# Punishing the Pioneers: The Medicare Modernization Act and State Pharmacy Assistance Programs

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The adoption of the new Medicare prescription drug benefit in 2003 added yet another iteration to the action-reaction or interactive style of federalism that has characterized this complex policy area for three decades. Though the federal government benefited from state-level policy learning, it penalizes states that were most generous and innovative in their experimentation with pharmaceutical assistance by making them pay for much of the program's costs. The federal government will administer the new benefit, leveling many state-to-state differences in drug coverage, but at the price of standardizing the program under federal rules and punishing pioneering states for their initiative. This precedent may come back to haunt federal-state relationships by discouraging risk taking that might lead to similarly adverse outcomes for innovative states in the future.

States have long been innovators in health policy (as in many other fields), including resource-based payment for physician services, prospective payment for nursing homes (budgets fixed in advance), requirements for certification of a need for new health care facilities before they can be built, state-mandated employer insurance programs, medical malpractice lawsuit limits, rights of dying patients to refuse medical treatments, statewide rate setting for providers regardless of payer, state uncompensated care pools to reimburse hospitals for serving patients who cannot pay, state taxation of providers to help pay for care for poor people, mandated wellness programs aimed at keeping people healthy, state-endorsed longterm care insurance, statewide fixed premiums for insurance by class of patient, medical savings accounts permitting patients to put money away tax-free for later use, prohibition against hospitals discharging costly patients before they have recovered, setting priorities for who gets served when public funds are not available, mandating insurers to pay for nontraditional health care services, making publicly available the profiles of physicians who have been disciplined, permission for patients to sue managed care companies, mandated minimum ratios of nurses to patients in all hospitals in the state, extension of home care services into assisted living settings, preadmission screening for hospitals and nursing homes,

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competitive contracts for managed care plan participation in public programs, health maintenance organization (HMO) regulation, and a multitude of other ideas that have often led the way for subsequent federal initiatives.<sup>1</sup> Invariably a limited cast of leader states takes the plunge (often large, wealthy, urban, heterogeneous states),<sup>2</sup> presumably in response to constituent or interest group demands and rational legislators' desire to claim credit, improve policy, or both. This is followed in a 'learning model' of state-to-state diffusion by a few, often geographically proximate, states.<sup>3</sup> Others then study these states and improve upon their policies, until eventually the federal government moves to standardize benefits across the states, dragging along states slow to act or limited in their policy choices.

Susan Welch and Kay Thompson,<sup>4</sup> in their study of 57 policy innovations, argue that states led the way "in almost every instance." However, the national government's role in these innovations has taken a variety of forms. These range from signaling that it would not be addressing the problem for the foreseeable future<sup>5</sup> to giving incentives to states through grants-in-aid, to issuing direct orders, crosscutting requirements that mandate policy changes in a variety of programs, and crossover sanctions that leverage potential sanctions in one policy area with demands for action in another. The national government's role also includes partial preemption of policy when states have not responded quickly or thoroughly enough to suit congressional preferences.<sup>6</sup> The national government—particularly federal agencies—may also provide advice and moral support.

This paper summarizes the three-decade-long history of state pharmacy assistance to poor and near-poor citizens, acknowledging unevenness in state response while noting that among the neediest and most costly state claimants were many beneficiaries of Medicare—the nationally financed and administered health insurance program for elderly and disabled people—which historically has not covered prescription drugs. The federal government's interactive involvement in that history is also chronicled,

<sup>4</sup>Susan Welch and Kay Thompson, "The Impact of Federal Incentives on State Policy Innovation," American Journal of Political Science 24 (November 1980): 715–729, at 719.

<sup>5</sup>Mahalley D. Allen, Carrie Pettus, and Donald P. Haider-Markel, "Making the National Local: Specifying the Conditions for National Government Influence on State Policymaking," State Politics & Policy Quarterly 4 (Fall 2004): 318–344.

<sup>6</sup>Chung-Lae Cho and Deil S. Wright, "The Devolution Revolution in Intergovernmental Relations in the 1990s: Changes in Cooperative and Coercive State-National Relations as Perceived by State Administrators, *Journal of Public Administration Research and Theory* 14 (October 2004): 447–468.

<sup>&</sup>lt;sup>1</sup>Carol S. Weissert and William G. Weissert, *Governing Health: The Politics of Health Policy* (Baltimore, MD: Johns Hopkins University Press, 2002).

<sup>&</sup>lt;sup>2</sup>Jack L. Walker, "The Diffusion of Innovations among the American States," *American Political Science Review* 63 (September 1969): 880–899.

<sup>&</sup>lt;sup>3</sup>Steve J. Balla, "Interstate Professional Associations and the Diffusion of Policy Innovations," *American Politics Research* 29 (May 2001): 221–245; Frances Stokes Berry and William D. Berry, "State Lottery Adoptions as Policy Innovations: An Event History Analysis," *American Political Science Review* 84 (June 1990): 395–415; Virginia Gray, "Innovation in the States: A Diffusion Study," *American Political Science Political Science Political* 7 (December 1973): 1174–1185.

ranging from signals that Medicare drug coverage would not be forthcoming to national legislation that strengthened the hand of state program administrators, to eventual passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (PL 108-173). The MMA institutes a national drug program for Medicare beneficiaries (Part D), ends state policymaking in drug choices and prices for Medicaid (the federal-state-financed and state-administered program for poor people), establishes regional organizations to administer the benefit, and demands state matching payments and beneficiary premiums and co-payments as important sources of funding along with authorization of substantial national general revenue payments.

Although an important objective of this paper is to summarize this complex piece of legislation, and the even more complicated history of policy related to state pharmacy assistance, a paramount goal is to signal arrival at an important milepost on the road of fiscal federalism, a milepost indicating that traffic has started going the other way. Rather than the federal government using financial incentives or threats to encourage states to adopt policy change, the MMA adopts federal policy while requiring state governments to pick up the tab. This is a new departure, certainly in degree if not in kind, and has significant implications for states and their relationship with the federal government:

- State policy innovation may suffer if states worry that they could be responsible for the costs of their policy experiments in perpetuity, even when the federal government follows their lead and takes over responsibility for a policy area.
- State fiscal capacity for innovation may be compromised by the consequences of federal management of program responsibilities for which the states are paying the bill but are no longer in a position to influence costs.
- Less congruence between public policy and public opinion may occur as serious moral choices traditionally devolved to states' more homogeneous preference venues will now be resolved nationally.<sup>7</sup> Examples include decisions on such controversial issues as coverage for lifestyle drugs,<sup>8</sup> pain-relieving narcotics, and contraceptives (e.g., for younger Medicare eligible women with mental retardation and developmental disabilities).

This article begins by describing state activity and federal-state interaction in relation to prescription drugs. This is followed by examination of

<sup>&</sup>lt;sup>7</sup>Christopher Z. Mooney, "The Decline of Federalism and the Rise of Morality-Policy Conflict in the United States," Publics: The Journal of Federalism 30 (Winter/Spring 2000): 171-188. <sup>8</sup>Robert Pear, "Companies Fight to Ensure Coverage for Erectile Drugs," New York Times

<sup>22</sup> February 2005, p. 12.

the federal response to state policy in three areas—assistance, litigation, and reimportation. Variation in pharmaceutical assistance and cost containment across states is also described. Next, the Medicare Modernization Act and its implications for state governments are discussed. The article concludes by exploring the ramifications of federal prescription drug policy for future innovation and risk taking by the states.

## THE STATES AND PRESCRIPTION DRUGS

U.S. health spending on prescription drugs reached \$162.4 billion in 2002, more than quadrupling since 1990, when it was \$40.3 billion. Although they constitute only 12.1 percent of personal health care expenditures, prescription drug expenditures have increased by double digits every year since 1995. Between 2001 and 2002, U.S. prescription drug spending grew by 15.3 percent, exceeding the annual growth rate for other health care services, including physicians (7.7 percent), hospitals (9.5 percent), and long-term care services (4.9 percent). Most prescription drugs are paid for privately, either out of pocket (29.9 percent) or by private health insurance (47.8 percent), though Medicaid (17.6 percent) also plays a large role, and Medicare's role (1.6 percent) will grow significantly following implementation of Medicare Part D in 2006.9 Medicaid is an especially important source of prescription drug coverage for low-income individuals, including the "dually eligible"-that is, individuals whose age or disability makes them eligible for Medicare, but whose poverty status or monthly health expenditures also make them eligible for Medicaid. Although it is an optional benefit, all states have elected to provide at least some level of pharmaceutical coverage under Medicaid. Between FY 2002 and FY 2004, state officials ranked prescription drugs as either the first or second most significant factor contributing to Medicaid program growth.<sup>10</sup> By 2002, Medicaid prescription drug spending had reached \$28.6 billion, more than five-and-a-half times its 1990 total of \$5.1 billion.<sup>11</sup>

Beyond requirements that states cover all drugs approved by the U.S. Food and Drug Administration (FDA) whose manufacturers have entered into Medicaid program rebate agreements with the federal government, states retain considerable discretion in establishing their prescription drug benefits under Medicaid. This is reflected in cross-state variation in Medicaid prescription drug spending for dual eligibles, which ranged from nearly 25 percent of total Medicaid expenditures for this population in Florida, Mississippi, and Vermont in 2002 to less than 10 percent in

<sup>&</sup>lt;sup>9</sup>Centers for Medicare and Medicaid Services, Office of the Actuary, *Health Accounts*, 6 December 2004; cms.hhs.gov/statistics/nhe/default.asp.

