool to benefit the uninsured, or to the Medicaid program.

A less comprehensive but still helpful approach would be to exempt drug manufacturers from liability when a doctor has prescribed a properly labeled FDA-approved drug. The FDA approves drugs for safety and efficacy. Manufacturers should not be subject to lawsuits if patients ignore labels or a doctor's instructions.

Direct-to-Consumer Ads

Explanation.

In 1997 the FDA reduced the restrictions imposed on direct-to-consumer (DTC) advertising by pharmaceutical companies, which in turn led to a significant increase in drug advertising in print and broadcast media.

Issues.

Some critics claim that this advertising has caused prescription drug prices to skyrocket and encouraged excessive, even unnecessary drug use. The pharmaceutical industry argues that the ads educate consumers about health issues and the values of the products.

What critics either fail to understand or fail to acknowledge is that advertising empowers patients and lowers prices. This is as true of prescription drugs as it is of groceries. The average price of an advertised prescription drug is less than the average cost of an unadvertised drug. For example, the average price of brand-name prescription medicines advertised to consumers was $78.19 in 2002; the average price of unadvertised prescription medicines was $90.65.

Because direct-to-consumer advertising helps to raise awareness of health issues, it can lead to physician visits and diagnoses of previously undisclosed conditions. *Prevention* magazine reported in 2000 that about 24.7 million Americans talked to their doctors about a medical condition they had never discussed before seeing or hearing an ad that mentioned it. In addition, responding to an ad for one drug may lead patients to receive treatment for other illnesses. According to the Pharmaceutical Research and Manufacturers of America, of 1 million men who visited their doctors as a result of seeing or hearing an advertisement for Viagra, 30,000 turned out to have untreated diabetes, 140,000 had untreated high blood pressure and 50,000 had untreated heart disease.

Of course, seeing an advertisement does not mean that consumers will get the prescription drug advertised. Physicians have to write a prescription first, and research indicates that unnecessary prescribings are quite rare. One survey showed that among consumers who saw a specific advertisement, only 13 percent received a prescription as a result.

Positive Steps.

Some state legislators have considered restricting drug advertisements in their states. But this action surely would be unenforceable because some ads are part of national programming. They also likely would be unconstitutional and doubtless would run counter to existing state laws.

If there is concern that DTC advertising encourages drug overuse or abuse, legislators could commission a study by an outside group, the health department or another state agency to see if patients are receiving appropriate care. The FDA recently did this for the second time nationwide and found that DTC advertising encourages patients with medical conditions to seek needed treatment, that very little abuse occurs, and that most doctors are comfortable with patients' drug inquiries.

Additionally or alternatively, state legislators could commission a study that asks what impact DTC advertising has on the costs of other products such as food, automobiles or over-the-counter drugs.

Prescription Drug Benefit

Explanation.

Medicare does not provide outpatient coverage for most prescription drugs. However, about three-fourths of the people on Medicare have some prescription drug coverage, including about 12 percent who get drug coverage from state Medicaid programs because their age and income qualify them for both Medicare and Medicaid (i.e., the so-called dual eligibles). What is needed now is a Medicare drug benefit that extends coverage to those seniors who need it.

Issues.

Prescription drug coverage was not included in the original Medicare legislation because drugs were a relatively minor component of health care at that time. Today, prescription drugs are recognized as essential to health and disease management.

Pharmaceutical companies have done a great deal to ensure that low-income seniors have access to prescription drugs. Most companies have drug assistance programs to help the poor obtain drugs free or at greatly

reduced prices. These programs provided more than 3 million people with nearly $1.5 billion worth of medicine in 2001. Several drug companies have additional programs that allow low-income seniors to buy needed drugs at deep discounts or for a low set amount per month. All this is in addition to about $10 billion worth of free samples the companies give to doctors, many of whom channel the samples to low-income patients.

Congress is considering a Medicare prescription drug benefit that would relieve the states from covering the dual eligibles. But no one knows whether such legislation will pass.

