# STATE PHARMACY DISCOUNT PROGRAMS: A VIABLE MECHANISM FOR ADDRESSING PRESCRIPTION DRUG AFFORDABILITY?†

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#### EXECUTIVE SUMMARY

In an effort to address prescription drug affordability for older persons in the face of budget constraints, a number of states have sponsored pharmacy discount programs. These programs provide some price relief to targeted uninsured, cash-paying customers by requiring discounts on retail prescription drug purchases, at little or no cost to the state.

As of December 2002, six states—California, Florida, Iowa, Maine, New Hampshire, and West Virginia—had pharmacy discount programs that were fully operating. These states were the subject of case studies for this article.<sup>1</sup> An additional seven states had passed legislation or issued gubernatorial executive orders to develop discount programs that were not yet implemented or had been halted by the courts. While a few of the operational and proposed programs limited enrollment to lower-income persons, most are not based on income and apply to elderly persons—or to all Medicare beneficiaries, including the disabled—regardless of income. As originally enacted, the Maine Rx program went further in terms of breadth, aiming to reduce prices for all state residents without other pharmacy coverage, regardless of age, income, or disability status.

States pursuing these programs have sometimes had to deal with complex legal issues concerning prescription drug pricing and the relationship of the new programs to Medicaid. Despite the heightened interest, few analyses are available on existing programs and the evolving boundaries of legally sustainable state action in this area. This article compares the various discount programs in place as of December 2002, by examining program design, participation rates, impact on consumers, pharmacies and manufacturers, and the legal challenges they face.

<sup>1.</sup> The Healthy Maine Prescription Drug program, which was operational at the time of our case studies in October 2002, was enjoined by court order in January 2003 and has been terminated.

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#### *How Are the Programs Structured?*

All state discount programs are still in their initial phases of implementation. While they all seek to accomplish a similar goal to lower retail prescription drug prices charged to cash-paying consumers—they employ considerably different approaches for achieving these lower prices, reflecting fundamental differences of opinion on the appropriate role of the state in addressing consumer drug costs.

Generally, the programs fall into three broad models:

1) Several programs extend to non-Medicaid eligible residents all or some portion of the reduced Medicaid pricing that is required under state and federal law. These programs can be further divided into those that provide discounts at the pharmacy level only, and those that also require manufacturers to pay rebates, comparable to those obtained by Medicaid, for drugs purchased by the targeted non-Medicaid eligible group. California and Florida extended only the Medicaid pharmacy discount. Vermont and the Healthy Maine Prescription Program (HMPP) extended both the Medicaid pharmacy discount and the Medicaid manufacturer rebate. One of several Maine initiatives, HMPP is distinct from Maine Rx, and is targeted to a smaller portion of the uninsured population, anticipating the legal challenge to the broader Maine Rx.

2) Maine Rx aims to negotiate manufacturer rebates for uninsured residents that are lower than those mandated for Medicaid. This model seeks to use the state's Medicaid purchasing power as leverage to obtain lower rebates than those mandated for Medicaid, by requiring Medicaid prior authorization for drugs produced by manufacturers that refuse to provide these rebates to uninsured residents of the state.

3) A third group of programs uses private pharmacy benefit managers (PBM) to provide pharmacy-level discounts. These programs typically do not provide manufacturer rebates. Examples include Iowa, New Hampshire, and West Virginia.<sup>2</sup>

Generally, programs that seek only pharmacy-level discounts have not been challenged in the courts, while those that seek manufacturer rebates have faced significant legal challenge.

<sup>2.</sup> New Hampshire's program was initiated by Executive Order in January 2000 as a two-year pilot. While the pilot period has ended, the Pharmacy Benefit Management company that was administering the state discount card has continued the program of its own accord.

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#### How Many People Use Them?

Programs that are extended to all Medicare beneficiaries and have no enrollment process have no mechanism for determining how many people actually use the benefit. In programs that enroll members, the proportion of enrollees who actually use the discount card was relatively low, ranging from 5% to 35% in Maine's Medicaid discount and rebate program. Participation was particularly low in the PBM programs, where an average of 8% of enrollees actually used the discount.

#### How Much Do They Save?

The estimates of discount savings to consumers provided by states are highly variable and difficult to validate and interpret. States that extend Medicaid discounts to Medicare beneficiaries, and thus have no official "enrollees," either have no data at all or project savings from requested price quotes, which do not reflect actual purchases. Thus, reliable estimates of savings from these programs are not available.

States estimate savings ranging from 12 to 25%, far below the drug benefit received through most drug subsidy state pharmacy assistance programs, offering participants only marginal relief. Programs that are likely to provide the greatest out-of-pocket savings by including a manufacturer rebate also have little data, either because they have not been implemented or have been suspended by legal challenge. Nonetheless, these programs have the potential to provide more savings than other models. Based on the experience of Maine's HMPP program in the year and a half it was operating, these programs offer about 25% savings.

Estimates indicate that state-sponsored programs operated by PBMs have saved 12 to 17% off the retail price. These estimates appear to be comparable to estimated savings achieved through private PBM discount cards, suggesting that state discount programs may provide little additional savings beyond programs already available. However, their broader availability, lack of enrollment fees, and sponsorship by the state may increase visibility, thereby providing greater access to discounts.

#### How Complete is Participation by Pharmacies?

Some states require pharmacies participating in Medicaid to offer a discount to the elderly, raising concern that the program might cause pharmacies to withdraw from Medicaid. This does not seem to have happened to any significant extent, although there is

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some evidence that eligible customers are not always offered the discount by pharmacies. Nonetheless, at least in theory, nearly all pharmacies are technically participating. In contrast, in programs in which the state contracts with a PBM, pharmacy participation rates are generally lower than those administered through Medicaid, limiting consumers' access to discounts. In West Virginia and New Hampshire, only half of the pharmacies participate, which has led to a large number of consumer complaints.

#### How Costly are Programs for States to Operate? How Much Outreach is Provided?

Discount programs are relatively inexpensive for states to operate. The highest cost was for Maine's Medicaid waiver program, in which the state contributed a nominal amount per prescription, requiring a budget of \$20 million. The remaining programs had much smaller budgets ranging from \$275,000 to \$500,000. Funding for outreach varied from virtually nothing to \$300,000. Some programs with minimal outreach at the outset increased this commitment over time in response to public criticism. In their outreach efforts, states found they needed to exercise care not to overpromise the program's benefits, finding that some consumers are disappointed by the actual savings they realize. Several program officials noted that outreach should not overstate the benefits and thus unduly raise consumer expectations.

#### What are the Implications of Recent Judicial Decisions for Discount Programs?

The Supreme Court Maine Rx decision, *Pharmaceutical Research* & *Manufacturers of America (PhRMA) v. Walsh*,<sup>3</sup> while somewhat ambiguous, has left the door open for states to leverage their Medicaid market share to negotiate rebates for non-Medicaid eligible persons. The opinions by a majority of the justices suggest that, so long as the Secretary of the Department of Health and Human Services (Secretary) finds that there is a Medicaid-related benefit and that there is not substantial harm to Medicaid beneficiaries, the states' extension of Medicaid mechanisms like discounts, rebates and prior authorization requirements is valid. However, it is still unclear whether the HMPP and the Vermont programs can go forward. These programs were enjoined based on the argument that the Secretary had no authority under Medicaid statutes to grant a

<sup>3. 123</sup> S. Ct. 1855 (2003).

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waiver without a state contribution. Walsh does not address the state contribution issue.

#### How Do State Programs Compare with the Proposed Medicare Discount Card Program?

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 includes an interim Medicare-endorsed discount card program to provide temporary relief to Medicare beneficiaries without drug coverage until the full benefit is available in 2006.

The Medicare-endorsed discount card program is built on a model of endorsing private discount card programs managed by private, non-governmental entities, which may include PBMs, wholesale or retail pharmacy delivery systems, insurers, and health plans.<sup>4</sup> In some ways, this interim Medicare discount card program will be similar to the privately managed state discount cards pursued in West Virginia, New Hampshire, and Iowa, which rely on private sector strategies to negotiate lower discounts. Based on these states' experience and the PBMs' inability to get manufacturers to offer rebates for statewide discount programs, federal officials may want to err on the conservative side of their estimates of 10–25% potential savings. At least in these three states, the PBMs were unable to convince manufacturers that traditional insurance methods of shifting market share would apply in a discount program.

Low pharmacy participation rates in PBM-administered state discount programs may also have implications for Medicare-endorsed private discount cards. Since private entities such as PBMs negotiate lower prices with pharmacists by promising a competitive advantage for that book of business, privately administered cards, by definition, are unlikely to have the universal pharmacy involvement that many Medicare beneficiaries are likely to expect. This may have the unintended consequence of significantly limiting seniors' access to the discount at their local pharmacy.

#### How Far Do the Programs Go in Addressing the Affordability Problem?

Whether or not discounts incorporate manufacturer rebates, state pharmacy discount programs are not a substitute for direct subsidies, particularly for low-income seniors. While the programs provide some relief to cash-paying seniors, the estimated price reductions are marginal compared to the benefit offered in most

<sup>4.</sup> Medicare Program; Medicare Prescription Drug Discount Card, 68 Fed. Reg. 69,840, 69,849 (Dec. 15, 2003) (to be codified at 42 C.F.R. pts. 403, 408).

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state pharmacy assistance programs, and may leave many of the lowest-income seniors and those with catastrophic drug costs unable to afford the drugs they need. In fact, many program officials acknowledged that the discounts afforded through these programs are not always as great as consumers had expected and can result in consumer dissatisfaction. Programs that include manufacturer rebates have greater potential for providing meaningful relief than those that only involve discounts at the pharmacy level. However, realizing even these limited benefits requires that consumers be aware of the discounts and that pharmacists offer the discounts to the consumer at the counter. Currently, this does not occur consistently, given states' limited outreach and enforcement efforts.

I.

# INTRODUCTION

For the past several years, prescription drug affordability for elderly and disabled persons has been a top issue for state policymakers. Prior to the passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003, cash-paying senior and disabled persons without another source of drug coverage paid the highest prices for prescription drugs and have increasingly looked to state policymakers for help. This pressure has come at a time when state budget deficits are growing. As a result, many states have developed solutions that reduce the price of drugs to consumers at little or no cost to the state.