<sup>&</sup>lt;sup>10</sup>Vernon Smith, Rekha Ramesh, Kathleen Gifford, Eileen Ellis, Robin Rudowitz, and Molly O'Malley, *The Continuing Medicaid Budget Challenge: State Medicaid Spending Growth and Cost Containment in Fiscal Years 2004 and 2005* (Washington, D.C.: Kaiser Commission on Medicaid and the Uninsured, October 2004).

<sup>&</sup>lt;sup>11</sup>Centers for Medicare and Medicaid Services, Health Accounts.

Connecticut, New York, and Rhode Island.<sup>12</sup> It is also reflected in the strategies states have chosen to address the tension between improving access to high-cost prescription drugs and maintaining control over program expenditures. In response to the economic downturn during 2001–2004, more than one hundered new laws were adopted in fourty-six states changing Medicaid coverage and payment policies for prescription drugs. State policy makers also became progressively more concerned with prescription drug issues as they relate to broader segments of the population. One indicator is the number of bills being considered on the topic, which grew from 63 to 413 to 588 from 1999–2000, 2001–2002, and 2003–2004, respectively. Enactments showed a similar increase with 17 prescription drug bills signed into law during 1999–2000 compared with 90 signed into law during 2001–2002 and 133 during 2003–2004.<sup>13</sup>

## FEDERAL-STATE POLICY LEARNING IN PHARMACEUTICAL ASSISTANCE

Federal-state interplay in prescription drug assistance policy has been dynamic, changing at times from close cooperation to grudging support to stormy conflict. At times, different parts of the national government have taken opposing positions over the same state policies. Initially, Congress strengthened the states' hand with the adoption of the Medicaid drug rebate program with the Omnibus Reconciliation Act of 1990 (OBRA'90) (PL 101-508). OBRA'90 requires drug makers to enter into rebate agreements with the Centers for Medicare and Medicaid Services (CMS) within the United States Department of Health and Human Services (DHHS), the federal agency responsible for administering Medicaid, as a condition of participation in the Medicaid program. Currently, the mandatory rebate for nongeneric drugs is the greater of the following: 15.1 percent of the average price paid by wholesalers or the difference between that price and the "best price," which is the lowest price offered in the United States. The law forced drug makers to give the discounts to all states or be barred from selling drugs to any state's Medicaid program.

Unfortunately, at the same time that Congress established the rebate program, it took away one of the states' most effective levers for garnering bigger discounts: the threat that a particularly expensive drug would simply not be offered by the state program. States had implemented highly restrictive "formularies" (lists of drugs covered under Medicaid) that excluded certain high-cost drugs. But with OBRA'90, the federal government ruled out this possibility, requiring that states carry all the

<sup>&</sup>lt;sup>12</sup>Brian Bruen and John Holahan, Shifting the Cost of Dual Eligibles: Implications for States and the Federal Government (Washington, D.C.: Kaiser Commission on Medicaid and the Uninsured, November 2003).

<sup>&</sup>lt;sup>13</sup>National Conference of State Legislatures, *Pharmaceuticals*, 10 January 2005; www.ncsl.org/ programs/health/pharm.htm (updated 3 January 2005).

drugs from any manufacturer who had a Medicaid rebate agreement with the federal government. States initially found the inability to exclude particular drugs constraining, but necessity being the mother of invention, they worked around this prohibition by carrying all of a manufacturer's drugs but subjecting some-typically the most expensive-to prior authorization (verbal or written approval) before they could be prescribed or filled.<sup>14</sup> Physicians and pharmacies quickly learned to avoid the transactions costs of prior authorization by simply picking a different drug. Prior-authorized drug sales fell accordingly, leading manufacturers to begin to provide price reductions and supplemental rebates in exchange for being excluded from state requirements for prior approval. As the practice matured, the size of the rebates was redesigned to grow with the volume of a drug's sales, giving states stronger incentives to prefer a company's particular drugs. Although the federal government eventually repealed the prohibition on excluding coverage for specific drugs in 1993, it set a high standard for doing so,<sup>15</sup> allowing states to refuse coverage only if a committee of clinicians concluded that a therapeutically equivalent drug in terms of safety, efficacy, and clinical outcome already existed on a state's formulary.<sup>16</sup> Consequently, most states continue to make all eligible drugs available to Medicaid recipients, usually in accordance with preferred drug lists (PDLs), which identify drugs that can be prescribed without first receiving special advance permission.

Meanwhile, the federal government learned from the states and would ultimately surpass its teachers in garnering price reductions. The so-called Big Four purchasers (the Department of Veterans Affairs, Public Health Service, Department of Defense, and Coast Guard), with insured populations larger than most state Medicaid programs, realized that they might be able to demand even greater discounts. But when these agencies approached the drug companies, they received a rude awakening: they were unable to acquire discounts as large as they wanted because manufacturers were reluctant to give them a price that ipso facto would grant an even bigger discount to the states under the Medicaid drug rebate program (because doing so would result in a lower "best price" to the states). So the federal government responded by exempting itself from the "best price" calculation used for state Medicaid pricing. It also established several federal-only discount programs with the Veterans Health Care Act of 1992 (PL 102-585), including one program targeted at federally supported safety-net providers and another setting maximum ceiling prices for the Big Four purchasers.

<sup>&</sup>lt;sup>14</sup>Section 1396r-8(d)(1)(A), Paragraph (5) of the Federal Medicaid Statute. Prior authorization programs must provide for twenty-four-hour responses and seventy-two-hour emergency supplies. <sup>15</sup>Dennis G. Smith, State Medicaid Directors Letter #04-006 (Baltimore, MD: Center for Medicaid and

State Operations, 9 September 2004).

<sup>&</sup>lt;sup>16</sup>Section 1396r-8(d)1(B),(d), Paragraph (4) of the Federal Medicaid Statute.

The discounts acquired by federal agencies have been so large (onethird to one-half or more in some cases)<sup>17</sup> that many states realized that they would have to develop new strategies if they were going to emulate federal success. In 2004, 36 states sought supplemental Medicaid rebates in addition to those mandated under federal law. Others have adopted state assistance programs, extending pharmaceutical discounts to low-income, medically needy residents not covered by Medicaid. With no federal law to strengthen their hand, however, states have had a harder time promoting compliance with their expanded discount programs. One approach has been to pass a state law similar to OBRA'90, requiring that any seller supplying drugs to a state assistance program must provide the state with rebates on the prescription medications sold. However, because state assistance programs are much smaller than states' Medicaid programs, vendors may choose not to participate-especially in small population states. Similar challenges apply if the state instead uses the threat of prior authorization for drugs that do not pay a rebate. These kinds of concerns have led states to adopt a variety of innovative approaches to extending pharmaceutical coverage to otherwise non-Medicaid eligible residents.

# FEDERAL RESPONSE TO STATE PHARMACEUTICAL ASSISTANCE EFFORTS

State budgets are finite as, unlike the national government, states cannot spend more than their annual revenues. Hence states have had to come up with a wide range of approaches and techniques for expanding access to prescription drugs while limiting the costs of their share of state pharmaceutical assistance programs. Major cost containment strategies include (1) preferred drug lists and other product coverage restrictions, including prior authorization and mandatory use of generic drugs when available; (2) eligibility limits, including income ceilings, asset tests, and other restrictions; (3) patient utilization controls, including monthly prescription limits, cost sharing requirements, case management, limits on the number of brand-name prescriptions per month, and limits on pharmacy fees; (4) intrastate and interstate compacts to leverage larger bulk purchasing discounts; (5) international imports of cheaper drugs from Canada and other countries; (6) negotiating supplemental rebates from manufacturers beyond federally mandated Medicaid levels; (7) decoupling discounts and subsidies by mandating that sellers and manufacturers who supply Medicaid patients also offer price reductions to non-Medicaid patients; and (8) contracting with pharmacy benefit managers to negotiate voluntary discounts with pharmacies and manufacturers.

<sup>&</sup>lt;sup>17</sup>William H. Von Oehsen, *Pharmaceutical Discounts under Federal Law: State Program Opportunities* (Oakland, CA: Public Health Institute, May 2001).

States relied on each of these strategies in 2004, whether for their Medicaid, non-Medicaid, or state employee benefit programs. Commonly used are prior authorization (used by 98 percent of the states), cost sharing (90 percent), multistate purchasing (90 percent), preferred drug lists (82 percent), supplemental Medicaid rebates (72 percent), mandatory use of generic drugs (62 percent), contracting with pharmacy benefit managers (60 percent), quantity limitations (40 percent), multiagency purchasing (90 percent), and reimportation (32 percent) (Table 1). To varying degrees, each of these strategies risks violating federal law or the federal constitution or both. And many are likely to raise the ire of the drug industry, fostering lobbying of Congress or federal lawsuits against state governments and sometimes their federal agency supporters. Other strategies may find the federal government siding with manufacturers against the states. The following discussion explores state activity and federal response in three areas: (1) state pharmacy assistance expansions and the CMS, (2) the pharmaceutical industry and federal courts, and (3) reimportation and the FDA. This section shows that interactions between the states and the federal government vary both over time and by the branch of government or mission of the federal actors involved.

