2005

The State Legislators Desktop Reference to Prescription Drug Policy

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For three years, states have been struggling to weather the economic downturn. It now appears things are turning around for most of them, as the economy and state revenues improve. More help will arrive in 2006, when the Medicare bill passed in 2003 shifts some of the burden of providing prescription drug coverage for poor seniors (the so-called "dual eligibles") from state Medicaid programs to the federal Medicare program.

In an effort to cut spending, many states restricted access to prescription drugs by creating preferred drug lists (PDLs) or imposed a new tax on drug manufacturers, referred to as a "supplemental rebate." Some joined bulk purchasing pools in order to obtain larger manufacturer discounts. Some looked for ways to help state employees, seniors or low-income citizens buy imported drugs from abroad.

However, squeezing savings from the drug budget is harder than it looks. 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 — and additional costs.

Legislators need to be prudent stewards of taxpayer dollars, but they also must ensure that vulnerable populations receive appropriate care. This Desktop Reference will help state legislators identify effective actions that may save the state money without reducing access to needed medicines.

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Medicare Drug Discount Card

Explanation

On June 1, 2004, the Medicare-approved prescription drug discount card came into being. It will stay in effect until December 31, 2005, at which point the full drug insurance program will take over. Anyone enrolled in Medicare Part A is eligible to select from the array of official cards available. Some cards have fees associated with them. Only seniors who participate in their state's Medicaid program are ineligible for the Medicare drug card. Seniors can enroll at any time. Questions regarding the program can be answered at www.medicare.gov or by calling 1-800-MEDICARE.

Low-income Medicare beneficiaries (individuals with incomes under $12,569 and couples with incomes under $16,862) are eligible for a $600 credit toward the purchase of needed medications. In order to receive the $600 credit for 2004, the application must be received by December 31, 2004. Anyone who received the $600 credit in 2004 will automatically receive an additional $600 in 2005. Any portion of that $600 not used in 2004 will roll over into 2005. The credit will appear on a user's drug card and be available for use at the pharmacy counter.

As of November 1, 2004, over 5 million seniors have enrolled in at least one of the Medicare-approved discount cards. That number is expected to climb as

states automatically enroll some seniors and news about the significant savings available results in greater participation.

Issues

The new Medicare drug discount card utilizes competition and price transparency to lower prescription drug costs for seniors. Evidence suggests that this approach has already led to significant price reductions.

A study conducted by the Lewin Group for the Healthcare Leadership Council examined the savings available to seniors. Researchers looked at the retail prices of 150 of the most commonly prescribed drugs for seniors and compared them to prices available to people enrolled in the Medicare discount card. All comparisons were based on a 30-day supply.

The Lewin study found:

- Overall, beneficiaries would save $1,247 on average over 18 months;
- Those with the $600 credit would save $1,548 over the same period;
- The best discount cards nationally offer savings of nearly $10 per prescription;
- Beneficiaries on a typical hypertension regimen would save $254 annually;
- Beneficiaries on a typical diabetes regimen would save $480 annually;
- Assuming enrollment meets CMS projections, seniors would save an aggregate of $7.7 billion.

According to the study, seniors in Louisiana would save over 50 percent per capita, the most in the country. Next are New Mexico (43.4%), Texas (43.1%), Georgia (42.4%), and North Carolina (42.3%).

Positive Steps

The Medicare-approved drug discount card is a federal program. But state legislators and others can be very helpful to seniors by discussing these cards, assisting with enrollment, and trading information on which cards offer the best discounts in their respective areas. State legislators may want to consider asking Congress for a continuation and expansion of the discount drug card program, even in lieu of the drug insurance program due to take effect on January 1, 2006.

Medicaid Restrictive Formularies

Explanation

A restrictive formulary is a limited list of medications that is often referred to as a "preferred drug list" or "PDL." 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. PDLs seek to steer patients and their doctors toward lower-priced drugs in the hope of saving state money. There are many other access-restriction programs that have a similar effect. "Step therapy" (or "fail first") programs start patients on a lower-cost medication, then move them up to more expensive therapies if the cheaper ones fail. "Therapeutic interchange" allows substitution of a less-expensive drug that has been determined, usually by a committee, to have the same therapeutic effect. "Prior authorization" programs require a physician to first get permission from the state before prescribing a drug not on the PDL.

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 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 limit access to several 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.

However, most of the increase in spending on drugs has come from increased utilization, not higher prices. Only about 10 percent of total health care spending is for prescription drugs. The fastest-growing component of health care spending — more than one-third — is for hospitals, and for Medicaid long-term care services, which continue to strain state budgets.