Several states have initiated state-sponsored pharmacy discount programs as a short-term solution to the drug affordability problem. These programs provide some price relief to targeted uninsured, cash-paying customers by offering a discount, below retail drug prices, that is primarily supported by pharmacies, and in some cases manufacturers. At the time of our case studies in the fall of 2002, thirteen states either had passed authorizing legislation or had gubernatorial executive orders to create one or more discount programs for uninsured elderly persons;<sup>5</sup> six of these states had programs that were fully operating.<sup>6</sup> States pursuing these programs have sometimes had to deal with complex legal issues concerning prescription drug pricing and Medicaid law. One state has

<sup>5.</sup> In 2003, Arizona, Illinois, Montana, South Carolina, and South Dakota also passed legislation authorizing discount programs. Maine and Washington passed legislation to create new programs to address court challenges to previous programs. South Dakota's program was anticipated to go into effect in July 2003.

<sup>6.</sup> Those states are Iowa, West Virginia, New Hampshire, California, Florida, and Maine.

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enacted a broad discount program that was enjoined for three years pending litigation,<sup>7</sup> and three other states implemented discount programs that were subsequently struck down by court rulings.<sup>8</sup> Nonetheless, these programs continue to proliferate. In 2003, five more states approved pharmacy discount programs.<sup>9</sup>

As is often the case with decentralized approaches to solving health care coverage gaps, state-sponsored discount programs are markedly different across states. The purpose of this article is to compare how state discount programs differ in design and scope, including how the discount is achieved, who is eligible, and how much they cost the state to implement. The article also examines how effective the different programs are in reducing consumers' out-of-pocket costs for prescription drugs, by evaluating the availability of the discount at pharmacies, the number of people who are actually using the discount and the estimated size of the savings to consumers. Finally, we assess the legal challenges states face in pursuing these programs, and the current status of the state programs that are being challenged.

# II.

#### **METHODS**

The findings of this article are based on case studies of six states with operational programs as of July 2002 and a document review of published literature, press reports, and court decisions related to three programs that were enjoined or overturned by the courts. The case study states were Maine, California, Florida, West Virginia, Iowa, and New Hampshire.<sup>10</sup>

Case-study data included semi-structured interviews with key informants and review of program documents from each state. Telephone interviews were conducted in the summer and fall of 2002 with program directors of the discount programs in each state and key stakeholders. The interview protocol focused on the impetus

<sup>7.</sup> In June 2003, the U.S. Supreme Court overturned the injunction of the Maine Rx program. *Walsh*, 123 S. Ct. at 1871. The ruling and its implications for states are discussed in detail below.

<sup>8.</sup> Vermont's PDP and Washington's AWARDS program had been struck down at the time of our case studies. The Healthy Maine Prescription Drug program, which was operational at the time of our case studies in October 2002, was enjoined by court order in January 2003 and has been terminated.

<sup>9.</sup> Arizona, Illinois, Montana, South Carolina, and South Dakota.

<sup>10.</sup> The Healthy Maine Prescription Drug program, which was operational at the time of our case studies in October 2002, was enjoined by court order in January 2003 and has been terminated.

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for the program; design decisions; program implementation and administration, including enforcement; and program impact in terms of the number of persons enrolled and utilizing the discount, pharmacy participation, and the level of savings to consumers. Respondents for key informant interviews varied somewhat by state but largely included program directors or other government officials and some representatives of pharmacy associations. State documents included authorizing statutes, information from program websites, press reports, outreach materials, requests for proposals, and program evaluations where available.

#### III.

# WHAT IS A STATE PHARMACY DISCOUNT PROGRAM?

State-sponsored pharmacy discount programs, initiated either through legislation or executive order, attempt to provide lower retail prices on prescription drugs for some or all state residents at little to no cost to the state. The reduction in price is absorbed either by participating pharmacies, participating pharmaceutical manufacturers, or both. These programs contrast with comprehensive drug coverage offered through a state Medicaid program or through state pharmacy assistance programs, in which the state pays a large share of the costs of drugs purchased by targeted elderly and disabled enrollees.<sup>11</sup> While Medicaid and direct subsidy state pharmacy programs for the elderly are popular because they provide comprehensive coverage to those who are eligible at minimal outof-pocket costs, they impose considerable cost on the state.

In contrast, in discount programs the consumer is responsible for the majority of the cost of drugs purchased, while state contributions are minimal. In periods of budgetary uncertainty when many existing public-sector health programs such as Medicaid face serious budget cuts, many state legislators see pharmacy discount programs as a short-term solution to provide some marginal relief for consumers faced with unaffordable drug prices.

Prescription drug discount cards sponsored by non-government organizations, such as the American Association for Retired Persons (AARP) or other associations, retail stores and pharmacies,

<sup>11.</sup> Medicaid and most state pharmacy programs have generous drug benefits requiring minimal enrollee cost-sharing. However, some state pharmacy assistance programs require that enrollees pay as much as 85% of the discounted drug costs.

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insurance companies, and PBMs<sup>12</sup> have been in place for some time. In contrast, state-sponsored pharmacy discount programs are a relatively new development. All state discount programs have been initiated since 1999. As shown in Table 1, of the seventeen discount programs in thirteen states that had been authorized by legislation or gubernatorial executive orders, six were operational (as of November 2002), three had been enjoined or terminated due to legal challenge, and another eight, passed in 2002, had not yet been implemented.

Most program officials interviewed indicated that the states had chosen to pursue discount programs largely in response to the public outcry by seniors and advocacy groups for some relief from the high cost of prescription drugs. Prior to developing discount programs, a few states convened advisory groups of consumers, pharmacists, doctors, and manufacturers to develop a solution for prescription drug affordability. In most cases, the charge to the advisory boards included criteria that any solution proposed must be accomplished with minimal or no cost to the state. Thus, the decision to pursue a discount approach rather than a direct benefit program was largely tied to budgetary constraints.

Vermont and Maine created discount programs to supplement their existing state pharmacy assistance programs for low-income elderly and disabled residents. Both states had expanded these direct benefit programs over time to include a larger list of drugs and to cover people with slightly higher incomes and the disabled. Despite these efforts, many non-qualifying elderly and disabled persons still could not afford the price of prescriptions. In addition, many non-elderly, non-disabled working poor persons had no drug coverage. Recognizing that their states could not fiscally support continued expansion of subsidy programs to other uninsured adults or moderate-income seniors, officials in both of these states looked to discount programs to lower the cost of drugs for other residents.

<sup>12.</sup> Manufacturer sponsored discount cards are an even more recent development, with the first being initiated in fall 2001. Gen. Accounting Office, Prescription Drug Discount Cards: Savings Depend on Pharmacy and Type of Card Used, GAO-03-912, at 5 (2003).

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State	Program Name	Year Implemented
Arizona	Arizona Prescription Discount Program <sup>13</sup>	June 2003
	CoppeRx (Arizona Prescription Discount Program) <sup>14</sup>	January 2004
California	Prescription Drug Discount Program for Medicare Recipients <sup>15</sup>	February 2000
	Golden Bear Pharmacy Assistance Program <sup>16</sup>	Not yet in effect
Florida	Medicare Prescription Discount Program <sup>17</sup>	July 2000
Hawaii	Hawaii Rx Discount Program <sup>18</sup>	Not yet operational
	Medicaid Prescription Drug Expansion Program <sup>19</sup>	Not yet operational; requires federal waiver
Illinois	Senior Citizens and Disabled Persons Prescription Drug Discount Program <sup>20</sup>	Not yet operational

# TABLE 1States with Pharmacy Discount Programs and<br/>Program Status, 2004

13. Exec. Order 2003–03 (Ariz. 2003), *available at* http://www.governor.state. az.us/eo/2003\_3.pdf (last visited Apr. 11, 2004).

14. Press Release, Governor of Arizona, Governor Announces 'CoppeRx Card' (Jan. 7, 2004), *available at* http://www.governor.state.az.us/press/0401/04\_01\_07a.pdf (last visited Apr. 11, 2004).

15. S.B. 393 (Ca. 1999), *available at* http://www.dhs.cahwnet.gov/mcs/mcpd/MBB/contracting/pdfs/sb\_393\_bill19991010\_chaptered.pdf.

16. S.B. 696 (Ca. 2001), available at http://www.leginfo.ca.gov/pub/01-02/ bill/sen/sb\_0651-0700/sb\_696\_bill\_20011010\_chaptered.pdf (last visited Apr. 11, 2004).

17. FLA. STAT. ANN. § 409.9066 (West Supp. 2004).

18. H.B. 2834, 21st Leg. (Haw. 2002), *available at* http://www.capitol.hawaii. gov/session2002/bills/hb2834\_cd1\_.htm (last visited Apr. 11, 2004).

19. H.B. 1950, 21st Leg. (Haw. 2002), *available at* http://www.capitol.hawaii. gov/session2002/bills/hb1950\_cd1\_.htm (last visited Apr. 11, 2004).

20. 320 Ill. Comp. Stat. Ann. 55/1-99 (West, Westlaw 2003).

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State	Program Name	Year Implemented
Iowa	Iowa Priority Prescription Savings Program <sup>21</sup>	January 2002
Maine	Maine Rx <sup>22</sup> Maine Rx Plus <sup>23</sup> Healthy Maine Prescription Program (HMPP)—Medicaid Waiver benefit <sup>24</sup>	Not in operation; U.S. Supreme Court favorable ruling 5/19/03 January 2004 Implemented June 2001. Struck down by federal court and halted Jan 2003
Maryland	Maryland Pharmacy Discount Program <sup>25</sup>	July 2003
Montana	Prescription Drug Expansion Program <sup>26</sup>	Not yet operational
New Hampshire	Prescription Drug Discount Program for Seniors <sup>27</sup>	January 2000
New Mexico	Senior Prescription Drug Program <sup>28</sup>	Not yet operational
Ohio	Golden Buckeye Card Program <sup>29</sup>	Operational October 2003
Ohio's Best Rx <sup>30</sup>	Not yet operational	
Oregon	Senior Prescription Drug Assistance Program <sup>31</sup>	Operational June 2003

21. Exec. Order No. 14 (Iowa 2002), *available at* http://www.governor.state. ia.us/legal/11\_15/exec\_order\_fourteen\_final.pdf (last visited Apr. 11, 2004).