#### State Pharmacy Assistance and the CMS

By 2004, thirty-eight states had adopted pharmaceutical assistance programs targeted mainly at the low-income elderly and disabled who do not qualify for Medicaid. These range from heavily subsidized, widely enrolling, and broad-coverage assistance programs to unsubsidized, narrow and restrictive efforts that in the least generous examples do little more than encourage drug manufacturers to provide discounts to the state's elderly and disabled citizens while incurring no costs to the state budget. Thirty-three states currently have at least one program in operation, and five have adopted programs that have yet to be implemented or are non-operational owing to a lack of appropriated funds. Whereas thirty-two programs use state funds to provide subsidies to assist in the purchase of prescription drugs, seventeen achieve price reductions through pharmaceutical discounts and manufacturer rebates with little or no state expenditure.<sup>18</sup> Several states also pursue discounts through multistate purchasing cooperatives.

States adopting the most basic discount initiatives, such as Louisiana and South Dakota, simply facilitate access to private programs established by drug manufacturers. Hawaii, Illinois, Ohio, and New Hampshire take a different approach: they contract with private sector pharmacy benefit managers (PBMs) who may be able to obtain voluntary discounts and

<sup>&</sup>lt;sup>18</sup>Edward A. Miller and William G. Weissert, Despite Medicare's New Drug Law Geography Will Still Dictate Rx Coverage for Many Near-Poor Seniors and Disabled (New Haven, CT: Yale University, Tallahassee, FL: Florida State University, 2005).

Table 1 prescription drug cost containment p
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	-		Stat	state prescription drug cost containment policies	table t drug cost co	ntainment	t policies			
	Pharmacy benefit manager	Prior authorization	Preferred drug list	Limits on number of prescriptions	Generics required	Cost sharing	Supplemental rebates	Multiagency purchasing	Multistate purchasing	Reimportation
Alabama		X	X				×	X	×	
Alaska		X	×	×	x	X	x		X	
Arizona	×		×			×			×	
Arkansas		X		X	X	X			×	
California		x	×	x		Х	x	×		x
Colorado		X			×	x			×	
Connecticut		X	X		x	X	x		×	X
Delaware		×			x	X			×	
Florida	x	X	×	X	X	X	x			
Georgia	X	X	x	X	x	X	×	X	X	
Hawaii	×	×	×		×				×	×
Idaho	X	X	X	X	x	X	X		×	
Illinois	x	X	×			×.	X	X	x	x
Indiana		X	×			×		×	×	
Iowa	X	X	×			×	x	x	×	
Kansas	×	X	×	X		Х	х		×	x
Kentucky		x	×		×	X	x		×	
Louisiana	X	X	x	X		×	×		×	
Maine		X	×		×	Х	x	X	×	x
Maryland		X	×	X	x	Х	x		×	
Massachusetts		X	×	X	×	×		X	×	
Michigan	×	X	×			×	×	x	×	
Minnesota	×	X	×		×	×	x		×	×
Mississippi	X	X	×	X	×	×			×	×
Missouri		X	×	×	×	X	×		×	X
Montana	×	X	×		x	X	×		×	
Nebraska	×	×			×	×	×		<b>x</b> .	
Nevada		X	×			×	×	X	×	X

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				)	Continued					
	Pharmacy benefit manager	Prior authorization	Preferred drug list	Limits on number of prescriptions	Generics required	Cost sharing	Supplemental rebates	Multiagency purchasing	Multistate purchasing	Reimportation
New	Х	×	×		×	X			X	
Hampshire									1	
New .	x	X		×	×	X	X			
Jersey										
New Mexico	X	X	X			X	X	×	X	
New York	X	X	×	×	×	×	×		×	
North Carolina	×	X		X	×	X	X		X	
North Dakota	×	X				X	×		X	
Ohio	×	×	×				X			
Oklahoma		X	×	X	×	X			X	
Oregon	X	X	x			×			×	×
Pennsylvania		×			×	X	X		X	
Rhode Island		X			X	X			X	×
South Carolina	X	X	×	×	×	×	×		×	
South Dakota		X	x			Х	x		X	
Tennessee			X				X		×	
Texas	×	×	×	×	×		x	x		
Utah	X	Х	×	х	X	x		x	X	
Vernont	×	Х	×		×	×	×	×	×	x
Virginia		×	×			X	X		x	
Washington		X	x	X	x		х		×	×
West Virginia	X	×	×		×	X	×	×	X	Х
Wisconsin		X	x			Х	x		x	×
Wyoming	x	x	x			X			×	
Number	30	49	41	20	31	45	36	15	45	16
Sources: Neva Kaye, Afford page.cfm?LID=666CB5DC Dccember 2004; www.nga.c Continuing Medicaid Budgat	aye, Affording , 666CB5DC-794 www.nga.org, caid Budget Cha	Presci Presci 8-111 (cda, (cda,	gs: State Init. 0A0CC76FF 7PHARMPR Trail, Kimb	intives to Contain (4C; National G OGRAM.pdf; N erly Fox, Joel Ca	n Cost and I overnors A Vational Co antor, Mina	<i>mprove Acc</i> ssociation nference o	rescription Drugs: State Initiatives to Contain Cost and Improve Access, 9 October 2004; www.nashp.org/_docdisp_ H11D6-BD1700A0CC76FF4C; National Governors Association, State Pharmaceutical Assistance Programs, July 2004, 18 da/files/0407PHARMPROGRAM.pdf; National Conference of State Legislatures, Pharmaceuticals, Vernon Smith et al., lenge, Thomas Trail, Kimberly Fox, Joel Cantor, Mina Silberberg, and Stephen Crystal, State Pharmacy Assistance Programs.	004; www.nashf tical Assistance , rres, Pharmaceu Trystal, State Ph	p.org/_docdis <sub>f</sub> Programs, July 2 tticals, Vernon 2 tarmacy Assistan	sp_ 2004, 18 : Smith et al., 
A Chartbook (New York: Th	v York: The	ie Commonwealth Fund, August 2004)	Fund, Augu	ist 2004).						1

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Table 1

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rebates from pharmacies, manufactures, or both by acting as purchasing agents for multiple clients. (This approach was adopted by the federal government in the 2003 MMA.) Two states—Florida and California mandate that pharmacies provide all beneficiaries of Medicare with retail discounts as a condition of participation in these two states' Medicaid programs. Others, such as Michigan, Connecticut, and Oregon, have established voluntary programs whereby state agencies negotiate discounts with participating pharmacies. Although most states implement pharmaceutical assistance programs under their own statutory authority, others do so, in part, under the auspices of federal Medicaid waivers, which enable states to implement changes that would otherwise violate Medicaid's fundamental principles.<sup>19</sup>

Most subsidy programs target low-income elderly individuals, though some include the low-income disabled as well. Although most programs are funded all or in part through states' general revenues, six states fund expanded coverage through Medicaid 1115 "research and demonstration" waivers, which allow states to study the benefits and costs of expanding Medicaid eligibility or services on what is nominally a temporary basisthough some nonpharmacy 1115 demonstration projects have gone on for many years. Tennessee and Vermont fund subsidy programs as amendments to broader waivers affecting Medicaid coverage and services generally. Florida, Illinois, Marvland, South Carolina, and Wisconsin do so through "Pharmacy Plus" waivers approved by the CMS. Essentially, these programs enable states to extend pharmaceutical coverage to lowincome elderly and disabled individuals who otherwise would not be eligible for Medicaid. Under these waivers, states may provide coverage to individuals on with incomes up to 200 percent of the federal poverty level (FPL).

Like other 1115 demonstration waivers, however, Pharmacy Plus demonstrations must be budget neutral to the federal government; that is, the costs of services under the waiver must not exceed the costs that would have been incurred without the demonstration. Waiver applications are reviewed and approved or rejected by the CMS.<sup>20</sup> "By providing this coverage, states reduce the likelihood that these individuals will become Medicaid eligible," thereby resulting in savings to the Medicaid program.<sup>21</sup>

<sup>&</sup>lt;sup>19</sup>States seek waivers to provide unusual services, extend eligibility to new groups, incorporate lock in and lock out providers, or implement novel service delivery models, often in restricted geographic areas, and often to selected subpopulations. <sup>20</sup>Indiana also has an approved Pharmacy Plus application pending further changes. Arkansas,

<sup>&</sup>lt;sup>20</sup>Indiana also has an approved Pharmacy Plus application pending further changes. Arkansas, Connecticut, Maine, Michigan, New Jersey, and North Carolina currently have applications under consideration, while Massachusetts recently withdrew its application. Waiver applications have also been authorized by legislatures in Nevada, New Mexico, Rhode Island, Washington, and Wyoming, though they have yet to be submitted.

they have yet to be submitted. <sup>21</sup>Thomas A. Scully, Letter to Philip Soule, Deputy Director, Medical Services, Department of Health and Social Services, State of Delaware (Baltimore, MD: Center for Medicare and Medicaid Services, 9 July 2003).