Spending on pharmaceuticals can save health care dollars while saving and improving the quality of lives. For example, Columbia University economist Frank Lichtenberg has 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 can also decrease patient access to appropriate care. In fact, a group of patients filed a class action suit against the state of Florida claiming that the state was denying them access to needed drugs as guaranteed under the federal agreement that created the Medicaid rebate program. The state settled with the patients out of court, agreeing to a provision that, while imposing some limitations, still ensures patient access. Ironically, most states in the 1990s legislated against HMOs' attempts to control costs by controlling access to care; yet states that impose restrictive formularies are doing the same thing.

Positive Steps

Implementing a preferred drug list can be harmful to patients. CMS guidance on PDLs says "When implementing PDLs, we urge states to be mindful of patients who are stabilized or previously prescribed, non-preferred medications . . . . we further urge states to consider the impact of beneficiaries of sudden changes in therapy as a result of a state's implementation of a PDL." 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. Such programs are reducing costs and improving patient outcomes by targeting the most expensive users who suffer from one or more chronic conditions such as asthma, congestive heart failure,

diabetes, coronary artery disease and/or depression. (See the Disease Management Association of America [www.dmaa.org]).

Another way is to focus on patients using many prescriptions and to carefully evaluate the treatment of these "high utilizers," which in extreme cases may be using 20 or more prescriptions in a six-month period. While this number of medications may be appropriate for some individuals, there is an increased potential for drug therapy problems, such as drug interactions, that will necessitate closer review. Such a review would intend to prevent these problems and minimize duplicative therapy.

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 approach does not limit access to drugs and still lowers 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.

The best way to ensure that all decisions about which drugs are chosen for the formulary is to require that all meetings and records be open to the public. This way, all interested parties can see why the committee decided on one drug over another and what research and testimony were used to make those decisions, while providing an opportunity for input. This process also allows for public input. Decisions should be made so that clinical and cost considerations are clearly understood. Clinically inferior drugs should not be sold to the public as superior products in order to meet cost goals.

Finally, any new drug should be available to all patients unless and until the committee decides otherwise. If the committee is going to err, it should err on the side of access and availability.

Importation

Explanation

Importation is the practice of bringing prescription drugs into the United States, but avoiding the FDA's processes for ensuring safety. "Reimportation" generally refers to the drugs that are made by U.S. drug manufacturers and sold and shipped to other countries, which are then sold and shipped back (reimported) to the states. While the two terms are often used interchangeably, reimportation is actually one form of the broader practice of importation.

Issues

It is against the law to import or reimport drugs into this country unless it is done by a medication's manufacturer. The FDA typically does not enforce rules against U.S. citizens returning from abroad with a small amount of medication intended for personal use (see http://www.fda.gov/ora/import/pipinfo.htm).

But that doesn't mean it's legal; for practical and political reasons the law has not been rigidly enforced. So elected officials who encourage or help the poor, seniors or government employees buy prescription drugs from Canada or other countries are helping those Americans break the law, and may be breaking the law themselves by facilitating the acquisitions.

The Food and Drug Administration opposes importation, saying it does not have the ability to ensure the safety of those drugs. Congress has given the secretary of the Department of Health and Human Services the authority to permit importation whenever the secretary can ensure the drugs are safe and would save Americans money, but neither the current secretary nor past secretaries have reached that conclusion. Moreover, 11 former FDA commissioners have sent a letter to Congress opposing importation, considering it a threat to public health.

Nevertheless, there are mayors, state legislators, governors and even members of Congress who are engaged in efforts to facilitate the purchase of foreign drugs over the Internet, despite the fact that such actions are explicitly illegal.

But isn't importation just free trade? The answer is that free trade presupposes it is legal trade; importation is illegal, just as cross-border trade in narcotics and certain types of military technology are illegal, even though allowing the transfers would boost trade numbers. Additionally, free trade implies the free flow of goods across borders competing freely on price and quality. Drugs imported from Canada do not compete freely on price; the prices of these products are not set in the marketplace, but by government bureaucrats in the Canadian health care system.

Furthermore, expanding importation will not save Americans money, as noted in a recent report from the U.S. Congressional Budget Office ("Would Prescription Drug Importation Reduce U.S. Drug Spending?" CBO Economic and Budget Issue Brief, at http://www.cbo.gov). Indeed, widespread drug importation would force prices up. Canada represents 2.6 percent of the global prescription drug market, while the U.S. represents 53.4 percent. This means that Canada has a very limited supply of prescription drugs relative to the U.S., and would never be able to meet the demands of the American market.

As any economist knows, when demand is greater than the supply, the price of a product typically will rise, or wholesalers will find other sources of supply. News stories are already emerging that in order to meet the demand, Canadian drug wholesalers are scrambling to find more drugs in what's known as the secondary market, where middlemen from all over the world buy and sell drugs. And some Internet pharmacies, as well as some elected officials, have flatly stated that they will go to other countries to find additional supplies without disclosing those countries or supply channels.