22. 2000 Me. Legis. Serv. 786 (West).

- 23. ME. REV. STAT. ANN. tit. 22, § 2681 (West Supp. 2003).
- 24. ME. REV. STAT. ANN. tit. 22, § 258 (West Supp. 2003).
- 25. Md. Code Ann., Health-Gen. I § 15-124.1 (Supp. 2003).

26. 2003 Mont. Laws 551.

- 27. Exec. Order (N.H. 2000).
- 28. N.M. STAT. ANN. § 10-7c-17 (Michie 2003).

29. Ohio Rev. Code Ann. § 173.06 (West 2003).

30. Amend. Sub. H.B. No. 311, 125th Gen. Assem., Res. Sess. (Ohio 2003-04), *available at* http://www.legislature.state.oh.us/bills.cfm?ID=125\_HB\_311 (last visited Apr. 11, 2004).

31. Or. Rev. Stat. § 414.340 (2001).

State	Program Name	Year Implemented
South Carolina	South Carolina Retirees and Individuals Pooling Together for Savings (SCRIPTS) <sup>32</sup>	Not yet operational
South Dakota	Senior Citizen Prescription Drug Benefit Program <sup>33</sup>	Not yet operational; repealed effective July 2005 by SL 2003, ch. 26, § 4
Vermont	Pharmacy Discount Program (PDP) <sup>34</sup> Healthy Vermonters Discount Program <sup>35</sup>	Waiver approved Nov 2000; implemented January 2001; federal court ruling halted operation in June 2001 Not yet operational; requires federal waiver
Washington	A Washington Alliance to Reduce Prescription-Drug Spending (AWARDS) <sup>36</sup> Discount pharmaceutical plan <sup>37</sup>	Began March 2001; program invalidated and terminated June 2001 Not yet operational
West Virginia	SPAN II <sup>38</sup> Golden Mountaineer Discount Card Program <sup>39</sup>	January 2000; phased out Fall 2001 September 2001

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Source: National Conference of State Legislatures' web site: *State Pharmaceutical Assistance Programs*, http://www.ncsl.org/programs/health/drugaid.htm (updated March 1, 2003) [hereinafter "NCSL Summary"].

Most discount programs were designed as "stop-gap" measures. Program officials in several states indicated that federal action on a Medicare prescription drug benefit would obviate the need for these programs, unless the federal benefit had significant gaps in coverage that would cause beneficiaries to seek out some relief for those uncovered costs.

<sup>32. 2003</sup> S.C. Acts 59.

<sup>33.</sup> S.D. Codified Laws § 3-12B (Michie Supp. 2003).

<sup>34.</sup> H.B. 842 § 117 (Vt. 2000).

<sup>35.</sup> VT. STAT. ANN. tit. 33, § 2003 (West Supp. 2003).

<sup>36.</sup> Exec. Order 00-04, WAC 246-30 (Wash. Aug. 29, 2000), *available at* http://www.governor.wa.gov/eo/eo\_00-04.htm (last visited Apr. 11, 2004).

<sup>37.</sup> S.B. 6088, 58th Leg. (Wa. 2003).

<sup>38.</sup> Exec. Order 20-00 (W.V. Oct. 18, 2000).

<sup>39.</sup> Exec. Order (W.V.).

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#### IV. STATES PURSUE DIFFERENT MODELS

While all state discount programs seek to accomplish a similar goal—to lower retail prescription drug prices charged to cash-paying consumers—states' approaches for achieving these lower prices differ considerably and reflect fundamental differences of opinion on the appropriate role of the state in addressing drug costs. As shown in Table 2, programs in place in 2002 or pending resolution of legal challenge fell into three broad categories, with different benefits and limitations. Key features that distinguish these three discount models include the way in which the discounts are leveraged and the source of the discount (i.e., pharmacies and/or manufacturers), both of which affect the size of the discount for consumers.

Some states have implemented multiple discount programs. For example, as shown in Table 1, Maine has two different though related programs. The state initially passed Maine Rx, which was originally targeted to all residents of the state. Confronted with legal challenge to this approach,<sup>40</sup> the state applied for a Medicaid waiver to create the Healthy Maine Prescription Program (HMPP) to extend Medicaid discounts and rebates to residents under 300% of the federal poverty level (FPL). HMPP represented an alternative strategy to provide discounts to the poorest of the uninsured in the state. After a year and a half of operation, the courts suspended HMPP in January 2003.<sup>41</sup> Maine Rx had also been enjoined, but this injunction was overturned by the Supreme Court in June 2003.<sup>42</sup> These legal challenges are discussed in more detail below.

# A. Extending Medicaid-Mandated Discounts and Rebates to Non-Medicaid Eligible Residents

Unlike private pharmacy benefit managers and insurers that negotiate discounts and rebates with individual pharmacies and manufacturers, state Medicaid programs receive discounts on prescription drugs as a matter of state and federal law. Medicaid pharmacy discounts are defined in state statutes as a condition of participation in each state's Medicaid program.<sup>43</sup> Minimum manu-

<sup>40.</sup> Pharm. Research & Mfrs. of Amer. v. Thompson, 313 F.3d 600 (D.C. Cir. 2002).

<sup>41.</sup> Id. at 602.

<sup>42.</sup> Pharm. Research & Mfrs. of Amer. v. Walsh, 123 S. Ct. 1855 (2003).

<sup>43.</sup> See, e.g., Cal. Bus. & Prof. Code §§ 4425–4426 (West 2003); Fla. Stat. Ann. § 409.9066 (West Supp. 2004).

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facturer rebates are defined by federal law as a condition of participation in the Medicaid program nationally.<sup>44</sup> Four states have implemented programs that extend Medicaid mandated discounts and/or rebates to persons not otherwise eligible for Medicaid.

#### 1. Mandated Pharmacy Discounts

Both Florida and California have enacted legislation that mandates the retail pharmacy discount price for all Medicare beneficiaries. California's Prescription Drug Discount Program for Medicare Recipients<sup>45</sup> was enacted in 1999 and became operational in February 2000. Under this program, any pharmacy that participates in the state Medicaid program (Medi-Cal) is obligated to limit charges for drugs sold to Medicare beneficiaries to the Medi-Cal pharmacy reimbursement rate plus a \$0.15 transaction fee.

At the time the program was passed, the Medi-Cal pharmacy discount rate for brand-name drugs was set at the average wholesale price (AWP)—the "sticker" price or average list price that a manufacturer suggests wholesalers charge pharmacies—minus 5%, plus a \$4.05 dispensing fee (see Table 3). In 2002, California passed legislation further lowering the Medicaid pharmacy discount rate and therefore the discount to Medicare beneficiaries, to AWP minus 10% for brand-name drugs. Discounts are larger for multiplesource drugs with brand or generic competitors. For generics, Medi-Cal pays the lowest acquisition price for any generic in that class as determined for each drug by either a list developed by the federal government known as the Federal Upper Limit (FUL) or a state-generated list of maximum allowable costs (MAC).

<sup>44. 42</sup> U.S.C. § 1396r-8 (2003). Note that, in addition to the minimum rebate, some states have negotiated or required supplementary rebates as well.

<sup>45.</sup> California Prescription Drug Discount Program for Medicare Recipients, S.B. 393 (Ca. 1999), *available at* http://www.dhs.cahwnet.gov/mcs/mcpd/MBB/ contracting/pdfs/sb\_393\_bill\_19991010\_chaptered.pdf (last visited Apr. 7, 2004).

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Model	Features	States
Extending Medicaid- discounts/rebates for non-Medicaid residents		
a) Mandated phar- macy discounts	<ul> <li>State legislation mandates pharmacies to extend specified discounts to non-Medicaid eligible persons as a condition of participation in the state Medicaid program.</li> <li>Discount supported entirely by pharmacies.</li> <li>Requires state legislation. Does not require federal Medicaid waiver, but possibly requires state plan amendment.</li> <li>No or minimal cost to state.</li> <li>No formal legal challenge.</li> </ul>	California and Florida
b) Mandated phar- macy discounts and manufacturer rebates	<ul> <li>Extends Medicaid drug benefit to persons otherwise ineligible for Medicaid net price (including both the pharmacy discount and manufacturer rebate) to the consumer.</li> <li>Discount supported by both pharmacies and manufacturers. May require nominal state contribution.</li> <li>Requires federal Medicaid waiver.</li> <li>Has been legally challenged.</li> </ul>	Maine HMPP and Vermont
State acts as PBM on behalf of uninsured using Medicaid prior authorization as leverage	<ul> <li>Discount supported by manufacturers and pharmacies.</li> <li>Discounts not limited to Medicaid level.</li> <li>Uses Medicaid prior authorization and public posting of lists of non-participating manufacturers to encourage participation.</li> </ul>	Maine Rx/ Maine Rx Plus

# TABLE 2 State Pharmacy Discount Program Models and Features

Model	Features	States
	<ul> <li>If manufacturers do not voluntarily participate, state reserves the right after three years to set prices.</li> <li>Requires state legislation. May require a federal waiver.</li> <li>Potential for greatest discounts, but has been legally challenged.</li> </ul>	
Contracting with pri- vate sector pharmacy benefit managers (PBM)	has been legally challenged.ntracting with pri- e sector pharmacy nefit managersState contracts with a private phar- macy benefit manager (PBM) to pro- vide discounts.	

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Source: Rutgers Center for State Health Policy. Typology based on case studies of all operational discount programs as of October 2002.