Failing to make a convincing case for projected savings results in rejection by the CMS. For example, the CMS rejected Delaware's Pharmacy Plus application because the population to be served was already being served under its existing state-only program. This decision raises questions about the viability of several pending applications that also appear to be aimed at subsidizing rather than expanding existing state-only programs. Despite the CMS's concern with achieving cost savings under Pharmacy Plus, a 2004 U.S. Government Accountability Office (GAO) report casts doubt on its ability to ensure budget neutrality in approved demonstrations.<sup>22</sup>

In contrast to subsidy programs adopted by other states, Vermont and Maine sought to fund expanded access to prescription drugs through mandatory manufacturer rebates. Both received 1115 waiver approvals from the CMS in 2001 to create a limited class of Medicaid enrollees eligible for federally mandated manufacturer rebates and pharmacy discounts, thereby extending the Medicaid net price to otherwise ineligible individuals. Promptly the drug manufacturers sued to stop them. As a result, both Vermont's Pharmacy Discount Program (VPDP) and Maine's Healthy Maine Prescription Program (HMPP) have been suspended pending revision (see discussion below). Before the HMPP, Maine tried to use its clout to leverage rebates for *all* its residents without drug coverage using Medicaid prior authorization and public posting of non-participating manufacturers. The program was called Maine Rx. Again, drug companies sued. Owing in part to delays caused by the litigation, the state adopted a new, more limited program, Maine Rx Plus, which relies on pharmacy discounts to provide prescription drugs at Medicaid prices only to individuals on with incomes below 350 percent of the FPL, though the state also began negotiating voluntary discounts with manufacturers in March 2004.

In addition to pursuing their own discounts, several states participate in multistate purchasing cooperatives. Operating the longest has been the Rx Issuing States (RxIS) Coalition, which consists of Delaware, Missouri, New Mexico, Ohio, and West Virginia. The coalition uses a single PBM to negotiate discounts for 676,000 state employees and retirees.<sup>23</sup> The State of Minnesota administers a second coalition, the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP), which consists of government-based health care facilities from more than forty states and which "formed to standardize and consolidate state requirements for pharmaceuticals, supplies and services, and to cooperatively contract for

<sup>&</sup>lt;sup>22</sup>U.S. Government Accountability Office, HHS Approvals of Pharmacy Plus Demonstrations Continue to Raise Cost and Oversight Concerns (GAO-04-480) (Washington, D.C.: U.S. General Accounting Office, June 2004).

 <sup>&</sup>lt;sup>13</sup> Mational Governors Association, State Purchasing Pools for Prescription Drugs: What's Happening and How Do They Work? (Washington, D.C.: National Governors Association Center for Best Practices, August 2004).

such requirements."<sup>24</sup> According to officials, the MMCAP achieves average cost savings of nearly 24 percent for brand-name drugs and 65 percent for generic medications. Finally, in April 2004, the CMS approved plan amendments<sup>25</sup> from five states—Michigan, Vermont, Nevada, Alaska, and New Hampshire—to participate in the National Medicaid Pooling Initiative (NMPI). Three other states—Minnesota, Hawaii, and Montana—intend to join as well. Under the NMPI, all participating states contract with a single PBM to negotiate supplemental Medicaid rebates with drug manufacturers, though each state continues to maintain control over its own preferred drug list to ensure adequate access to needed medications. Estimated 2004 savings include \$8 million for Michigan, \$1 million for Vermont, \$1.9 million for Nevada, \$1 million for Alaska, and \$250,000 for New Hampshire.<sup>26</sup>

#### PhRMA and the Federal Courts

In the context of pharmaceutical assistance, the CMS and the states have been mutually supportive partners, the states trying out new ideas and the CMS using its discretionary authority to defer to state leadership. Other actors-particularly the drug industry-have not been as friendly toward state efforts. Since manufacturers have not found much of a sympathetic ear in Congress for defense against states' discount demands, and state policy makers are often supported in their approaches by the CMS, drug companies have turned to another venue: the federal courts. Through their primary trade association, Pharmaceutical Research and Manufacturers of America (PhRMA), the manufacturers have sued, asserting that states' discounts violate the Supremacy and Commerce clauses of the U.S. Constitution. The Commerce Clause prohibits the states from interfering in interstate or foreign commerce, and the Supremacy Clause prohibits the states from implementing laws that contravene federal statutes or entering into areas of regulation that the federal government has come to occupy, either explicitly or by implication of laws adopted. PhRMA has sued to halt programs approved by the CMS and adopted by four states: Michigan, Florida, Vermont, and Maine.

In May 2001, Florida adopted a preferred drug list under Medicaid.<sup>27</sup> PhRMA challenged Florida's PDL in federal court based on the claim that Florida's PDL and prior authorization provisions were preempted under the Supremacy Clause, alleging that they do not (1) satisfy all of the

<sup>25</sup>Under Medicaid, states file "State Plans" with the federal government, which then reviews for compliance with regulatory interpretations of federal law. Once approved, states must submit "State Plan Amendments" to the CMS to alter the program in any significant way.

<sup>26</sup>Dennis G. Smith, State Medicaid Directors Letter #04-006.

<sup>27</sup>Cathy Bernasek, Catherine Harrington, Rajeev Ranchand, and Dan Mendelson, *Florida's Medicaid Prescription Drug Benefit: A Case Study* (Washington, D.C.: The Hentry J. Kaiser Family Foundation, February 2002).

<sup>&</sup>lt;sup>24</sup>Minnesota Multistate Contracting Alliance for Pharmacy, Agreement of Understanding and Joint Powers Agreement (St. Paul, MN: Minnesota Multistate Contracting Alliance for Pharmacy, 2004), p. 1.

requirements of a formulary as defined under the Medicaid statute or (2) serve the primary purposes of the Medicaid statute. Although clinical factors are the only criterion that can be used when excluding drugs from a Medicaid formulary, the U.S. Court of Appeals for the 11th Circuit agreed in a 6 September 2002 ruling with a district court decision that the PDL was not a formulary under federal law but instead a prior authorization list that merely conditioned usage of non-preferred drugs on state approval.<sup>28</sup> As such, the Court concluded that the state did not err in using both clinical *and nonclinical* (i.e., economic) criteria when putting its list together. By driving down the costs of prescription drugs for low-income individuals, the Court further concluded, Florida's law did not stand as an obstacle to the accomplishment and execution of the objectives of Congress in enacting Medicaid. The Supreme Court declined to hear the case.

In February 2002, Michigan began implementing the Michigan Pharmaceutical Product List (MPPL), a selection of at least two "best in class" drugs in forty-four therapeutic categories, which can be prescribed with little or no restriction.<sup>29</sup> Excluded drugs may be included on the MPPL, and thereby avoid prior authorization, if manufacturers agree to extend supplemental rebates to Medicaid and two non-Medicaid pharmacy assistance initiatives. PhRMA challenged the MPPL in both state and federal court, losing in both venues.<sup>30</sup> In a 2 April 2004 ruling, the U.S. Court of Appeals for the District of Columbia upheld the earlier district court ruling that the CMS acted lawfully in approving Michigan's use of the MPPL, and that none of PhRMA's challenges to prior authorization. supplemental rebates, or non-Medicaid program linkages was problematic valid under the Medicaid statute. As in Florida, both courts concluded that Michigan could use nonclinical criteria in developing the MPPL because it merely conditioned coverage for nonpreferred drugs on prior authorization and did not constitute a formulary as defined by the Medicaid statute. They also concluded that Congress clearly envisioned supplemental rebates above federally mandated rebates and that imposition of prior authorization as a result of failure to extend rebates to non-Medicaid populations was not necessarily contrary to the "best interests" of Medicaid recipients. Finally, the courts concluded that Michigan's pricing strategy did not constitute the regulation of out-of-state prices in violation of the Commerce Clause.

<sup>&</sup>lt;sup>28</sup>Pharmaceutical Research and Manufacturers of America v. Meadows, U.S. District Court for the Northern District of Florida, affirmed by 304 F.3d 1197 (11th Cir. 2002), cert. denied, 123 S. Ct. 2213 (2003), 184 F. Supp. 2d 1186 (N.D., Fla, 2001).

<sup>&</sup>lt;sup>29</sup>Cathy Bernasek, Jeff Farkas, Helene Felman, Catherine Harrington, Dan Mendelson, and Rajeev Ranchand, Case Study: Michigan's Medicaid Prescription Drug Benefit (Washington, D.C.: The Henry J. Kaiser Family Foundation, January 2003).

<sup>&</sup>lt;sup>30</sup>Pharmaceutical Research and Manufacturers v. Department of Community Health, 657 N.W.2d 162 (Mich. Ct. App. 2002); Pharmaceutical Research and Manufacturers v. Thompson, 259 F. Supp. 2d 39 (D.D.C. 2003), Affirmed, No. 03-5117 (D.C. Circ. 2004).