Nevertheless, two U.S. cities have decided to import drugs from Canada for city employees and retirees, and several states are considering a similar program, even though the FDA has adamantly opposed such actions and sent warning letters to those attempting such pro-

grams. Such efforts by elected officials raise serious questions about potential future litigation against entities promoting this type of activity and whether, long-term, there will be any cost savings.

Positive Steps

While some elected officials have gained headlines trying to import drugs, such programs will likely be a short-lived response. Shortages emerging in Canada are driving Canadian officials to restrict or eliminate efforts to export drugs to the U.S., especially for large groups such as city employees.

There are a number of options available for states wanting to help low-income people gain access to affordable prescription drugs. To begin with, most drug manufacturers have programs to provide low-income patients with access to prescription drugs at greatly discounted prices or free. States should help promote information about these and other programs to expand awareness of what is available and how to access the programs. For example, Pfizer makes its medications available to all those who are uninsured for a significant discount or for free depending on their income level (www.pfizer.com).

Maryland has taken some positive steps toward increasing access to prescription drugs by creating a new program that could be a model for other states to follow: the Maryland Medbank. This program, partially funded by a state appropriation, is a clearing-

house that provides Marylanders with information about existing programs (www.medbankmd.org).

According to Medbank, the program has provided $56.2 million worth of free medicine and processed 245,000 prescriptions for 28,676 patients (through August 2004). The typical Medbank patient has a monthly income of $1,300, or 175 percent of the Federal Poverty Level (FPL). Thus the state has played a leading role in educating consumers about available programs that help them get prescription drugs at little or no cost.

But states can do more. For example, New York has taken an innovative step to promote price transparency by posting on the state's web site the prices of the 25 most popular drugs from pharmacies in all 62 counties. The prices are taken from the state-mandated Drug Retail Price List, which requires all state pharmacies to list the prices of the 150 most popular medications. There can be significant price breaks, depending on which pharmacy a person chooses. New York has demonstrated that patients need not cross borders to find affordable drugs. They may only have to go across town.

Purchasing Coalitions

Explanation

An attempt by several states to join together in the hope of getting large group discounts when buying prescription drugs.

Issues

The Centers for Medicare and Medicaid Services (CMS) has approved a multi-state purchasing pool that includes Michigan, Vermont, New Hampshire, Nevada, Alaska, Minnesota and Hawaii. Other states are also looking to form or join a pool.

The states' goal is to "negotiate" greater savings from drug manufacturers. There is nothing wrong in theory with states joining together in voluntary arrangements to negotiate discounts. That's just relying on economies of scale. In practice, however, the key mechanism for extracting greater discounts or supplemental rebates is through the threat of access restrictions, not economies of scale.

Thus, what is touted as using the market to negotiate discounts is little more than an attempt to create a monopsony (i.e., a market where there is only one buyer; the flip-side of a monopoly). Indeed, a large enough pool could significantly influence the direction

of both the research and development of new products. Thus, the wants and desires of those making up the approval committee could carry more weight in deciding which diseases and new drugs are most important, rather than making those decisions based on what patients need or what research-based companies think are promising therapies.

Positive Steps

The Centers for Medicare and Medicaid Services has released guidance to state Medicaid directors (SMDL #04-006) for states wanting to join a purchasing pool. It is clear that CMS wants to balance states' desire to "achieve cost savings while at the same time protecting the interests of Medicaid beneficiaries and promoting competition."

If a state wants to enhance its buying power by joining with other states, negotiations should be free of coercion. Using the threat of limiting the poor's access to certain drugs is an unethical, and probably illegal, bargaining chip.

In addition, the negotiations should be decentralized as much as possible. Investing some type of committee with the power to make decisions about which drugs will and will not be available to a population of millions of people would be an invitation for all types of interest groups to become involved, politicizing the entire process.

If a committee is formed, the best way to limit political influences is to ensure that all records are open. This way, the public can see why the committee decided on one drug over another and what research and testimony were used to make those decisions. In addition, CMS recommends that states "annually evaluate and issue a public report on the aggregate cost savings associated with their participation to determine whether expenditures in other Medicaid areas, such as hospitalizations or physician services, have increased as a result of the implementation of a multi-state pooling agreement."

Finally, any new drug should be available to all patients unless and until the committee decides otherwise. If the committee is going to err, it should err on the side of access and availability.

Drug Price Controls

Explanation

Under federal law, pharmaceutical companies participating in Medicaid must rebate 11 percent for generic companies and about 30 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. After nearly four years, Maine's program has not yet been implemented due to legal challenges. It was due to be implemented early in 2004, but was put on "indefinite hold" because the upcoming Medicare discount cards may provide better benefits to many Maine residents than the Maine program.