Florida's Prescription Affordability Act for Seniors<sup>46</sup> took effect in July 2000. The legislation limits the amount a pharmacy that participates in the state Medicaid program can charge Medicare beneficiaries to 91% of average wholesale price (or AWP minus 9%), plus a \$4.50 dispensing fee. While both states use Medicaid conditions of participation for pharmacies as the conduit for mandating discounts, California mandated the full Medicaid pharmacy discount, while Florida set a separate discount that is not as large as the discount received by the state Medicaid program.<sup>47</sup>

The benefit of this approach is its simplicity. Because the discount is targeted to all Medicare beneficiaries, there is no application or enrollment process. Medicare beneficiaries need only show their Medicare card at a pharmacy that accepts Medicaid to receive the discount. Officials in both states said that more than 95% of pharmacies in their states accept Medicaid payments. Application

<sup>46.</sup> FLA. STAT. ANN. § 409.9066 (West Supp. 2003).

<sup>47.</sup> Florida Medicaid pays AWP minus 13.25% for brand-name drugs, FUL or state MAC for generics.

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processing and eligibility determination can be costly to administer, and California and Florida avoided these costs by using Medicare enrollment as the requirement for eligibility. One disadvantage of not having an enrollment process for these programs is that neither Florida nor California is able to track how many people are actually accessing the discounts or how much consumers are saving as a result of the discounts. This makes it very difficult to document the impact of these programs on consumers.

The California and Florida discounts are supported entirely by pharmacies—the pharmacies are not reimbursed by state or federal dollars or manufacturer rebates for the difference between the discount price and the retail price that they would have normally charged a cash-paying customer. In Florida, according to state officials, after the law's enactment, the National Association of Chain Drug Stores threatened to sue the state, arguing that the state did not have the authority to require pharmacies participating in Medicaid to give discounts to non-Medicaid customers without approval from the federal government. In response, Florida submitted a state plan amendment for its Medicaid program to the Centers for Medicare and Medicaid Services (CMS), which was approved in September 2001. No further legal challenge has been pursued to date. No legal action has been taken against California's program, which has not submitted a Medicaid state plan amendment.

Seeking to avoid legal challenge by manufacturers and the possible need for a Medicaid waiver,<sup>48</sup> neither California nor Florida included mandatory Medicaid manufacturer rebates in the legislation creating their discount programs. However, California has subsequently passed legislation establishing another discount pro-

<sup>48.</sup> According to the CMS website, "Section 1115 of the Social Security Act provides the Secretary of Health and Human Services with broad authority to authorize experimental, pilot, or demonstration project(s) which, in the judgment of the Secretary, (are) likely to assist in promoting the objectives of (the Medicaid statute)." States apply to CMS under the 1115 waiver statute to establish programs that "test substantially new ideas of policy merit." These projects often provide for federal matching funds to either cover services not typically covered under Medicaid, or to expand Medicaid coverage to persons not otherwise eligible for Medicaid (often through the expansion of persons covered under managed care). Projects typically run for five years, at which point the state may apply to continue the waiver project. Approved projects must be evaluated to determine their effectiveness. Demonstration projects must be budget-neutral in that they "cannot be expected to cost the Federal government more than it would cost without the waiver." Ctrs. for Medicare & Medicaid Serv., 1115 Waiver Research and Demonstration Projects, at http://www.cms.hhs.gov/medicaid/1115/default.asp (last visited Apr. 6, 2004) (copy on file with the NYU Annual Survey of American Law) ["CMS 1115 Website"].

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gram for Medicare beneficiaries—known as the Golden Bear State Pharmacy Assistance Program<sup>49</sup>—in which the discount would be partially supported by voluntary rebates negotiated with manufacturers by the state Department of Human Services. Similar attempts in Maine and Iowa have been unsuccessful. Prior to passing Maine Rx, Maine attempted to induce manufacturers to voluntarily offer rebates for the uninsured, but no manufacturers participated. However, given California's size and the large market share of its Medicare population, state officials expressed optimism that manufacturers will want to participate. As a part of this program, the state planned to work closely with the industry to coordinate its enrollment process with existing manufacturer discount cards. As of May 2003, the state was still under negotiations with drug manufacturers for voluntary rebates and it was unclear how many manufacturers would be willing to voluntarily offer such price concessions.

#### 2. Mandated Pharmacy Discounts and Manufacturer Rebates

Vermont and Maine were the only two states, as of December 2002, to have been granted Medicaid 1115 waivers to extend the Medicaid manufacturer rebate to non-Medicaid eligible persons with limited or no state contribution.<sup>50</sup> Both programs were challenged successfully and, as of July 2003, were suspended pending CMS' approval of modified waiver applications. In contrast to Medicaid pharmacy reimbursement rates that are set by states, federal law mandates the basic minimum manufacturer rebate on Medicaid prescription drug purchases.<sup>51</sup> The purpose of the Medi-

51. Some states have also negotiated supplemental rebates above this federally required minimum. For example, Florida and Michigan require supplemental rebates from the manufacturers of some drugs in order for their products to be included on the states' preferred drug lists. Drugs not on the lists are subject to prior approval by the states. National Conference of State Legislators, Recent Medicaid Prescription Drug Laws and Strategies, 2001–2003, *at* http:// www.ncsl.org/programs/health/medicaidrx.htm (last updated Nov. 17, 2003).

<sup>49.</sup> S.B. 696 (Cal. 2001), *available at* http://www.leginfo.ca.gov/pub/01-02/ bill/sen/sb\_0651-0700/sb\_696\_bill\_20011010\_chaptered.pdf (last visited Apr. 4, 2004).

<sup>50.</sup> Note that these 1115 waivers are separate from the Pharmacy Plus waivers that the federal government has recently granted several states. The Pharmacy Plus waivers extend Medicaid full drug coverage, in which the consumer pays a nominal copayment and the state and federal government pay the remainder of the discounted Medicaid price. Maryland's 1115 waiver (which has been referred to as a Pharmacy Plus waiver given similarities in design), approved in July 2002, allows Medicare beneficiaries up to 175% FPL to purchase drugs at 65% of the Medicaid discounted price. The remaining 35% is funded by the state. This discount program was implemented in July 2003. CMS 1115 Website, *supra* note 48.

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# TABLE 3:Pharmacy Discount Rate and Formula for Manufacturer Rebates<br/>in Case Study State Pharmacy Discount Programs, 2002

State	Pharmacy Discount Rate	Manufacturer Rebate Formula
California	AWP—10% plus a \$0.15 processing fee. FUL and state MAC apply	NA. New Golden Bear Pro- gram to attempt to negotiate voluntary manufacturer rebates.
Florida	AWP—9% plus a \$4.50 dis- pensing fee	NA.
Iowa	Brand: AWP—10% plus a \$2.50 dispensing fee or MAC plus \$4.25 Generic: AWP—30% plus a \$3.25 dispensing fee or MAC plus 25%	Negotiated by PBM. As of September 2002, contracts were in place with 3 manufac- turers for 27 drugs.
Maine HMP	AWP—13% or MAC or FUL	Same as Medicaid. For brand name drugs: AMP—15.1% or best price, the CPI adjust- ment applies. AMP—11% for generics.
New Hampshire	Brand: AWP—15% plus a \$2.50 dispensing fee Generic: AWP—40% plus a \$2.50 dis- pensing fee	NA.
West Virginia	Brand: AWP—13% plus a \$3.50 dispensing fee Generic: AWP—60% plus a \$3.50 dis- pensing fee	PBM to negotiate with manu- facturers for rebates. No con- tracts signed as of July 2002.

Source: Interviews with program officials conducted by Rutgers' Center for State Health Policy in six operational state discount programs, Fall 2002.

caid rebate program is to reduce federal and state government spending on outpatient prescription drugs and ensure that Medicaid pays no more—and preferably less—than any other purchaser, with certain exclusions. For brand name drugs, the law establishes a basic rebate of the greater of either a 15.1% discount off the drug's Average Manufacturer Price (AMP) or the difference be-

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tween the AMP and the manufacturer's "best price" for that drug. "Best-price" is the lowest price paid for prescription drugs by any purchaser in the United States, with a few exceptions including federal agencies such as the Veterans Administration. In addition, if the AMP increases more than the Consumer Price Index (CPI), an additional rebate is due. Rebates for generic drugs tend to be lower than for brands, as they are set at AMP minus 11% and best price does not apply.<sup>52</sup> As rebates are mandated federally, states that wish to extend the Medicaid rebate to non-Medicaid eligible persons are required to seek a waiver from CMS.

Vermont's Pharmacy Discount Program (PDP), approved in November 2000, was the first waiver program to be approved. It created a new "limited purpose" class of Medicaid beneficiaries who were eligible only for Medicaid drug discounts and rebates. Under the program, pharmacies would charge PDP enrollees the Medicaid retail price, less the estimated average manufacturer Medicaid rebate. The state would reimburse the pharmacies for the estimated manufacturer rebate and then bill manufacturers for Medicaid rebates on these drug sales. The program was to be entirely financed by pharmacists and manufacturers, except that the state would have to set aside some funds to temporarily reimburse pharmacists for the manufacturer portion of the price reduction. The program was challenged in court by the Pharmaceutical Research and Manufacturers of America (PhRMA), which contended that, because the state made no payment, the program violated the Medicaid statutory requirement that limits manufacturer rebates to drugs for which Medicaid funds are expended.<sup>53</sup> PhRMA eventually won its argument in court, and the PDP program was invalidated.<sup>54</sup>

Approved in January 2001, Maine's waiver program—Healthy Maine Prescriptions—was inspired by the Vermont program, but differs from Vermont's in two key respects. First, whereas Vermont's program was extended to all Medicare beneficiaries as well as all residents under 300% FPL, Maine's program was limited to all individuals in the state earning up to 300% FPL. Second, the discount was financed not only by manufacturers and pharmacies, but also by a small state subsidy. For each drug purchased, Maine contributed \$1 or 2% of the price, whichever was less; this further lowered the price to the consumer. This state contribution was not included in the original waiver request to CMS, but was added by

<sup>52. 42</sup> U.S.C.A. § 1396r-8.

<sup>53.</sup> Pharm. Research & Mfrs. of Amer. v. Thompson, 251 F.3d 219, 221 (D.C. Cir. 2001) (*Thompson I*).

<sup>54.</sup> Id.