PhRMA's challenges to Vermont and Maine in federal court were more successful, suspending Vermont's VPDP<sup>31</sup> and Maine's HMPP<sup>32</sup> programs from June 2001 and December 2002, respectively. In both cases, PhRMA disputed CMS approval of the 1115 Medicaid waivers enabling these programs because neither Vermont, Maine, nor the federal government made contributions, thereby violating statutory provisions that manufacturers owe rebates only for drugs for which payments are made under the state plan. The states' plans simply mandated discounts without providing any financial support. Although the trial court in the Vermont case initially rejected this argument, the U.S. Court of Appeals for the District of Columbia agreed, reversing the decision and ruling in favor of manufacturers. "Because Congress imposed the rebate requirement in order to reduce the cost of the Medicaid program, and because no Medicaid funds are expended [under Vermont's program] and thus no Medicaid savings produced by the required rebates," the Court concluded that the CMS lacked authority to authorize the VPDP demonstration. Subsequently in 2003, Vermont submitted a new waiver application to the CMS to implement a new initiative, the Healthy Vermonters Discount Program, that includes a 2 percent per prescription state contribution. Initially, Maine modeled the HMPP program after Vermont's but later modified itadding a 2 percent state contribution-after the appellate court issued its ruling in Vermont. Based on this modification, the district court ruled in favor of HMPP, though the U.S. Court of Appeals for the District of Columbia subsequently reversed because the 2 percent contribution was not included in the original waiver proposal reviewed by the CMS. Not until the CMS endorses the modified version of HMPP can the courts rule on the legality of the revised version of the program.

Maine adopted HMPP, in part, because of a legal challenge to another program, Maine Rx, which used the threat of prior authorization to try to extend manufacturer rebates to all residents, regardless of income.<sup>33</sup> PhRMA's challenge argued that prior authorization was not in the "best interests" of Medicaid recipients and may pose a significant administrative burden and source of potential harm without serving any valid Medicaid purpose. It also argued that the program served to regulate out-of-state transactions between manufacturers and wholesalers. The U.S. District Court for the District of Maine found both of PhRMA's claims persuasive and issued a preliminary injunction preventing implementation of Maine

<sup>&</sup>lt;sup>31</sup>Pharmaceutical Research and Manufacturers v. Thompson, 135 F. Supp. 2d 1 (D.D.C. 2001), reversed by 251 F.3d 219 (D.C. Cir. 2001).

<sup>&</sup>lt;sup>32</sup>Pharmaceutical Research and Manufacturers v. Thompson, 191 F. Supp. 2d 51 (D.D.C. 2002), reversed by 313 F.3d 600 (D.C. Cir. 2002), as amended, 321 F.3d 1134 (D.C. Cir. 2003).

<sup>&</sup>lt;sup>33</sup>Pharmaceutical Research and Manufacturers v. Commissioner, 200 U.S. District LEXIS 17363 (D.Me, Oct. 26, 2000), reversed by Pharmaceutical Research and Manufacturers v. Concannon, 249 F.3d 66 (1st Cir. 2001), cert. granted, Pharmaceutical Research and Manufacturers v. Walsh, 536 U.S. 956 (2002), affirmed by 123 S. Ct. 1855 (2003).

Rx on 26 October 2000. The U.S. Court of Appeals for the First Circuit reversed this decision on 16 May 2001. The Court concluded that Maine's prior authorization program met all federal requirements (i.e., it provided for twenty-four-hour responses and seventy-two-hour emergency supplies) and that there was little evidence that it would harm Medicaid recipients. In fact, the Court cited evidence that making prescriptions more accessible under Maine Rx might reduce Medicaid expenditures by preventing worsening health conditions that drive more people into poverty. Furthermore, the Court concluded that Maine Rx did not interfere with out-of-state transactions but only regulated in-state activities.

But the story did not end there. On 28 June 2002, the U.S. Supreme Court granted a writ of *certiorari* to review the circuit court's decision because "the questions presented are of national importance." The Bush Administration sided with the manufacturers and in its brief recommended that the Supreme Court reverse the circuit court's decision voiding the preliminary injunction against the program.<sup>34</sup> Despite agreeing that the Court of Appeals was correct in rejecting PhRMA's claim that Maine Rx regulated out-of-state transactions,<sup>35</sup> the U.S. Solicitor General argued that the court should nonetheless hold the program invalid as a result of federal preemption. Because the state did not limit eligibility to low-income groups, it did not serve a Medicaid purpose, the Administration argued. Furthermore, the state had adopted Maine Rx unilaterally without review by the CMS either as a Medicaid waiver or as an amendment to the state plan. In a six-to-three ruling, however, the Supreme Court voted to lift the preliminary injunction against Maine Rx. All nine justices agreed that the program did not violate the Commerce Clause, but they disagreed over evidence of benefits to the Medicaid program. Given the diversity of opinions issued in PhRMA v. Walsh, legal scholars believe that the future of Maine Rx and other discount programs remains to be resolved.<sup>36</sup>

#### Reimportation and the FDA

The CMS and the federal courts are not the only federal watchdogs reviewing state drug programs. The FDA, pursuing its statutory charge to assure the safety and efficacy of drugs and biologicals, has repeatedly sought to stymie efforts by state and local governments to buy drugs from Canada and other countries at prices well below U.S. prices for what appear to be the same drugs. Approximately 4.8 million shipments comprising 12 million

<sup>&</sup>lt;sup>34</sup>Brief for the United States as Amicus Curiae Supporting Reversal, Pharmaceutical Research and Manufacturers of America v. Walsh, 123 S. Ct. 1855 (2003) (No. 01-188).

 <sup>&</sup>lt;sup>35</sup>Brief for the United States as Amicus Curiae Opposing Certiorari, Pharmaceutical Research and Manufacturers of America v. Concannon (May 2002) (No. 01-188).
<sup>36</sup>Kimberly Fox, Thomas Trail, David Frankford, and Stephen Crystal, "State Pharmacy Discount

<sup>&</sup>lt;sup>50</sup>Kimberly Fox, Thomas Trail, David Frankford, and Stephen Crystal, "State Pharmacy Discount Programs: A Viable Mechanism for Addressing Prescription Drug Affordability?" *New York University Annual Survey of American Law* (August 2004): 187–240; Michelle M. Mello, David M. Studdert, and Troyen A. Brennan, "The Pharmaceutical Industry versus Medicaid—Limits on State Initiatives to Control Prescription-Drug Costs," *The New England Journal of Medicine* 350 (February 2004): 608–613.

prescription drug products worth \$695 million entered the United States from Canada in 2003, including \$480 million from Internet pharmacies and \$287 million from foot traffic sales.<sup>37</sup> It is estimated that an equivalent amount arrives in the United States from other countries, primarily through mail and courier services.<sup>38</sup> By 2004, U.S. spending on personal drug importation reached \$3 billion according to some estimates.<sup>39</sup>

The Federal Food, Drug, and Cosmetics Act (FFDCA), as amended by the Prescription Drug Marketing Act of 1988 (PL 100-293), prohibits the reimportation of prescription drugs manufactured in the United States by anyone other than the original manufacturers (though the FDA rarely enforces this prohibition for small amounts-up to ninety days' supplyintended for personal use). In this way under this provision, the FDA has long sought to discourage states and localities from promoting reimportation. Citing the Supremacy Clause in a letter to the Deputy Attorney General of the State of California, for example, William K. Hubbard, then Associate Commissioner for Policy and Planning at the FDA, argued that "the drug importation scheme set forth by Congress preempts the State of California (or any city or county within the State) from passing conflicting legislation that would legalize the importation of certain drugs from Canada in contravention to the FFDCA."40 Several states (Illinois, Iowa, Maine, New Hampshire, Oregon, Vermont, and Wisconsin) have sought permission from the federal government to implement legal reimportation programs. All have been rejected, because, according to Acting FDA Commissioner, Lester M. Crawford, "such state pilot projects are not authorized under current law and present added safety concerns."41 Recently in a 2004 report, a DHHS-appointed Task Force on Prescription Drug Reimportation recommended maintaining current federal policy in this area.42

Although the FDA has issued several warning letters to state and local government officials,<sup>43</sup> the agency has yet to prosecute cities and states

<sup>37</sup>U.S. Department of Health and Human Services Task Force on Drug Importation, Report on Prescription Drug Importation, 27 December 2004; www.hhs.gov/importtaskforce/report.pdf (Rockville, MD: U.S. Department of Health and Human Services, 21 December 2004).

<sup>8</sup>Ibid.

<sup>39</sup>Tommy G. Thompson and Donald L. Evans, Letter to the Honorable J. Dennis Hastert, Speaker, Untied States House of Representatives (Rockville, MD: U.S. Department of Health and Human Services, 21 December 2004).

<sup>40</sup>William K. Hubbard, Letter to Mr. Gregory Gonot, Deputy Attorney General, State of California, 27 December 2004 (Rockville, MD: U.S. Food and Drug Administration, 25 August 2003); www.fda.gov/ opacom/gonot.html, p. 4.