Issues

A number of states are attempting to use the federal statute authorizing special Medicaid drug pricing to leverage discounts from pharmaceutical companies to offer deep discounts to persons not in the federal program.

The Maine program 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 typically increase prices and decrease access, especially for low-income people. The result is that low-income people needing the lowest price may pay more, while higher-income people may get the product for less.

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

States have several options to shortsighted and ultimately unsuccessful attempts to control prescription drug prices. First, legislators need to recognize that prescription drug prices can vary significantly from pharmacy to pharmacy. And the fact that it is difficult for consumers to compare prices at different pharmacies exacerbates the problem.

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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.

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States could expand disease and case management programs that promote effective drug use to reduce other health care costs. For example, the Disease Management Association of America (www.dmaa.org) provides an online searchable database that includes the most costly chronic medical conditions such as asthma, congestive heart failure, diabetes, coronary artery disease and depression. Therapeutic solutions

for these diseases usually rely heavily on prescription drugs. States that manage these patients well, will both improve health outcomes and save money.

The goal of price controls is to reduce spending. But there are other ways of accomplishing this end. For example, the state of Nevada has contracted with a private insurance company to offer 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 than $21,500 a year and not qualify for Medicaid. 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.

Tort Reform

Explanation

The United States has become the most litigious society in history. The tort system costs about $233 billion in 2002, or 2.2 percent of U.S. gross domestic product — 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 of dollars in savings throughout the health care system.

Issues

The U.S. tort system is costly and inefficient. The "litigation tax" on every American is estimated to cost about $809 each year. The country spends about $60 billion to $100 billion for "defensive medicine" — the cost of extra tests and other measures intended to discourage litigation. 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 (not economic) damages. California's model of a $250,000 cap on non-economic damages has worked very well. (For more information, see ALEC's model legislation.) For example, in 2003 Texas enacted sweeping and comprehensive tort reform that included California-style noneconomic damage caps of $250,000. Medical malpractice insurance rate hikes have already been eliminated for 2004 premiums and are even declining for some doctors. In addition, in 2004 Mississippi made significant strides that include many of the best aspects of the California and Texas reforms.

Alternatively, states could redirect punitive damages to someone or some group other than the plaintiff and the plaintiff's attorney. For example, diverted punitive damages could help to fund the state's provision of prescription drugs to low-income families or its coverage of the uninsured.

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 Advertising

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 advertising has caused prescription drug prices to skyrocket and encourages excessive, even unnecessary drug use. Proponents argue 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

may lower prices. This is as true of prescription drugs as it is of groceries, automobiles and computers. Suggestive of this relationship is the fact that the average monthly price of an advertised prescription drug ($78.19 in 2002) is less than the average cost of an unadvertised drug ($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 2002 that more than 61 million Americans talked to their doctors about a medical condition they had seen advertised, and 25 million talked to their doctor for the first time about a medical condition. According to a 2003 FDA survey, 88 percent of responding physicians said patients inquiring about a drug had a disease the drug treated.

Of course, seeing an advertisement does not mean that consumers will get the prescription that was advertised. Physicians have to write a prescription first, and research indicates that unnecessary prescriptions 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

The states' primary concern over DTC advertising is whether it is increasing utilization among populations whose prescriptions are subsidized with state money, primarily Medicaid and other public health program recipients and state employees.

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. However, 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. These findings are important because two of the biggest problems facing Medicaid populations are awareness and compliance. By advertising, the manufacturers actually heighten public awareness about certain illnesses that can and should be treated. And the ads implicitly serve as reminders that patients already on medications should take them.

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.

Rather, what a state could do is sponsor its own ad encouraging those concerned about a medical condition to see their doctor. The ad could refer the audience to a web site or a phone number that provides information about available programs and services. The point is not to fight advertising and the media, but to use them to enhance the state's message.

Supplemental Rebates

Explanation

Under federal law, pharmaceutical companies participating in Medicaid rebate 11 percent for generic companies and about 30 percent for branded companies. In exchange, Medicaid was 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. 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 10 cents of every dollar of Medicaid spending on health care. And, under federal law, pharmaceutical companies already pay states 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 essentially a new tax on drug companies under another name. Requiring supplemental rebates can effectively limit the selection of medi-

cines available to low-income patients (through the use of preferred drug lists), which can lead to increases in total costs if patients are substituting hospital or institutional care for drug therapy. 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 means, on average, only 43 cents in savings for states.

Positive Steps

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.

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 only running a little more than $40 per person per month, plus overhead and administrative fees. Thus it provides a very affordable alternative while retaining access to needed medications.

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