

Q. In December 2003, Congress extended Medicare coverage to prescription drugs. Meanwhile, several states have developed their own prescription drug plans. How do the states' strategies compare with the new federal initiative?

A. Both the states and the federal government are dealing with the same situation but in fundamentally different ways.

States, which have a track record handling prescription drug benefits through Medicaid, are employing strategies aimed at reducing costs. The federal government, on the other hand, focuses on expanding coverage but has no plan for reducing costs. This different focus shows up in many ways. In fact, some provisions of the new federal law could well undermine state efforts.

The situation both states and the federal government are confronting is this. Prescription drug costs have become a key driver of higher overall medical expenses, especially for the elderly. In 2002, prescription drugs cost \$162.4 billion, up from \$100 billion in 1992. The costs are expected to rise to some \$240 billion by the end of 2005. As of 2002 prescription drug costs accounted for 10.5 percent of all health care costs and 23 percent of out-of-pocket health care costs.¹

The federal strategy

Since the early 1980s, Congress has debated whether to add a prescription drug benefit to Medicare.² In December 2003, the Medicare Prescription Drug, Improvement and Modernization Act (MMA) included such a benefit. The program goes into effect on January 1, 2006.³ At that time, Medicare will pay 75 percent of the premiums for Medicare beneficiaries enrolled in a private prescription drug plan or a new Medicare prescription drug plan.

Voting on the bill split along party lines. Eighty-eight percent of Republicans in both Houses of Congress supported the bill. Eighty-nine percent of Democrats opposed it.

The bill's primary objective was to extend prescription drug coverage, not to restrain rising drug costs.

Indeed, provisions of the law expressly prohibit certain strategies widely used to curb costs. Medicare recipients can enroll in either a drug plan offered by Medicare or one offered through a private company (which will be reimbursed by Medicare). The Medicare plan cannot negotiate prices with the manufacturers. The private insurers and

¹ *Time*. February 2, 2004.

² A prescription drug benefit was added in 1988, but was repealed in 1989 before being implemented.

³ In the interim Congress approved the issuance of drug discount cards and a \$600 per year subsidy to drug purchases by low-income seniors. Both the discount cards and the subsidy end when the full program begins. The interim program will not be discussed here.

Pharmacy Benefit Managers (PBMs) they contract with can, but the law does not require that any savings from these negotiations be passed on to the enrollees.

With 29 million expected beneficiaries, Medicare would be the largest drug-buying block in the U.S. Health plans and PBMs will negotiate prices for smaller buying blocks, as is now the case with employer-sponsored coverage.

The law also keeps in place the ban on importing drugs produced in the U.S. and sold in countries like Canada, where the price is much lower because the Canadian government negotiates steep discounts with suppliers.⁴

Congress initially estimated the program would cost \$400 billion over its first ten years. But in September 2004 the White House Office of Management and Budget and Medicare projected a total cost of \$576 billion.⁵ The director of the Congressional Budget Office informed Congress the program's "cost would exceed \$1 trillion and could approach \$2 trillion during the following decade".⁶

Despite this enormous outlay the benefits are uncertain. Health experts have identified several significant shortcomings in the federal program.

1. Without restraints on rising drug costs, benefits will be modest.

Under the new program, enrollees pay a premium of about \$420 a year and must pay the first \$250 of drug expenses. "In order to gain a financial benefit that exceeds out-of-pocket expenditures, a beneficiary will have to incur annual drug expenses of at least \$810, on average", one health analyst points out.⁷

The cost-benefit arithmetic is sobering. In 2003, average prescription drug spending was \$2322. An uninsured senior would have had to pay the full cost out of pocket. In 2006, average prescription drug spending is expected to rise to \$3,160. Under the provisions of the new program the Medicare beneficiary will spend \$2180 out of pocket, only \$142 less than in 2003! The Kaiser Family Foundation projects that one in four enrollees will have

⁴ I will not be discussing buying prescription drugs from Canada, despite the enormous attention it has received in the media. Importing prescription drugs from Canada is not a long-term solution. The American market dwarfs the Canadian market, and Americans are willing to pay much higher prices than Canadians. It is likely that if American purchases rose significantly, pharmaceutical companies would impose a quota on drugs purchased by the Canadian government based on previous year's sales. When that happens Americans will begin cannibalizing the tiny Canadian market, a prospect that is both unseemly and cowardly. We need to solve our own problems.

⁵ Ceci Connolly, *Washington Post*, September 26, 2004.

⁶ Douglas Holtz-Eakin, "The economic cost of long term obligations", Testimony before the U.S. House Committee on the Budget. July 24 2003. Washington, D.C. Congressional Budget Office. 2003.