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the state, in an effort to avert legal challenge. While HMPP withstood legal challenge by PhRMA in the district court, the court of appeals reversed this decision in January 2003, ruling that CMS did not have the authority to approve the waiver without a state contribution.<sup>55</sup>

The novel approach of extending the full Medicaid discount on prescription drugs has an uncertain future due to current and potential future legal challenges. For one thing, as we discuss below, it is unclear whether the Secretary has the authority to extend these discounts to non-Medicaid populations. For another, PhRMA successfully challenged both Maine's HMPP and Vermont's PDP on the ground that the Secretary could not approve them without adequate state contributions.<sup>56</sup> At this writing, both states' amended waiver requests, which include nominal state contributions, were pending.

# B. State Acts as PBM on Behalf of Uninsured Using Medicaid Prior Authorization

In the second model, the state acts as a pharmacy benefit manager on behalf of all uninsured residents without drug coverage and negotiates with pharmaceutical companies to obtain rebates on prescription drugs. Two states, thus far, have enacted this type of program. The most highly publicized example is the Maine Rx program, enacted in May 2000, which had been enjoined due to legal challenge. The passage of Maine Rx preceded the implementation of Healthy Maine Prescription Program discussed above. In part because of the legal challenges facing Maine Rx, Maine decided to submit a waiver for HMPP which would apply to a more limited portion of the population. The injunction on the Maine Rx program was overturned by the Supreme Court in June 2003,<sup>57</sup> while the Healthy Maine Prescription Program was suspended in January 2003 by court order.58 In 2002, Hawaii passed a program modeled after Maine Rx, but the program had not yet been implemented at the time of writing. Other states, including Arkansas and Iowa, have proposed similar models pending the outcome of the legal challenges to Maine Rx.

The key feature of the Maine Rx program is that the state seeks to lower drug prices for the estimated 325,000 Maine residents who

<sup>55.</sup> Pharm. Research & Mfrs. of Amer. v. Thompson, 313 F.3d 600 (D.C. Cir. 2002) (*Thompson II*).

<sup>56.</sup> Thompson I, 251 F.3d at 219; Thompson II, 313 F.3d at 600.

<sup>57.</sup> Pharm. Research & Mfrs. of Amer. v. Walsh, 123 S. Ct. 1855 (2003).

<sup>58.</sup> Thomspon II, 313 F.3d at 602.

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lack prescription drug coverage through a combination of mandated retail discounts at participating pharmacies and state-negotiated rebates with participating manufacturers. The intent is to negotiate rebates that are lower than Medicaid and are comparable to or lower than the federal supply schedule—the prices negotiated for federal agencies such as the Veterans Administration. While manufacturer participation is "voluntary," the enacting legislation provides the state with powerful sanctions not available in the private sector to promote manufacturer participation.<sup>59</sup> First, the statute authorizes the Maine Department of Human Services to release the names of all non-participating manufacturers and labelers to all consumers in order to use public pressure to encourage manufacturers to participate. Second, the statute grants the department the power to impose prior authorization requirements in the Medicaid program for the dispensing of prescription drugs provided by those non-participating manufacturers and labelers. Finally, as a measure of last resort, the Commissioner of Human Services has the authority to invoke Maine's profiteering statute, which makes it illegal to demand an "unreasonable" price when basic human needs are at stake, thereby giving the state the authority to set prices at the retail level.

Although somewhat similar to the state Medicaid discount approach, key differences between Maine Rx and rebates achieved through extending Medicaid eligibility include the way in which the rebate level is decided and the consequences for non-participation. In the Vermont PDP and Maine HMPP program (had they been upheld), the state would have extended Medicaid eligibility, thereby forcing manufacturers to pay the Medicaid rebate or be excluded from participation in the Medicaid program nationally. In Maine Rx, while the state seeks to negotiate rebates at the level of the federal supply schedule, the rebates may be set at any level agreed to by the state and manufacturer—not necessarily tied to Medicaid. The consequence to manufacturers for not participating in these programs does not extend to national proportions, but is state-specific. Because the discounts would not be limited to the Medicaid level, this approach could provide greater cost savings to consumers than any of the other discount options pursued by states. However, it faces significant legal challenge, and its viability rests on the Supreme Court decision in Walsh, which is discussed in more detail below.60

<sup>59.</sup> An Act to Establish Fairer Pricing for Prescription Drugs, 2000 Me. Legis. Serv. 386 (West).

<sup>60. 123</sup> S. Ct. at 1855.

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#### C. Contracting with Private Sector Pharmacy Benefit Managers

Three states—Iowa, West Virginia, and New Hampshire opted to subcontract with private pharmacy benefit managers to negotiate voluntary pharmacy discounts for program enrollees. All three programs were created by executive order rather than through legislation. These programs rely on the PBMs' network of pharmacies to provide discounts to program enrollees who present their discount card. These programs mainly provide discounts on prescription drugs through retail discounts at the pharmacy. The programs that have attempted to negotiate voluntary manufacturer rebates to further increase consumer discounts have been largely unsuccessful.

New Hampshire's and West Virginia's programs rely on retail pharmacy discounts to support lower prices to consumers. New Hampshire's program was initiated in January 2000 as a two-year pilot program. The PBM has continued the program, of its own accord, beyond the two-year pilot. West Virginia's discount program was initially run by the state and was later subcontracted to a PBM and folded into a pre-existing retail discount card.

The Iowa Priority program originally required that all discounts be based on voluntary manufacturer rebates negotiated by a PBM subcontractor. The state created an independent not-forprofit corporation to oversee the program so that manufacturers would not feel that their rebate agreements with the state would be under regulatory control. However, as of December 2002, only three of the country's twenty major pharmaceutical companies had agreed to participate in the program.<sup>61</sup> According to program officials, the state was in negotiations with another manufacturer to provide discounts to persons with incomes below 300% FPL.<sup>62</sup> In response to the low voluntary participation of pharmaceutical companies in Iowa Priority, the Governor declared the program a failure and introduced legislation to require manufacturers to offer

<sup>61.</sup> Bristol-Myers Squibb, Schering-Plough, and Merck. *Fourth Drug Company* to Offer Discounts to Elderly, Associated Press Newswires, Apr. 8, 2003 (on file with the NYU Annual Survey of American Law).

<sup>62.</sup> In April 2003, the state announced that Novartis would offer discounts to Iowa Priority members making less than \$28,000 annually or approximately 300% FPL. The discount, which is as low as \$12 per prescription for the lowest income groups and amounts to  $25{-}40\%$  of the cost of the drug for those with higher incomes, is identical to that offered through its own national discount card and through the cooperative discount card from multiple manufacturers called Together Rx. *Id.* 

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drugs at reduced costs, following a model similar to that of Maine  $Rx.^{63}$ 

The failure of PBMs to negotiate voluntary manufacturer rebates for discount programs is not necessarily surprising. In negotiating rebates for insurers or health plans, PBMs are able to persuade manufacturers to participate by offering to influence enrollees' purchasing decisions, thereby increasing market share for a manufacturer's drug, through the use of formularies, tiered copays, or prior authorization. However, none of these methods can be used to their full effect in discount programs. The savings to the consumer of choosing a drug with an additional discount from a rebate would not be particularly easy to explain, nor would they necessarily convince the consumer to switch from the drug that was prescribed by his or her physician.

States have subcontracted or considered subcontracting with an existing pharmacy benefit manager to negotiate discounts for several reasons. Depending on the PBM that the state selects, the PBM may already manage drug benefits for a large number of individuals in the state, and so would have pre-existing contractual relationships with pharmacies. This approach can also present less of an administrative burden to states since program enrollment, outreach, and operations are often handled by the PBM. In addition, these programs are non-legislative initiatives that offer a quick and low-cost way to provide discounts to participants.

These state programs are similar to the interim Medicare-approved discount cards in that they utilize the private sector. The programs differ in that the interim Medicare-approved discount card program will endorse multiple private discount cards that meet certain criteria, rather than have a contract with one private card sponsor, as has been the case in state programs. However, based on the experience of these PBM-run state discount cards, the Medicare-approved discount cards are likely to rely most heavily on retail pharmacy discounts and are much less likely to convince manufacturers to offer voluntary rebates.

<sup>63.</sup> Statelines—Iowa: *Gov. Proposes Mandatory Rx Discounts for Seniors*, American Health Line, Aug. 7, 2002, *available at* LEXIS, News Library, American Health Line File.

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# V.

# ELIGIBILITY REQUIREMENTS AND ENROLLMENT FEES

While most state pharmacy discount programs are targeted toward all Medicare beneficiaries who lack drug coverage, six states extend the discount only to older adults, not to younger disabled persons<sup>64</sup> (see Table 4). Given that these programs come at little or no cost to states, it is unclear why some states have opted to exclude the disabled. Officials in West Virginia indicated that disability status is more difficult to verify, increasing administrative costs. Limiting West Virginia's Golden Mountaineer discount card may have been more straightforward administratively, as it added a pharmacy discount to a pre-existing multi-product retail discount card for older residents.

Most state discount programs are open to all seniors regardless of income. However, some state programs, particularly those that extend Medicaid rebates to Medicare beneficiaries, have established income eligibility requirements to ensure that the expansion is focused on lower-income persons.

A few discount programs extend the discount to uninsured non-elderly as well. Maine's HMPP was available to all residents with incomes below 300% of poverty regardless of age, and the Maine Rx program was originally designed to be available to all residents of the state regardless of age or income. Vermont's PDP was originally designed to be available to all Medicare beneficiaries and other persons with incomes below 300% of FPL. After being struck down by the courts, Vermont submitted a new waiver request to CMS, which would limit participation to Medicare beneficiaries earning less than 400% FPL.

In contrast to many private pharmacy discount programs, most state pharmacy programs do not require an annual fee to enroll. Of our six case study states, only Iowa had a \$20 annual enrollment fee. In some cases, individuals need not "enroll" in the discount program at all. In Florida and California, they need only show their Medicare card to the pharmacist to be eligible for the discount. Annual fees for the states that have them are used to support the administration of the program. Other programs, such as California's Medicare Discount program and Maine's Healthy Maine Prescription program when it was operational, charged per-use fees, ranging between \$0.03 and \$0.15 per prescription. Program offi-

<sup>64.</sup> New Hampshire, New Mexico, Oregon, South Carolina, Washington, and West Virginia.