Several states were exploring ways to fund their own benefits through a source such as tobacco settlement money. More than half of the states have implemented senior drug assistance programs, but with their budgets in crisis, they are finding it more difficult to fund these programs without federal assistance. Several states have shelved their programs because of funding shortfalls.

The Medicare program itself is incomplete and badly designed. Comprehensive reform could focus on the most efficient use of all the government and private funds now spent by or for Medicare recipients.

Positive Steps.

The most useful immediate action states could take would be to call on Congress to add a Medicare prescription drug benefit.

A less costly option would ask Congress to pass a drug benefit that would cover the aforementioned dual eligibles. This program could be funded with a block grant permitting maximum state flexibility.

Several states have received Section 1115 waivers for "Cash and Counseling" programs that are now providing disabled Medicaid patients receiving care at home with a defined contribution they can use to contract for the services they need. This approach is proving to be an overwhelming success. States should consider applying for a waiver that would allow them to provide Medicaid recipients with a defined contribution for prescription drugs. Nevada provides a model for this approach. Using a private insurance company, Nevada offers low-income seniors a prescription drug benefit that could serve as a model for other states. To be eligible, a Nevada resident must be at least 62 years old, make less that $21,500 a year and not qualify for Medicaid drug coverage. The roughly 7,500 seniors in the program pay only $10 for a generic and $25 for a brand-name drug. Although the coverage is limited to $5,000 per person per year, the state pays the entire insurance premium. With a federal waiver, a state could apply the Nevada model to its Medicaid population by contracting with a private insurer to provide the coverage.

Supplemental Rebates

Explanation.

Under federal law, branded pharmaceutical companies participating in Medicaid rebate between 15 percent and 25 percent, while their generic counterparts rebate 11 percent. In exchange, Medicaid is supposed to allow broad coverage of manufacturers' products, although states can exert some restrictions to control spending. Now some states facing budget pressures are requiring or considering additional — "supplemental" — rebates of 10 percent to 80 percent. Only by paying these additional rebates could firms assure that their products appeared on the Medicaid formulary, the list of approved drugs for that state's Medicaid recipients.

Issues.

Pharmaceuticals account for an average of 12 cents of every dollar of Medicaid spending on health care. By law, Medicaid already gets the lowest price offered to any private purchaser. And pharmaceutical companies already pay a rebate of almost one-sixth of the cost of providing prescription medicines to Medicaid

patients. The Congressional Budget Office estimated that, under the 1990 law, collections would be $1.9 billion over five years; collections were $4.7 billion in 2001 alone.

Supplemental rebates are new taxes on drug companies under another name; legislators who have signed “no new taxes” pledges will be violating the pledges if they agree to the new charges. Further, requiring supplemental rebates effectively limits the selection of medicines available to low-income patients. Restricting access to medications can engender increases in total costs. Studies show that restrictions have led to more hospitalizations, emergency room visits and physician visits.

Finally, all supplemental rebates collected by states must be shared with the federal government at the same rate as the federal Medicaid matching grant. Thus a dollar in supplemental rebates may mean only 30 or 40 cents in additional state revenue.

Positive Steps.

States are turning to supplemental rebates as a way to save money. But they could save significant monies if Congress passed a prescription drug benefit that included poor seniors who qualify for both Medicare and Medicaid, the so-called dual eligibles. So calling on Congress to quickly pass a prescription drug benefit would solve part of the problem.

Legislators could emphasize the danger that tighter restrictions on formularies pose to the overall health of low-income patients and the disabled, and especially those with mental illness. Those who support supplemental rebates could make it even harder for the poorest and sickest to access new drugs.

Since supplemental rebates are a new tax on drug manufacturers, legislators can take a strong anti-new-tax stand by challenging those who support supplemental rebates.

Federal law does not clearly authorize supplemental rebates or punitive access restrictions. Legislatures can clarify the matter by specifically prohibiting both.

States also could let competition drive drug costs down by giving Medicaid participants a defined contribution as Nevada has done for its low-income seniors who are not qualified for Medicaid. Claims costs in Nevada were running only about $43 per person per month, plus overhead and administrative fees. Thus the state's program provides a very affordable alternative while retaining access to needed medications.

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