<sup>41</sup>Lester M. Cawford, Letter to Governor Rod R. Blagojevich 27 December 2004 (Rockville, MD: U.S. Food and Drug Administration, 3 June 2004); www.fda.gov/oc/opacom/hottopics/importdrugs/ GovB63.pdf, p. 2.

<sup>42</sup>U.S. Department of Health and Human Services Task Force on Drug Importation, Report on Prescription Drug Importation. <sup>43</sup>Warning letters have been sent to Washington, D.C. Mayor Anthony Williams, Boston Mayor

Thomas M. Menino, Wisconsin Governor Jim Doyle, Rhode Island Governor Donald L. Carcieri, Illinois Governor Rod R. Blagojevich, Minnesota Governor Tim Pawlenty, Caldwell County North Carolina's Manager Bobby White, and New Hampshire Governor Craig Benson (U.S. Food and Drug Administration, 2003-2004). U.S. Food and Drug Administration, Importing Prescription Drugs: Letters to implementing reimportation programs. Given limited resources and significant popular and political support during the 2004 election cycle. the agency instead chose to highlight the dangers of imported drugs through "import blitz exams" of mail shipments to U.S. consumers and inspections of medications purchased over the Internet, along with enforcement actions against the "middlemen" in reimportation transactions—Internet and storefront operations that assist U.S. consumers in ordering prescriptions drugs from Canadian and other foreign pharmacies. Several states have gone ahead with their reimportation programs anyway. Minnesota launched the first reimportation program, Minnesota RxConnect, in January 2004. The program lists prices for 829 medications and contact information for three Canadian pharmacies. which also provide prescription drugs for Wisconsin's Drugsavings program, launched in April 2004. Both states have inspected participating pharmacies, signed performance agreements, and listed prices for hundreds of medications on their websites.<sup>44</sup> Under the Minnesota and Wisconsin programs, residents mail or fax prescriptions, medical history forms, and order forms to one of the three state-approved pharmacies, where a licensed Canadian physician reviews the information submitted and writes new prescriptions that are shipped at prices averaging 35 percent less than U.S. prices.45

New Hampshire and the multistate I-SaveRx Program also link residents to state-approved pharmacies. Washington simply links residents to pharmacies approved by other states. Several local governments have also established reimportation programs, including Springfield, MA; Boston; San Francisco; Columbia, SC; Washington, D.C.; and Montgomery County, MD. Like Washington State, most simply link residents to Canadian pharmacies that have been inspected and approved by Minnesota and Wisconsin. In August 2004, Vermont filed a lawsuit in the U.S. District Court against the FDA for failing to approve its proposal to establish a pilot program covering 20,000 state employees, retirees, and their families, who would be able to buy prescription drugs from Canada.

## THE 2003 MEDICARE PRESCRIPTION DRUG LAW

Seniors without prescription drug coverage are about twice as likely as those with coverage to skip doses of their prescribed medications for serious chronic diseases such as heart failure, diabetes, and

State and Local Officials 27 December 2004 (Rockville, MD: U.S. Food and Drug Administration, 25 August 2003-20 August 2004); www.fda.gov/importeddrugs.

<sup>&</sup>lt;sup>44</sup>Kaiser Daily Health Policy Report, Minnesota Launches Web Site to Help State Residents Reimport Prescription Drugs from Canada, 21 September 2004 (Washington, D.C.: Kaiser Family Foundation, 2 February 2004); www.kaisernetwork.org/daily\_reports.

<sup>&</sup>lt;sup>45</sup>Kaiser Daily Health Policy Report, States Release Sales Information From Reimportation Web Sites; Boston Mayor to Announce Pilot Program, 21 September 2004 (Washington, D.C.: Kaiser Family Foundation, 21 July 2004); www.kaisernetwork.org/daily\_reports.

hypertension.<sup>46</sup> Lack of supplemental drug coverage beyond Medicare has been shown to reduce utilization of drugs and in some studies to increase morbidity and mortality.<sup>47</sup> The MMA will help address this concern, but it will not solve it, both because its coverage is limited and because states are still likely to differ in how they choose to respond to it.

After passage of the conference report in the U.S. House of Representatives by a single vote preceded by an unprecedented nearly three-hour vote count delay while party leaders twisted arms, the MMA was signed by President Bush on 8 December 2003. Despite being assigned to the conference committee, most Democrats had been excluded from its deliberations. In fact, few details other than Democratic frustration at being locked out of the negotiations have leaked out for documentation. However, the GOP-dominated conference appears to have meant that state governments did not enjoy much of an opportunity to challenge the Republican majority's approach to financing the new law, in part through premiums, coverage gaps, and mandated payments by the states in addition to U.S. general revenues-not the Medicare trust fund that is funded through payroll taxes and set aside for Medicare inpatient care.

Senator Edward M. Kennedy (D-MA) tried to filibuster the measure as it came out of conference after supporting the earlier Senate proposal, and Senate Minority Leader Tom Daschle (D-SD) raised a point of order aimed at defeating the bill, but lost sixty-one to thirty-nine.<sup>48</sup> The legislation became Section 1860D-14(b)(2) of the Social Security Act. Supporters of the conference-approved version (despite some misgivings) included the Association for the Advancement of Retired Persons, American Medical Association, American Association of Health Plans, and American Hospital Association, and opponents included the American Federation of Labor-Congress of Industrial Organizations, Families USA, and the Heritage Foundation. Cost estimates were highly controversial, especially after revelations that the Medicare actuary's estimates-which were substantially above Congressional Budget Office (CBO) estimates-were suppressed by the outgoing CMS administrator. Estimates reported after the bill became law exceed half a trillion dollars over the coming decade. Later they were raised to three-quarters of a trillion dollars when the estimate covered slightly different years.

The new law is to be phased in via two major stages. During the transitional phase through 2005, the drug needs of dual eligibles will

<sup>&</sup>lt;sup>46</sup>Dana Gelb Safran, Patricia Neuman, Janna E. Montgomery, Wenjun Li, Ira B. Wilson, Michelle 5. Kitchman, Andrea E. Bowen, and William H. Rogers, "Prescription Drug Coverage and Seniors: How Well Are States Closing the Gap?" *Health Affairs*. Web Exclusive (July 2002): w253–w268. <sup>47</sup>John A. Poisal and Lauren Murray, "Growing Differences between Medicare Beneficiaries with

and without Drug Coverage," Health Affairs 20 (March-April 2001): 74-85; Thomas Rice and Karen Y. Matsuoka, "The Impact of Cost-Sharing on Appropriate Utilization and Health Status: A Review of <sup>48</sup>Mary Agnes Carey, "Provisions of the Medicare Bill," CQ Weekly (24 January 2004): 238–255.

continue to be met by Medicaid, and other low-income Medicare beneficiaries-the partial dual eligibles (those only eligible for Medicaid payment of Medicare's cost-sharing requirements) and others-will receive a Medicare drug discount card issued by one of seventy private firms, so far qualified as Medicare vendors. If someone is poor enough, he or she will have the premiums for the card waived and will receive an additional drug subsidy of \$600 per year for two years. Discount cards must be applied for from the vendor, and the choice is important because changes in discount cards can only be made annually. Whereas Medicaid broadly covers medically necessary drugs, these transition period card vendors will have their own individual formularies, restricting coverage to whatever medications they choose to cover. Some states are automatically enrolling their pharmacy assistance program beneficiaries in the new card and transitional subsidy programs. Others are simply encouraging beneficiaries to enroll, and still others are opting to continue their assistance programs without direct coordination with Medicare. Some have urged the CMS to automatically enroll all partial dual eligibles in the transitional subsidy program.49

After 1 January 2006, when the second phase is implemented, poor beneficiaries will receive coverage for their drugs from Medicare (though bearing small copayments), and near-poor beneficiaries will face steeper copayments (including premiums, deductibles, and coinsurance charges) on a bracketed scale adjusted to income, provided they meet an asset test. This differentiation by income and the necessity to meet an asset test are a departure for Medicare that has not been tried since the abortive incomerelated premiums of the Medicare Catastrophic Act of 1988, repealed a year later on the heels of outrage by higher-income beneficiaries who were required to fund most of the benefit expansions included in that act.

With the initiation of the second phase, Medicare beneficiaries will be covered under one of four major approaches. The first type of coverage is called Part D, through which private risk-bearing prescription drug plans (PDPs) will provide drug coverage to beneficiaries who receive their Part A institutional services and Part B ambulatory services separately through feefor-service arrangements.<sup>50</sup> The second type of drug coverage is Part C, which relies on private, risk-bearing, comprehensive capitated managed care plans that cover most Medicare services including prescription drugs. These plans existed before the new law, but will have their names changed from Medicare+Choice to Medicare Advantage (MA) plans, and their rates

<sup>&</sup>lt;sup>49</sup>Marc Steinberg, "Gearing up: States Face the New Medicare Law, 25 September 2004" (Washington, D.C.: Families USA, September 2004); www.familiesusa.org.