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cials in Maine chose a per-use fee over an annual enrollment fee because they anticipated that an up-front fee would be a barrier to enrollment.

State (Program)	Age/Disability Requirements	Income Limits	Annual Fee
Arizona	All Medicare beneficiaries	None	\$9.95 annual fee
California (PDDPMR)	All Medicare beneficiaries	None	No fee
California (Golden Bear)	All Medicare beneficiaries	None	Fee to be determined
Florida	All Medicare beneficiaries	None	No fee
Hawaii (Hawaii Rx)	No age or disability restrictions	None	No fee
Hawaii (MPDEP)	No age or disability restrictions	300% FPL	No fee
Illinois	All Medicare beneficiaries	None	\$25 annual fee
Iowa	All Medicare beneficiaries	None	\$20 annual fee
Maine (HMPP)	No age or disability restrictions (as originally passed)	300% of FPL	Fees deducted from prescription discounts
Maine (Maine Rx)	No age or disability restrictions	None	No fee
Maryland	Medicare beneficiaries	250% FPL, applied for federal waiver to expand to all Medicare beneficiaries	No fee
Montana	Age 62 or over; disabled 18 or over	200% FPL	\$25 annual fee
New Hampshire	Age 65 or over	None	No fee
New Mexico	Age 65 or over	None	Fee to be determined but not to exceed \$60
Ohio	Age 60 or over, disabled persons	None	Fee to be determined
Oregon	Age 65 or over	185% of FPL	\$50 annual fee

TABLE 4:	
State Discount Program Eligibility Requirements,	2003

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State (Program)	Age/Disability Requirements	Income Limits	Annual Fee
South Carolina	Age 65 or over	None; must not be eligible for Medicaid prescription benefits	Fee to be determined
South Dakota	Age 65 or over, or disabled	None	Fee to be determined
Vermont (PDP)	All Medicare beneficiaries and others with limited incomes	No income limit for Medicare beneficiaries, 300% of FPL for others	\$24 annual fee
Vermont (HVP)	Medicare beneficiaries and others with limited incomes	Medicare beneficiaries with incomes below 400% FPL and other persons with incomes below 300% FPL	Fees will be deducted from prescription discounts
Washington	Age 55 or over	None	\$15 annual fee
Washington (2)	Age 50+, disabled 19+	300% FPL	Fee to be determined
West Virginia	Age 60 or over	None	No fee

Source: National Conference of State Legislatures' web site: *State Pharmaceutical Assistance Programs*, http://www.ncsl.org/programs/health/drugaid.htm (updated November 7, 2003).

# VI.

# COSTS OF STATE-SPONSORED DISCOUNT PROGRAMS

Part of the appeal to states of discount programs is that they aim to provide a needed benefit to constituents without requiring large expenditures by the state. While the costs of discount programs are minimal in comparison to subsidy programs, states still incur some costs to run discount programs. Maine, which paid \$1 or 2% of the discounted price for enrollees prior to being halted by the courts, was the only state that contributed state general funds to subsidize the consumer discount.<sup>65</sup> For example, in 2001, Maine appropriated \$20 million for this subsidy. However, states that do not help subsidize the discount still incur some operating and advertising costs.

<sup>65.</sup> In response to legal challenge, Vermont has submitted a new waiver request to CMS, which includes the same state subsidy toward the discount.

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#### A. Administrative Costs

Administrative costs vary by program, but generally include a processing fee per claim paid to the state's claims processor or PBM, as well as personnel costs. States have covered these costs in a variety of ways, including user or enrollment fees, funds from existing department budgets, lottery funds, federal grants, and rebates from manufacturers. In general, administrative costs have been relatively modest in these programs.

California requires consumers to help cover claims processing fees through a \$0.15 charge per prescription, while the state pays three cents per claim. For Fiscal Year 2003, the state estimated its portion of the per claim costs to total \$380,000. Other non-claimsprocessing costs, including two full-time staff members and costs to support a hotline, were absorbed through the Department of Human Services budget. Florida also uses departmental funds to cover administrative expenses.

Before the Maine HMPP was terminated, administrative costs were covered by a portion of manufacturer rebates and by a nominal per use fee. Iowa received a \$1 million federal grant to implement the program, and the state has received another \$500,000 in federal funding for continuing program operations. The state also collects an enrollment fee which helps pay for administrative costs. West Virginia used state lottery funds to pay \$275,000 in start-up costs and \$1050 in ongoing costs for card production and mailing. For undisclosed reasons, the PBMs that contracted with West Virginia and New Hampshire both agreed to administer these programs at no cost to the state. In West Virginia, the PBM—Advance PCS—already had a national discount program that was open to any consumer willing to enroll, so the administrative costs of adding more enrollees was probably minimal. The respective PBMs cover the claims processing costs for the programs, and the PBM for New Hampshire's program also conducts some outreach for the discount program.

#### B. Outreach and Education Costs

Outreach for discount programs can affect utilization of the discount, particularly when pharmacies do not voluntarily offer the discount, thereby forcing consumers to ask about the discounts.<sup>66</sup> Despite this, California initially set aside no funding for outreach

<sup>66.</sup> Joy H. Lewis et al., Compliance Among Pharmacies in California with a Prescription Drug Discount Program for Medicare Beneficiaries, 346 New Eng. J. Med. 830 (2002).

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and mainly relied on existing mechanisms (e.g., Medicaid alerts to pharmacies and counselors who work for the State Health Insurance Information Counseling and Assistance Programs) and press coverage to advertise its programs. After the first year of operation, a study published by the Kaiser Family Foundation found that 77% of California seniors in the survey had not heard of the state discount program, and only 35% of those who had heard of the program reported that they actually had used it.<sup>67</sup> In response to these criticisms, the state enacted a law in September 2002 that provided for an outreach program to inform Medicare beneficiaries about the discount and required participating pharmacies to display stateproduced signs advertising the discount program.<sup>68</sup> The outcome of this new initiative has not yet been evaluated.

The amount of funds set aside for outreach in states that contract with PBMs varied considerably. New Hampshire had no estimate of how much money was spent on outreach, as this state's program relies on the PBM for outreach and publicity. West Virginia initially allocated \$10,000 from lottery funds to advertise the program, and has supplemented this with \$50,000 from departmental funds to produce television commercials and newspaper advertisements. The most substantial financial expenditure for outreach appears to have taken place in Iowa, where \$300,000 from federal grant funds was spent to promote the program through direct mail, television, and newspaper advertisements. For those states that have invested in outreach, no studies have been conducted to measure whether the outreach has had the desired effect, but officials reported that they felt, based on enrollment, it had been fairly effective.

Several program officials noted that outreach for these types of programs should not overstate the program's benefits and thus raise consumer expectations to an unreasonable level. One respondent suggested that outreach materials should provide consumers with actual figures illustrating the size of the discount for prototypical drugs, emphasizing the accumulated benefit of small discounts on annual drug spending for the individual. Program officials also said that outreach programs should focus on consumer education

<sup>67.</sup> THE HENRY J. KAISER FAMILY FOUNDATION, CALIFORNIA SENIORS & PRESCRIPTION DRUGS: BASED ON FINDINGS OF A 2001 SURVEY OF SENIORS FROM EIGHT STATES 4, 27 (Nov. 2002), *available at* http://www.kff.org/statepolicy/loader.cfm?url=/Commonspot/security/getfile.cfm&PageID=14183 (last visited Apr. 6, 2004).

<sup>68.</sup> S.B. 1278 (Cal. 2002), *available at* http://www.leginfo.ca.gov./pub/01-02/ bill/sen/sb\_1251-1300/sb\_1278\_bill\_20020915\_chaptered.pdf (last visited Apr. 7, 2004).

about ways to decrease out-of-pocket prescription drug costs through generic substitution and other means, including use of the discount program.

#### C. Quality and Safety Features

In addition to providing price discounts, discount programs can be used as a mechanism to reduce the risk of medication errors or harmful drug interactions by identifying potential problems before the consumer purchases the drugs. Most state subsidy programs, such as Medicaid and state pharmacy programs, have systems in place that flag the pharmacist, and in some cases will even stop payment, when the drugs being purchased could have harmful effects. While the state cannot stop payment in discount programs since the consumer is the purchaser, the state could integrate systems to inform consumers of potential risks. Three out of the six operational programs indicated that they had some type of drug utilization review (DUR) built into the discount program claims processing system. The level of DUR varied, from standard software used by the PBMs in West Virginia and New Hampshire, to the use of Medicaid DUR edits including prior authorization for higher cost drugs in some drug classes in the Maine HMPP waiver program. In contrast, California and Florida had not incorporated drug utilization edits into their discount programs.

Although Iowa also does not have an on-line drug utilization review system, the Iowa Priority Program offers an innovative consumer education program about prescription drugs, known as the "Brown Bag Assessment." Under this program, when applicants enroll in Iowa Priority they are given a \$25 certificate to have a pharmacist or physician review their current drug regimen. The pharmacist or physician will then recommend ways for the individual to save money through drug substitution, eliminating therapeutic duplication, or other means. The pharmacist or physician also looks for potentially harmful combinations or doses of prescription drugs, over the counter drugs, and/or herbal remedies, and suggests safer alternatives. The state also publishes a list of interactions between prescription drugs and herbal remedies on its website. State officials felt that this program helped seniors lower drug expenditures by enabling them to make better purchasing decisions.