⁷ John K. Iglehart, "The New Medicare Prescription-Drug Benefit—A Pure Power Play", *The New England Journal of Medicine*. February 19, 2004.

higher out-of-pocket spending than they would have without the new law, *even without including the annual premium.*⁸

2. Congress created a gap in coverage that will adversely affect many beneficiaries.

Medicare covers 75 percent of drug costs up to \$2,250. However, to keep expenditures within the original \$400 billion projected cost, Congress inserted in the coverage what has come to be known as the doughnut hole. For drug costs between \$2,250 and \$5,100, the beneficiary pays 100 percent of expenses. If expenses rise above \$5100, Medicare coverage kicks in again, this time covering 95 percent of the cost.

The Kaiser Family Foundation estimates that about 20 percent of Medicare beneficiaries will have drug expenditures exceeding \$5,000 annually in 2006.⁹ They will pay about \$4,000 of this out-of-pocket, plus 5 percent of any costs beyond \$5,100.

3. Employers may cut back or drop prescription drug coverage when the new Medicare program kicks in.

More than one-third of seniors enrolled in Medicare also have employer-sponsored health care plans that pay for services not covered by Medicare, including prescription drugs. The percentage of companies offering retiree health benefits has already plunged from 66 percent in 1988 to 38 percent in 2003, and the new Medicare program could further the decline.¹⁰

To encourage employers to maintain drug coverage for retirees after 2006 the Medicare Modernization Act of provides \$88 billion in direct and indirect subsidies. Despite these subsidies the Congressional Budget Office (CBO) projects that many employers will drop coverage. The CBO further predicts that 24 percent of retirees with private employer-sponsored benefits (nearly one in five Medicare Part B enrollees) will see their benefits scaled back.¹¹ Why? Because employers qualify for the federal subsidy merely by offering coverage equal to the actuarial value of Medicare's basic drug benefit, which is considerably less generous than most retirees' drug plans.

4. Many low-income people¹² who qualify for both Medicare and Medicaid ("dual eligibles") will be adversely affected by the new law.

⁸ Kaiser Family Foundation, [Prescription Drug Spending under the MMA: Modeling the Impact on Out-of-Pocket Costs](#), News Release, November 22, 2004.

⁹ Kaiser Family Foundation, [Medicare and Prescription Drug Spending Chartpack](#), June 2003.

¹⁰ Kaiser Family Foundation/Health Research and Educational Trust, [Employer Benefits Survey](#), September 2003.

¹¹ Congressional Budget Office [Letter to Representative Bill Thomas](#), November 14, 2003 and [Letter to Senator Don Nickles](#), November 20, 2003.

¹² This group is defined as those with incomes of less than 150 percent of the federal poverty level, or less than about \$14,000 for individuals and \$18,700 for couples in 2004.

Under the current system, Medicare and Medicaid jointly cover virtually all drug expenditures by dual eligibles. Under the new law their Medicaid drug coverage will end and they will have to qualify for the Medicare plan. The new plan takes into account both income and assets. The CBO estimates that 1.8 million people with incomes of less than 150 percent of poverty – one-eighth of current dual eligibles – will not qualify because of the addition of the asset test.¹³ Many more with incomes between 135 percent and 150 percent of poverty will pay more than they are paying now, and receive lesser coverage.

State strategies

State prescription drug strategies, unlike that of the federal government, focus on lowering the cost of prescription drugs and ensuring that any resulting savings are passed onto the beneficiaries.

Medicaid, unlike Medicare, is a state program funded by a matching grant from the federal government. The state establishes benefits and coverage levels. The federal match varies significantly from state to state, based mainly on state median income. All states receive a minimum of a 50 percent federal match. Mississippi, with the country's lowest per capita income, earns the highest match, 77 percent.¹⁴

State Medicaid spending has increased by almost 50 percent since 2000. It is among the fastest growing items in state budgets and drug spending is one of the fastest growing components of Medicaid. In Illinois, for example, about 60 percent of Medicaid cost increase is tied to increased spending on drugs.

Thus, to keep the overall Medicaid costs down, many states are trying to reduce the cost of prescription drugs. State officials argue that pharmaceutical companies can significantly lower their product costs without endangering their R&D efforts.

State officials point out that since 1997, when the FDA loosened the rules governing drug advertising aimed at consumers, television drug advertising has soared. Today pharmaceutical companies spend nearly 3 times more on advertising and marketing the newest drugs than they do on R&D. And their heavy spending on direct-to-consumer advertising is associated with large increases in drug spending.¹⁵

But not every new drug promoted represents a breakthrough. Most aren't even an advance over current treatments. Instead, they are new formulations of existing medications, or

¹³ The asset test includes liquid assets like savings and investments, but excludes the value of a primary residence. The limit on assets is \$10,000 for individuals and \$20,000 for couples.

¹⁴ See [Ask Dr. Dave on Medicaid](#) for a more extensive discussion.