<sup>&</sup>lt;sup>50</sup>Medicare originally had two major parts: A, which all eligibles are required to join, covers hospital and other inpatient care costs from a trust fund supported by a payroll tax, and B, which covers physicians, therapists, and other ambulatory services and is paid for by premiums and general revenue. Later a Part C was added to provide managed care. The MMA will modify Part C and add a new Part D.

of payment from the federal government will be increased to promote greater participation. The third type of coverage is private employer retiree health benefits, for which Medicare will pay employers a subsidy to promote continued coverage of Medicare-eligible beneficiaries. A fourth approach is a demonstration project that begins in 2010 and emphasizes competitive coverage of all Medicare services.

Part D is the new, dramatic element included in the MMA. It is the first broadly available Medicare coverage of prescription drugs to all Part A entitled and Part B (voluntarily enrolled) beneficiaries. It will cover most prescription drugs, including lifestyle drugs, dietary supplements, and other non-prescription drugs, except those already covered by Parts A or B. Non-risk-bearing versions of Part D's PDPs (i.e., PBMs) have been around for four decades serving insurers and self-insured employer health programs, the U.S. Defense Department TRICARE program, the Federal Employees Health Benefits Program, Medicare managed care plans, and some state pharmacy assistance initiatives. For these programs, PBMs contract with retail pharmacies, process drug claims, manage formularies, and deliver volume-based efficiencies including pharmacy discounts, manufacturers' rebates, and cost controls. They also undertake counterdetailing (advising physicians on cheaper alternative drugs)<sup>51</sup> and patient education mailings, including compliance enhancement and high-risk beneficiary information provision. Under the new Medicare program, PDPs will negotiate for discounts, whereas the CMS itself is barred from participating in price-setting negotiations with manufacturers. The U.S. GAO<sup>52</sup> concluded that PBMs can and do deliver substantial savings, finding, for example, that

[the] average price PBMs obtained for drugs from retail pharmacies was about 18 percent below the average price cash-paying customers would pay at retail pharmacies for fourteen selected brand-name drugs and 47 percent below the cash price for four selected generic drugs. For the same quantity, the average price paid at mail order for the brand and generic drugs was about 27 percent and 53 percent below the average cash-paying customer price, respectively.

Furthermore, a few PBMs have survived long enough and have acquired enough of their competitors to become the industry leaders: Caremark Rx, Medco Health Solutions, and Express Scripts collectively processed about \$80 billion in drug claims in 2004.<sup>53</sup> Unfortunately, PBMs' lack of

<sup>&</sup>lt;sup>51</sup>Drug companies use sales representatives, office visits, and incentives to provide prescribers with information (i.e., details) regarding the benefits of using their products. Insurers (including some states) have adopted a wide range of "counterdetailing" activities to increase prescriber awareness of the risks, costs, and benefits of a wide range of available medications.

<sup>&</sup>lt;sup>52</sup>U.S. Government Accountability Office, Federal Employee Health Benefits Program: Effects of Using Pharmacy Benefits Managers on Health Plans, Enrollees, and Pharmacies (GA0-03-196) (Washington, D.C.: U.S. Government Accountability Office, 2003), p. 9. <sup>53</sup>Robert F. Atlas, "The Role of PBMs in Implementing the Medicare Prescription Drug Benefit,"

Health Affairs (October 2004): W4-504-W4-515.

experience in risk management will present them with a challenge under the new Medicare program. For this new enterprise, they will have either to develop new strategies and acquire new skills or to work through insurance partners.

Under Part D, poor beneficiaries with no or very low assets will not face many costs other than nominal copayment fees, which may be slightly higher for brand-name medications. Beneficiaries who do not qualify as poor or near-poor will participate heavily in the costs of their coverage. They will pay monthly premiums that increase annually, an annual deductible of \$250 in 2006, estimated to rise to \$445 by 2013, and 25 percent cost sharing for expenditures for drugs between \$250 and \$2,250 (2006 estimates; rising annually thereafter). The big burden will be for sicker patients-those who spend more than \$2,250 per year. Known as the "donut hole," spending between \$2,250 and \$5,100 annually will not be covered. Above \$5,100 Part D will pay most costs, except for a copayment of \$2 for generic drugs and \$5 for brand names, or 5 percent coinsurance, whichever is greater. This "donut hole"-no coverage for nearly \$3,000 worth of spending-has been a source of great anxiety and criticism, and it is likely to become a burden for states either because they choose to help make up the difference for near-poor patients or because they share in some of the costs of the adverse consequences of patients skimping on medications when they must pay so heavily out of pocket.

States will also face tough choices in deciding how generous to be in supplementing Medicare's limited national coverage. If they do it on their own, they may find that they have limited ability to demand discounts from manufacturers now that most drugs will be bought by Medicare. And they may fear that decisions to extend supplemental benefits will doom them to having to subsidize coverage in perpetuity if the national government ever decides to expand its own benefits. This is because a major source of financing for the new plan is "clawback" payments imposed on the states by the MMA. These payments are equal to much of what states were spending under Medicaid on behalf of dual eligibles in 2003. Initially, states must pay the national government 90 percent of savings resulting from the fact that Medicare will now provide coverage to those formerly covered under Medicaid. This percentage will decline through 2014 (from  $88\frac{1}{3}$  percent in 2006 to  $86\frac{2}{3}$  percent in 2008, 85 percent in 2009,  $83\frac{1}{3}$  percent in 2010, 80 percent in 2012,  $78\frac{1}{3}$  percent in 2013, and  $76\frac{2}{3}$  percent in 2014), and then become 75 percent thereafter.<sup>54</sup> The formula for calculating these amounts reflects base-year spending (2003), adjusted upward annually for growth in Part D expenditures (over which states have no control and

<sup>&</sup>lt;sup>54</sup>Health Policy Alternatives, Inc., Summary of the Final Rule to Implement the Medicare Prescription Drug Benefit (Title 1 of the Medicare Modernization Act of 2003) (Washington, D.C.: Kaiser Family Foundation, 10 February 2005).

others have argued that the federal government does not really either<sup>55</sup>), the number of dual eligibles enrolled in the state, and the state's share of Medicaid spending. The CBO<sup>56</sup> estimates that state charges over the 2006–2013 period will total \$88.5 billion, approximately what they would have paid had they continued to provide prescription drug coverage to dual eligibles. The CBO estimates that after the clawback payments, the states will experience net savings of only about 15 percent of what they would have spent on the same patients had no MMA been passed.<sup>57</sup>

Although states will no longer receive federal matching funds for covering drugs under their Medicaid programs for Medicare-eligible individuals, there are some important exceptions. First, a state will continue to receive federal Medicaid matching payments for certain Medicare-excluded drugs if it chooses to provide them to beneficiaries. Second, states will continue to receive federal matching funds to cover overthe-counter drugs in their Medicaid programs if they were already covering them before the MMA. Third, states could receive matching funds to pay Medicare copayments for partial dual eligibles if they choose to provide such coverage. (Ironically, the extent to which some generous states do these things while others do not will partially defeat the goal of implementing national standards for dual eligibles' drug benefits.)

Administration of Medicare's new drug plans will be through a new center within the CMS devoted to coordinating Part C and Part D benefits. Beneficiary participation in Medicare Part D is optional, to avoid the backlash that followed the mandatory Medicare Catastrophic Act,<sup>58</sup> and some employers have recommended that their retirees decline the new plans as inferior to their existing retiree health benefits. But the voluntary feature will be a burden on the states. They and the federal government will share responsibility for educating and enrolling poor and near-poor beneficiaries and smoothing their transition from Medicaid to Medicare coverage. States are required to inform potential eligibles of the program, provide application forms and assistance to those filling them out, verify and certify the accuracy of the information provided, screen those who apply for subsidies, determine and redetermine eligibility, offer Medicaid eligibility to those who meet state eligibility criteria, and provide the CMS with the information it needs to implement the program.

<sup>&</sup>lt;sup>55</sup>Jackie Koszczuk, "Medicare Overhaul Leaves Questions about How to Control Rising Drug Prices," CQ Weekly (6 December 2003): 3034–3039.

 <sup>&</sup>lt;sup>56</sup>Congressional Budget Office, A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit (Washington, D.C.: Congressional Budget Office, July 2004), Table 9.
<sup>57</sup>Douglas Holtz-Eakin, Letter to Senator Don Nickles, Chairman of Senate Budget Committee (Washington,

 <sup>&</sup>lt;sup>57</sup>Douglas Holtz-Eakin, Letter to Senator Don Nickles, Chairman of Senate Budget Committee (Washington, D.C.: Congressional Budget Office, 20 November 2003).
<sup>58</sup>Ricard Himelfarb, "Echoes of Catastrophic Care? The Passage of the Medicare Prescription

<sup>&</sup>lt;sup>58</sup>Ricard Himelfarb, "Echoes of Catastrophic Care? The Passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003 and Its Implications for the Future of Medicare" (presented at the Annual Meeting of the Midwest Political Science Association, Chicago, IL, 1–10 April 2005).

government will reimburse the states for administrative expenses under usual Medicaid administrative expense procedures and limitations.