The program also may help in improving appropriateness of drug use, particularly for persons who take many prescribed medications. A state-commissioned evaluation of the Brown Bag Assessment program found that while only 13% of enrollees received a medication assessment six months after the program had started,

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most of the people who took advantage of it were taking five or more medications. One-third of those assessed had at least one potential patient safety issue identified; these individuals tended to take more medications and have medical conditions such as asthma, diabetes, high blood pressure or high cholesterol. Of the patient safety problems identified, one-third were related to nonprescription medications. Program officials concluded that the research findings suggest that seniors lack awareness of the ways in which over-the-counter medication can interact with prescription drugs, and that more education in this area may be needed.<sup>69</sup>

#### VII.

# HOW MANY PEOPLE USE THE DISCOUNTS AND HOW MUCH DO THEY SAVE?

State discount programs have limited information on how many eligible persons apply for and use the state discount card. The states that do collect this information report varied success in getting eligible persons to enroll. The California and Florida programs, which require pharmacies to provide the discount to all Medicare beneficiaries who show their Medicare card, have no enrollment process or claims transactions and, therefore, have no mechanism for determining how many people actually use the benefit. While all Medicare beneficiaries have access to the discount in that they only need to present their Medicare cards to be eligible, the states do not know whether people are aware that the discount is available to them or how many people use it. Florida has no mechanism for tracking how many people use the benefit because there is no claims processing or electronic price quote query system in place. California tracks the number of price quotes requested by pharmacists, which averaged approximately 850,000 per month in 2002, up from 500,000 per month the prior year. This implies that awareness of the program has increased and more people are using the benefit. However, there is no way of knowing the number of individuals requesting these quotes or whether the consumer actually purchased the drug at the discounted amount.

In the remaining four state-sponsored discount programs, participation rates in 2002 differed significantly. The PBM-administered programs in Iowa, West Virginia, and New Hampshire had varied success in getting people enrolled, but the percent of enroll-

<sup>69.</sup> Press Release, University of Iowa, IU Researchers Urge Awareness of Drug Interactions, Duplication (Dec. 20, 2002), *available at* http://www.uiowa.edu/~ournews/2002/december/1220drugstudy.html (last visited Apr. 6, 2004).

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ees that actually used the card was fairly low in all three programs. West Virginia mailed cards to all 360,000 persons in the state who were over 60 and had a driver's license or identification card through the state Department of Motor Vehicles. While all of these people technically were enrolled because they were sent a discount card, only 5% of those sent a card actually used it. Iowa Priority enrolled 24,000 people as of December 2002, or 5% of the estimated 480,000 Medicare beneficiaries who were potentially eligible in the state. New Hampshire enrolled 76,000 people or approximately 52% of the Medicare beneficiaries in the state, but only 16% of enrollees actually used the card. While officials did not comment on the reasons for these low use rates, it may be tied to the lower participation by pharmacies in PBM-administered programs, which is discussed in more detail below. In contrast, the Healthy Maine Prescription program, which reported higher pharmacy participation and better discounts than the other three states, enrolled 114,000 persons or 35% of those eligible. State officials indicated that nearly all of these enrollees had used the card at some point during the year.

#### A. Factors Influencing Size of Savings to Consumers

Assessing the value of any discount card program for consumers, whether a private or public program, is difficult because retail prices for prescription drugs vary greatly from pharmacy to pharmacy. Therefore, the amount that consumers save with these programs depends on the retail price that would otherwise be charged at the pharmacy they visit. In addition, many pharmacies have senior citizen discount programs that already provide retail discounts to persons over the age of sixty-five who enroll. As shown in Table 3 above, the discount rates at which pharmacies must sell prescriptions to enrollees are based on AWP, but the association between the AWP and the retail price charged to cash-paying customers is variable. In addition, for states that are able to obtain manufacturer rebates to supplement the pharmacy discount, information on manufacturer rebates is deemed proprietary.<sup>70</sup> To provide a more accurate measure of consumer savings off of retail, most states have pharmacists submit their "usual and customary" price to the state when filling a discounted prescription. According to one in-

<sup>70.</sup> DEP'T HEALTH & HUMAN SERVS., REPORT TO THE PRESIDENT: PRESCRIPTION DRUG COVERAGE, SPENDING, UTILIZATION, AND PRICES 206 (2000), *available at* http://aspe.hhs.gov/health/reports/drugstudy/ (last visited Apr. 6, 2004) ["HHS DRUG REPORT"]; *see* HEALTH POLICY ALTERNATIVES, INC., KAISER FAMILY FOUNDATION, PRESCRIPTION DRUG DISCOUNT CARDS: CURRENT PROGRAMS AND ISSUES vii (2002).

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terview respondent, this price would ideally represent the retail price that would normally be charged to the person making the purchase, but pharmacies are able to define usual and customary however they wish, so the actual meaning of this term may vary among pharmacies.

In general, most cards have not provided the level of savings promised by officials when the programs were first initiated. As shown in Table 5, in some cases, these initial projections were not based on particularly reliable information but were essentially rough estimates. For example, while Maine and California originally thought that consumers would save 40% on drugs, the estimated savings in the first year were only 24–25%.

The type of discount model that states have pursued has a direct relationship to the magnitude of the discount available to consumers. For example, prior to being halted by the courts, Maine's HMPP, which extended both the Medicaid pharmacy discount and manufacturer rebate to consumers, was estimated by state officials to result in a 25% reduction in price to participants. Models that seek discounts only from pharmacies—either through the private sector or Medicaid—were estimated to offer anywhere from 12 to 24% discounts.

The pharmacy discount rate and dispensing fee set by the state also affect consumer savings, as do any fees that are charged to join the program and the retail price charged in any given state. A drug pricing study conducted by the United States Department of Health and Human Services revealed wide regional variation in the usual and customary prices charged to cash-paying customers.<sup>71</sup> Since most states measure the actual savings for consumers based on the percentage reduction from usual and customary price, it is difficult to compare relative savings across state discount programs. For example, California's program, which includes only a pharmacy discount that is estimated at AWP minus 10% for brands, reported a savings to the consumer of 24% off of usual and customary prices. This savings estimate was provided by the California Department of Human Services and is based on an internal analysis comparing the average retail price entered by pharmacists on price quote requests with the Medi-Cal price for 300 to 400 commonly requested drugs (with more than 100 queries). It is difficult to evaluate the accuracy of this estimate since the state did not provide a copy of the actual analysis to confirm the number of queries included, the breakdown of drugs included by brand or generic name, or the accuracy of self-

<sup>71.</sup> HHS DRUG REPORT, supra note 70, at 203–09.

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reported retail prices. Maine's HMPP, which includes both a pharmacy discount that is estimated at AWP minus 13% for brands and manufacturer rebates, reported similarly that consumers had saved about 25% off of usual and customary prices.

#### TABLE 5:

# Estimated and Actual Consumer Savings<sup>†</sup> on Prescriptions in Case Study State Pharmacy Discount Programs, 2002

State	Estimated Savings
California	24% off of usual and customary price on average, ranging from 0 to 70% based on DHS analysis of 300–400 commonly used drugs.
Florida	Unknown.
Iowa	12% off of usual and customary on average.* Total consumer savings \$1.9 million in 2002 and average annual savings of \$122.24 per member.**
Maine HMP	25% off of usual and customary on average.
New Hampshire	17.2% off of usual and customary on average. Total consumer savings \$1.5 million in 2002 and an average savings of \$126.95 per active member for fiscal year 2002–2003.
West Virginia	17.5% off of usual and customary. Total consumer savings of \$1.7 million in first five months of 2002 and average savings of \$20.43 per member per month.

<sup>†</sup> Unless otherwise indicated, estimated consumer savings were provided by state program directors in interviews. Most states were unable to supply detailed calculations or analyses of how estimated consumer savings were calculated. Therefore we are unable to verify the accuracy of these estimates.

\* Estimate based on first six months of operation, which only included the pharmacy discount.

\*\* Estimate as reported on May 22, 2003. Iowa Priority News Release, Iowa Priority Prescription Program Saves Iowans Nearly \$1.9 Million in First Year, *at* http://www.iowapriority.org/newsrelease-firstyear.asp (last visited Apr. 6, 2004).

Source: Interviews with program officials conducted by Rutgers' Center for State Health Policy in six operational state discount programs, Fall 2002.

The PBM programs that rely solely on pharmacy discounts reported much lower savings off of customary and usual prices, averaging between 12 and 17%. These estimates were difficult to corroborate or compare as states estimated savings using different measures, and supplied only aggregate data.

#### B. Savings Compared with Private Discount Cards

In addition to state drug discount cards, consumers may be eligible for a variety of other private drug discount cards including those offered through an association such as the AARP, their for-

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mer employer's retirement health plan, their local retail pharmacy, or by manufacturers. Comparing the benefits of state discount cards with each of the private discount cards available is beyond the scope of this study. However, a report released by the United States General Accounting Office (GAO) in September 2003 found that relative discounts offered by private cards vary by program, and by drug and by retail outlet, making it difficult to assess whether state discount card savings are higher than those obtained through the use of private discount cards.<sup>72</sup> If the state program does not have an enrollment fee, as was the case for five out of six of our case study states, savings achieved through PBM-administered cards also need to be reduced by the annual or one-time fee that the card charges. Savings are often expressed in different ways, making it difficult to compare savings across programs. More importantly, state discount cards differ from private discount programs with respect to eligibility, the range of drugs they cover, enrollment fees, and the number of pharmacies that will accept the card. For example, while some manufacturer discount cards may offer lower price discounts than the state programs, their cards are only available to Medicare beneficiaries with low-incomes who have no prescription drug coverage, whereas state-sponsored cards are usually available to all residents. A manufacturer discount card also only provides discounts on drugs that the manufacturer produces.

State discount programs, especially those administered by PBMs, are more similar to discount cards issued by associations, such as the AARP, or employers or insurers, who often subcontract to PBMs. On average, these PBM-administered private cards offer pharmacy discounts of 10 to 15% off of average wholesale price, which is comparable to those offered by state programs (see Table 3).<sup>73</sup> In fact, based on a survey of pharmacies' prices on nine drugs commonly used by the elderly, GAO found that in California, many private PBM cards offered better discounts than the state discount. It is hard to know if this would hold true on average for all discounted drugs, since savings varied significantly by drug. For example, two drugs were cheaper through California's state discount. Savings from the private PBM-administered cards for the remaining seven drugs ranged from \$0.44 to \$13.06. This does indicate that private discount cards may offer comparable or even higher savings for some drugs.

<sup>72.</sup> Gen. Accounting Office, Prescription Drug Discount Cards: Savings Depend on Pharmacy and Type of Card Used, GAO-03-912 (2003).

<sup>73.</sup> This estimate is based on advertised prices.