¹⁵ The National Institute for Health Care Management found that nearly half(47.8 percent) of the increase in retail spending on prescription drugs from 1999 to 2000 resulted from increases in sales of the 50 most heavily advertised drugs. The number for prescriptions written for those drugs rose nearly 25 percent, compared to an increase of only 4.3 percent for less heavily advertised drugs. See National Conference of State Legislatures.

www.ncsl.org/programs/health/bulkrx.htm

so-called "me too" drugs. Cialis and Levitra, for example, are me-too drugs that work the same way as the anti-impotence drug Viagra.

During the first 11 months of 2004, the U.S. Food and Drug Administration approved 99 new drugs. Just 19 of those were classified by the agency as a "significant improvement" over available treatments. That's about the same ratio as in previous years.¹⁶

States have embraced a number of strategies to curb prescription drug costs.

1. Substituting cheaper generic drugs for brand name drugs.

Some 37 states require generic drugs be dispensed to Medicaid recipients if they are available. Generics cost as much as 70 percent less than brand name drugs, on average.

2. Developing a formal list of qualifying drugs based on cost and effectiveness.

In 1993, Congress amended the law to allow state Medicaid programs to control the use of certain formulary drugs. States were allowed to develop a list of pre-approved drugs and require physicians to gain prior authorization before they could prescribe other more costly drugs.

More than 33 states now have Preferred Drug Lists (PDLs) for Medicaid recipients. A PDL, as defined by the National Governors Association, "steers Medicaid beneficiaries toward drugs that are therapeutically appropriate and less expensive". Doctors can prescribe other drugs, but they need permission from the state to have these drug costs reimbursed.

Manufacturers who want to be included in PDLs often provide "supplemental rebates" to the state to get their products in the right price range.¹⁷

Recently, the federal Center for Medicare and Medicaid Services (CMS) has approved a arrangement whereby Alaska, Hawaii, Michigan, Minnesota, New Hampshire, Nevada and Vermont can coordinate their Medicaid PDLs in order to achieve rebates from manufacturers greater than those allowed under federal Medicaid law.

West Virginia is currently creating a single preferred drug list not just for Medicaid but also for all state agencies.

The courts, for the most part, have ruled in favor of state prescription drug interventions.¹⁸

¹⁶ St. Louis Post-Dispatch December 29, 2004

¹⁷ Rebates are supplemental in the sense that all drugs purchased by Medicaid programs are already discounted deeply by the manufacturers. All drug companies sell products to Medicaid programs at a discount set by the federal government, usually about 20 percent below the average wholesale price.

3. Relying on evidence-based medicine

As part of the development of Preferred Drug Lists, states have begun to establish their own testing facilities to evaluate the comparative therapeutic effectiveness and costs of drugs. Currently the Oregon Health and Science Center in Portland has contracted with 12 states to perform such an evaluation. Dr. John S. Santa, the center's medical director observes, "In most of the 15 drug classes reviewed to date, we found no evidence that one drug was more effective than others intended to treat the same illness." Medicaid officials steer doctors and patients away from costly drugs found to have no proven clinical advantage over less expensive products.

Oregon's reviewers detected safety problems with Vioxx in 2002. As a result it was excluded from their list of preferred drugs.

4. Bulk purchasing.

Prices for prescription drugs vary dramatically depending on who buys them and in what quantity. Several federal agencies purchase drugs through a bulk discount established by the federal Supply Schedule. The Department of Veterans Affairs, for example, saves 52 percent off the list price of a drug (i.e. the average wholesale price). The Canadian government negotiates bulk purchasing agreements with US based pharmaceutical companies and pays about 40 percent less than the average wholesale price.

On the other end of the spectrum, uninsured patients pay the highest price for prescription drugs. One study found residents of Los Angeles, for example, paid 69 percent more for common prescriptions than the federal government. Another study, prepared for Indiana Congressional Representative Peter J. Visclosky, found that his district's seniors paid an average of 117 percent more than the VA for the five best selling drugs for older Americans.

Prior to 2000 only a few multi-state purchasing pools existed, and most involved purchasing drugs for state health facilities. Intrastate bulk purchasing was also done solely for state health agencies. In the last few years, more than two-dozen states have joined purchasing pools.

¹⁸ The primary initiator of these lawsuits has been a trade group, Pharmaceutical Research and Manufactures Association of America(PhRMA). When Maine lawmakers extended the federal Medicaid drug discount negotiated with manufacturers to people not on Medicaid but who have low or moderate incomes, PhRMA sued. Maine suspended its program pending a decision by the U.S. Supreme Court. PhRMA lobbied strongly against a 2004 Indiana bill that would have established an internet site listing comparable drugs by price. The bill passed the Indiana House but did not get a Senate hearing. PhRMA sued Florida, whose PDL law took effect May 2001, arguing that the formulary provision violates a federal statute that requires states to offer all prescription drugs to Medicaid beneficiaries "unless there is a written finding that the drug offers no clinically meaningful benefit". The court ruled in Florida's favor

West Virginia called a special legislative session in November 2004 to consider legislation that authorizes a single state coordinator to negotiate deep discounts on drugs purchased for virtually all the state's insurance and health care programs. The measure passed unanimously. West Virginia's plan could potentially cover more than a third of its 1.8 million residents. Moreover, private employers and individuals might join the state's drug purchasing pool in the future.