The optional aspect of the new benefit also places a burden upon beneficiaries to enroll in a Medicare drug plan and, if they are low income, in the premium subsidy program. Because states might otherwise be liable for coverage, they will want to make sure that beneficiaries enroll in both programs. Other program experiences suggest that this will involve serious educational, outreach, enrollment, and redetermination efforts. Achieving enrollment among these beneficiaries above the historically low 60 percent of eligibles who enroll in some support programs will be a challenge for the states. Plan selection will also be a challenge for some impaired beneficiaries because of the coverage complexities.

Overall, the MMA represents a major change in federal-state relations vis-à-vis prescription drugs. Beneficiaries will pay premiums based upon income-previously anathematic to those who see means testing as potentially stigmatizing and a risk to broad popular support. The new law will subsidize private employers for keeping their retirees in private plans and out of MMA coverage; unlike the case with other program benefits, drug costs will not be paid from the Medicare trust fund. The new policy will leave open the strong possibility of continuing state-to-state differences in coverage under a nominally national program. Furthermore, states will be required to pay back most of the savings generated by the new law, and the state role will shift from managing a prescription drug program with national subsidies to subsidizing a program managed by the national government.

# CONCLUSION

Historically, the trend has been away from "dual federalism," with distinct and uncoordinated federal and state responsibilities, toward "cooperative federalism," with shared responsibilities and a stronger federal role. Although there have been cycles of greater and lesser state activity within this longer trend,<sup>59</sup> the state and federal governments are "locked in an unbreakable interactive partnership,"<sup>60</sup> with states influencing federal policy and administration and vice versa. Since the founding of the Republic, the federal and state governments have worked interactively to expand health care coverage to increasingly larger swaths of the poor and near-poor population. Typically, the states have led the way, (1) covering populations and services before Medicare and Medicaid existed through state-only programs, subsequently through (2) various federal categorical programs administered and typically supplemented by the states, then

<sup>&</sup>lt;sup>59</sup>Richard P. Nathan, "The Role of the States in American Federalism," The States of the States, ed., Carl E. Van Horn (Washington, D.C.: Congressional Quarterly Press, 1989), pp. 15–32. <sup>60</sup>Thomas J. Anton, "New Federalism and Intergovernmental Fiscal Relationships: The Implications

for Health Policy," Journal of Health Politics, Policy and Law 22 (Summer 1997): 691-720, at 713.

through (3) Medicaid program options, next, in some cases, through (4) Medicare when the federal government finally acknowledged its responsibilities and expanded covered populations or services; and, in a few cases, once again through (5) Medicaid after the federal government reconsidered its Medicare expansion. For example:

- The states were covering health care for poor elderly and disabled individuals long before the federal government entered the field with the cooperative Kerr-Mills program, the forerunner of Medicaid.
- Medicaid has always had broader coverage of people who are aged and disabled than has the federal government—in the earliest days a small segment of poor elderly and disabled people were not eligible for Medicare (and are not even to this day). Currently, despite the existence of Medicare and other federal health care programs, states contribute more than a quarter of all health care spending.
- Medicaid has typically covered a broader range of services and treatments than has Medicare, including prescription drugs, eye glasses, intermediate levels of nursing home care, home and personal care services, assisted living, case management, and other services outside the hospital.
- Expansions in Medicaid home- and community-based services took up the slack after Medicare pulled back on broadened home health coverage in 1997.

The MMA will present states with the opportunity to wrap around coverage with lower stop-loss ceilings (maximum out-of-pocket payments by beneficiaries), and to help with deductibles and co-payments, and with coverage of over-the-counter drugs and prescription medications excluded from Medicare covered plans. Some states already provide out-of-pocket stop-loss thresholds that will partially fill the MMA's "donut hole." Should they maintain that high level of generosity? If they do, will later changes in the Medicare law force them to keep up that coverage whereas less generous states are allowed to assume less responsibility for program costs? The "clawback" provision commits states to subsidizing federal prescription drug benefits at very high levels initially and then slightly lower levels in future years (but importantly, with no end in sight), based upon past state generosity. This provision will confront the states with a major question for policy: how much they wish to lead in program change and innovation. This is a clear case of "punishing the pioneers," done not out of mean-spiritedness but rather to hold down the costs of the new program, which started with a budget target and was then designed to try to fit the target. Although even generous states are probably no worse off than they were in terms of financial obligations for drugs and may even save a few dollars, they were in the past in control of their own spending, and could, if budget shortfalls necessitated, cut costs. From January 2006 onward, they will not be in charge. They will not have the option of innovating with new ways of controlling utilization and spending, or restricting the drugs that Medicare chooses to cover. Traditional roles will be reversed: the national government will administer the program, and the states will pay the bill. Will the federal government-typically more rule bound than the statesdo a better job? Some research suggests not.<sup>61</sup> Worse, by requiring that the most generously drug-covering states maintain their past efforts while letting states that had been stingy and slow in covering drugs off the hook financially, the federal government may have created an incentive for states to be more resistant to acting as leaders in policy areas where the federal government may someday assume partial or full administrative or financial responsibility. Moreover, because the formula for the clawback causes it to increase with the number of Medicare beneficiaries qualifying for Medicaid, the states face a clear incentive to limit the number of dual eligibles served.<sup>62</sup> State Medicaid officials clearly recognize these and other seemingly perverse incentives contained in the new law and are very concerned about them.<sup>63</sup>

Are these provisions of the MMA good intergovernmental policy? It has never been all states that innovate. A few states lead the way. Others then copy them and improve upon them. Policy decisions have been interdependent among levels of government for perhaps a century,<sup>64</sup> and some argue that interstate networks of state policymakers have grown more extensive and improved,<sup>65</sup> especially among states whose officials are active in relevant professional associations.<sup>66</sup> Innovations with positive federal incentives diffuse much faster than those without such incentives, and even those without positive incentives diffuse much faster than policies with negative federal incentives, regardless of substantive functional area.<sup>67</sup> Federal incentives are not the only determinant of state innovation, but they are important,<sup>68</sup> and the clawback represents a negative incentive that

<sup>&</sup>lt;sup>61</sup>Thomnas M. Koontz, "Differences between State and Federal Public Forest Management: The

Importance of Rules," Publius: The Journal of Federalism 27 (Winter 1997): 15–37. <sup>62</sup>Robert Pear, "Cost-Cutting Medicare Law Is a Money Loser for States," New York Times, 25 March 2005; www.nytimes.com/2005/03/25/politics/25drug.html; Andý Schneider, The "Clawback": State Financing of Medicare Drug Coverage (Washington, D.C.: Henry J. Kaiser Family Foundation, June

<sup>2004).</sup> <sup>13</sup>Vernon Smith, Implications of the Medicare Modernization Act. Observations from a Focus Group Discussion with Medicaid Directors (Washington, D.C.: Kaiser Commission on Medicaid and the Uninsured,

March 2005). <sup>64</sup>Daniel Elazar, The American Partnership: Intergovernmental Cooperation in the 19th Century United States (Chicago: University of Chicago Press, 1962).

<sup>&</sup>lt;sup>35</sup>Welch and Thompson, "Impact of Federal Incentives."

<sup>&</sup>lt;sup>66</sup>Balla, "Interstate Professional Associations."

<sup>&</sup>lt;sup>67</sup>Welch and Thompson, "Impact of Federal Incentives."

<sup>68</sup> Robert Eyestone, "Confusion, Diffusion and Innovation," American Political Science Review 71 (June 1977): 441-447.

is likely to stifle state innovation. In making policy choices, states' officials carefully take into account their view of what the federal government is likely to do down the road.<sup>69</sup> Even if the possibility of national policy change is small, state policymakers face an incentive to structure current policy choices in anticipation of future federal changes.

If the federal government stymies innovation by setting in place a national program with complex standardized rules and procedures but insists that the states pay a large part of the tab while having limited influence on program operation, what will this mean for future innovation and risk taking by the states? Democratic amendments proposed as the new law was working its way through both houses of Congress concentrated heavily upon trying to close the "donut hole" in coverage, that is, the gap in coverage between \$2,250 and \$5,100 in prescription drug spending. Yet for states the real issue is likely to become what happens if state officials fill the "donut hole" while waiting for federal officials to follow suit. Will those that do then find themselves stuck with the bill for having done so early? High on state policymakers' agenda is likely to be an effort to persuade Congress to (1) gradually reduce states' burden for the clawback provision and (2) hold states harmless in the future if they choose to limit Medicare beneficiaries' out-of-pocket spending in the donut hole while they wait for Congress to fix the problem it has created. Otherwise, the federal government's newest intergovernmental innovation-punishing the pioneers-may prove the accuracy of an old truism: when you tax something, you get less of it. In this case, it may be fewer state "creations" and a much slower rate of state innovation. As Justice Brandeis famously averred, "To stay experimentation in things social and economic is a grave responsibility."70

<sup>69</sup>Jeffrey Hill and Carol S. Weissert, "Implementation and the Irony of Delegation: Politics of Low-level Radioactive Waste Disposal," *Journal of Politics* 57 (May 1995): 344–369. <sup>70</sup>New State Ice Co. v. Liebmann, 285 U.S. 262, 309–311 (1932).



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