5. Reigning in Pharmacy Benefit Managers (PBMs).

PBMs are companies that act as intermediaries between health care plans and drug companies and pharmacies. They do the bargaining. Unfortunately, in a number of cases the PBMs are guilty of conflicts of interest, including direct and indirect ties to pharmaceutical manufacturers.

The four largest PBMs--AdvancePCS, Merck's Medico Health unit, Express Scripts and Caremark Rx—have been sued by California's AFSCME, representing 1.3 million public employees in the state. AFSCME claims these companies have failed to pass on savings from secretly negotiated rebates and have earned "spreads" on drugs by paying drug stores a lower price for medicines than they charge their clients.

To improve this situation, Georgia enacted a law in 2002 that requires PBMs to be licensed by the state board of pharmacy. In 2003, Maryland required the state insurance commissioner to examine PBMs at least every three years. The same year Maine enacted a more far-reaching statute. It clarifies that PBMs work for health plans and individuals covered by the health plans, not for the drug manufacturers or other parties. In other words, it assigns a "fiduciary responsibility" to the PBM on behalf of its clients. And it requires PBMs to adopt ethical rules to prevent conflicts of interest and to pass savings from negotiations onto consumers.

A number of states and health plans are moving toward a fee-based service arrangement with PBMs. The PBM is paid an administrative fee, but all rebates and other negotiated advantages are passed through to the plan.

A federal Medicaid time bomb: the clawback.

As noted above, the 100 percent federally funded Medicare system will take over paying prescription drug benefits in 2006 from the partially federally funded state Medicaid programs. This might be expected to save the states many billions of dollars. At the last minute, however, Congress inserted into the Medical Modernization Act of 2003 a provision that calls for the states to pay the federal government a large part of the savings they would otherwise have gained from the shift in financing.¹⁹

¹⁹ Neither the House nor the Senate version of MMA contained this provision. It was added in the Conference Committee as a way to reduce the federal outlay below the statutory \$400 billion ceiling.

The statutory term is “phased-down State contribution”. It is popularly known as “the clawback”. The clawback provision requires states to pay the federal government 90 percent of their estimated savings in calendar year 2006, a percentage that gradually drops to 75 percent over the next nine years. The savings are calculated from the expenditures the state would have had to make if it had continued to pay outpatient prescription drugs through Medicaid on behalf of dual eligibles, that is, low-income elderly or disabled individuals who are enrolled in both Medicaid and Medicare.²⁰ Dual eligibles account for a majority of state Medicaid costs.

Because of rising drug costs, state clawback payments are estimated to increase from \$6 billion in 2006 to \$15 billion in 2013.

The clawback provision has several ramifications. One is that the states’ fiscal liability is now directly linked to federal budget policy. If Medicare prescription drug costs increase at their recent rate, the federal government could ask the states to contribute more or reduce the scope of coverage.

Another problem is that the formula penalizes generous states. The formula relies heavily on each state’s per capita expenditure (PCE). The amount is determined largely by each state’s Medicaid spending on outpatient prescription drugs for dual eligibles in the calendar year 2003. State data for 2002 show a wide variation in prescription drug spending per dual eligible, ranging from \$375 in Tennessee to \$1371 in New Hampshire.

States that have high per capita spending in calendar year 2003 would have their clawback amounts calculated each year using this higher amount. That is true even if they implement effective prescription drug cost containment measures that reduce their per capita spending in later years. Thus states with a high per capita drug spending in 2003 would be permanently disadvantaged vis a vis states with a low per capita expenditure for that year. That disadvantage would grow as the annual rate of increase in per capita national prescription drug spending on all populations, is applied equally among the states.

Kaiser observes, “In short, the more effective a state is in managing the costs for its prescription drug benefit in the future, the more likely it is that the state’s clawback payments will exceed its savings from Medicare Part D coverage.”

For further information

National Conference of State Legislatures. 2004 *Prescription Drug State Legislation*. www.ncsl.org/programs/health/drugdisc04.htm. www.ncsl.org

²⁰ In 2002, according to Kaiser, 6.1 million low-income Medicare beneficiaries were enrolled in Medicaid for outpatient prescription drugs.

National Governors Association. [Center for Best Practices](#). *State Purchasing Pools for Prescription Drugs*. www.nga.org

[Resources on the Medical Prescription Drug Benefit](#). Kaiser Family Foundation.
www.kff.org