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#### C. Consumers' Perceptions of Discounts

States have learned that these marginal discounts are not always as great as consumers had expected and can result in some political backlash if the discounts have been touted as a solution to lowering drug costs. Officials in several states noted that they received numerous calls from consumers complaining that the discounts were not as generous as they had originally thought. Program officials felt that consumer dissatisfaction with the discounts was often fueled by lack of understanding of how the programs work and unrealistic expectations raised by public officials promoting the programs.

#### D. Not All Pharmacies May Offer the Discount

Having a discount program does not necessarily mean that consumers will be offered the discount at their local pharmacy. Pharmacy participation in state discount programs is voluntary: pharmacies can choose to participate but they are not mandated to do so. Even in Florida, California, and Maine, where all pharmacies that participate in Medicaid are required to provide the discount, pharmacies still have the option of not accepting Medicaid. In fact, the California Department of Health Services was initially concerned that the Medicare discount requirement might reduce access for Medicaid beneficiaries by driving pharmacies out of the state's Medi-Cal program. However, California program officials reported that a year and a half after program implementation, none of the pharmacies that had been participating in Medi-Cal have dropped out due to the discount program. Similarly, Florida and Maine reported that no pharmacies had dropped out of Medicaid due to the state discount program. Pharmacy participation in Medicaid, and thus the discount programs in these states, is very high—ranging from 95 to 100% of the pharmacies in the state (see Table 6).

In contrast, some of the states that subcontract with PBMs have lower pharmacy participation rates than those administered through Medicaid, limiting accessibility to the discount for seniors. In reviewing bids received through their request for proposal process for subcontractors, all states considered the size of the PBMs instate existing pharmacy network as one criterion in their final selection. However, respondents noted that the fact that a pharmacy contracts with a PBM does not necessarily mean that the pharmacy has to participate in a discount program administered by the PBM. One respondent noted that, when a pharmacy contracts with a

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PBM, it is usually required to participate in all of the PBM's plans; however, some pharmacies have an exception in their contracts for retail discount programs administered by the PBM. For example, West Virginia's Golden Mountaineer Discount Card has 306 participating pharmacies (51% of pharmacies in the state), with at least one pharmacy in each of the fifty-five counties in the state. However, according to state officials, some of the state's largest pharmacies, including two chain drug stores—CVS and Rite Aid—refused to participate in the program, arguing that the discounted prices were too low. According to program officials, a large number of the consumer complaints about the discount program are related to the lack of pharmacies willing to provide the discount.<sup>74</sup> Limited access to only some pharmacies is also an issue for private discount card programs.

Finally, even when pharmacies are technically mandated to participate in the discount program, they may or may not choose to offer or publicize the discount. Both California and Florida have received numerous consumer complaints about pharmacies either not accepting the discount card, or not giving pricing information to participants. Indeed, one study of pharmacy participation in the California discount program found that only 75% of the 494 pharmacies visited honored the discount and only 45% of the pharmacies voluntarily offered the discount before it was requested.<sup>75</sup>

#### E. Impact on Pharmacies

All of the discount models that states have pursued thus far have required that pharmacies bear some portion of the discount given to participants. In general, pharmacy organizations have been more supportive of programs that also require manufacturer rebates than those that provide only a pharmacy discount. Several pharmacy representatives stated that manufacturer pricing was the source of most of the cost of prescription drugs, so manufacturers should bear at least part of the discount to consumers. Pharmacists also expressed a preference for programs that had income eligibility requirements, stating that state residents who are multi-millionaires should not be eligible for the same discounts as someone living near poverty. Still, pharmacy representatives in several states

<sup>74.</sup> Implementation of Ohio's Golden Buckeye discount program, which is also administered by a PBM, had been delayed due to low pharmacy participation, specifically CVS and Rite Aid, but began operation in October 2003. *See* NCSL Summary, *at* www.ncsl.org/programs/health/drugaid.htm, (updated November 7, 2003) (copy on file with the NYU Annual Survey of American Law).

<sup>75.</sup> Lewis et al., supra note 66, at 830.

unknown

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#### participation rate) Pharmacies Participating in Pharmacies in the Program Manufacturers State Discount Model State (% of Total) Participating Maine HMP Medicaid 360 360 (100%) 520 Mandate Florida Medicaid 3,367 3,300 (98%) NA Mandate Iowa PBM Negotiated 1,050 1,019 (97%) 3 California Medicaid 5,263 5,000 (95%) To be Mandate determined New Hampshire PBM Negotiated 216 120 (55.6%) None 600 West Virginia PBM Negotiated 306 (51%) None

Sources: Rutgers Center for State Health Policy Survey of State Pharmaceutical Assistance Programs, December 2000 and December 2002; Rutgers interviews with program officials conducted by Rutgers' Center for State Health Policy in six operational state discount programs, Fall 2002.

said that the discount programs did not have as large an impact on their members as they had feared. Many pharmacies already offered discounts to senior citizens, and pharmacies reported that the discounts offered through the state programs were often not lower than the pharmacies' usual and customary price. The extent to which pharmacies were already providing discounts could not be quantified. However, the fact that pharmacies were already furnishing discounts raises further questions about the degree to which the "average savings" reported by the state program officials vary for individual consumers.

#### VIII.

# LEGAL STATUS OF STATE DISCOUNT PROGRAMS IN LIGHT OF PHRMA V. WALSH

So far, discount programs in which the state contracts with a PBM, negotiating voluntary agreements with manufacturers or pharmacies, have not been challenged, and there seem to be no legal barriers to their implementation. By contrast, the legal status of programs that utilize Medicaid discounts, rebates and prior authorization requirements is uncertain. As discussed above, each of

# TABLE 6:Pharmacy and Manufacturer Participation in Case Study StatePharmacy Discount Programs, 2002 (Sorted by pharmacy<br/>participation rate)

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these programs has been challenged in litigation by the Pharmaceutical Research and Manufacturers of America (PhRMA), albeit with mixed results. As of June 2003, the Supreme Court had lifted a preliminary injunction against implementation of the Maine Rx program,<sup>76</sup> while Vermont's PDP and Maine's HMPP waiver programs remain enjoined.<sup>77</sup> Although all of this litigation raises many legal issues, the Supreme Court's decision regarding Maine Rx is the most important and has ramifications for all types of discount programs (except the state PBMs). We therefore limit our discussion to this important case.

In *PhRMA v. Walsh*, PhRMA challenged Maine Rx on two grounds. First, PhRMA claimed that Maine is not permitted to use Medicaid's prior authorization requirements as the inducement for manufacturers to enter into rebate agreements with the state. According to PhRMA, this use of the Medicaid mechanism will harm Medicaid beneficiaries, and will, in any event, not benefit them.<sup>78</sup> Second, PhRMA claimed that Maine's rebate program effectively regulates out-of-state transactions between manufacturers and wholesalers. This extra-territorial regulation, PhRMA argued, violates the Commerce Clause of the United State Constitution.<sup>79</sup>

The district court before which the case was brought granted PhRMA's request for a preliminary injunction, but the United States Court of Appeals for the First Circuit reversed, finding that PhRMA had not carried its burden of showing probable success on the merits.<sup>80</sup> With regard to Maine's use of Medicaid's prior authorization requirement, the court of appeals found that there was no conflict with the Medicaid statute because the Maine legislation incorporates Medicaid's requirements for use of prior authorization.<sup>81</sup> Moreover, the court found sufficient evidence that Maine Rx could save Medicaid expenditures by making prescription medications more accessible to persons not currently in the Medicaid program. The court was swayed by studies showing that lack of access to prescription drugs can cause a deterioration of health and a

<sup>76.</sup> Pharm. Research & Mfrs. of Amer. v. Walsh, 123 S. Ct. 1855 (2003).

<sup>77.</sup> Pharm. Research & Mfrs. of Amer. v. Thompson, 251 F.3d 219, 221 (D.C. Cir. 2001) (holding the Secretary has no authority under Medicaid statutes to grant a waiver without a state contribution); Pharm. Research & Mfrs. of Amer. v. Thompson, 313 F.3d 600, 602 (D.C. Cir. 2002) (same).

<sup>78.</sup> Walsh, 123 S. Ct. at 1860.

<sup>79.</sup> Id.

<sup>80.</sup> Pharm. Research & Mfrs. of Amer. v. Concannon, 249 F.3d 66 (1st Cir. 2001), aff d sub nom. Walsh, 123 S. Ct. at 1855.

<sup>81.</sup> Id. at 75-76.

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decline into poverty.<sup>82</sup> The court of appeals also rejected PhRMA's Commerce Clause argument. It disagreed that Maine was regulating the content of out-of-state transactions. Instead, the court ruled that "the Maine Act simply regulates activity that occurs in state: (1) the purchase of the prescription drugs that triggers the rebate; (2) the negotiation of a rebate amount; and (3) the State's action subjecting a manufacturer's drug to prior authorization . . . .<sup>"83</sup> PhRMA appealed the court of appeals decision.

Before the Supreme Court, the United States Solicitor General filed a brief in support of reversal.<sup>84</sup> While finding the Commerce Clause argument to be specious,<sup>85</sup> the Solicitor General argued that Maine Rx stands in violation of the Medicaid statute because the program's beneficiaries are not limited to low-income persons, and Maine did not seek a waiver or file a plan amendment with the Secretary. According to the United States, if Maine Rx were so limited, it would be legal.

While a unanimous Supreme Court agreed that PhRMA's Commerce Clause arguments were specious,<sup>86</sup> the Court was divided over the question whether the Medicaid statute pre-empted Maine Rx. Spread across four opinions, six Justices voted to affirm the First Circuit's lifting of the district court's grant of a preliminary injunction. Three Justices voted to reverse and reinstate the pre-liminary injunction.

In a plurality opinion joined by Justices Souter and Ginsburg, Justice Stevens concluded that in light of the limited factual record and the lack of a dispositive ruling by the Secretary, the District Court abused its discretion in granting PhRMA a preliminary injunction. Justice Stevens found that Maine Rx was not pre-empted "by the mere existence of the federal statute"<sup>87</sup> because "the program on its face clearly serves some Medicaid-related goals"<sup>88</sup> and because PhRMA had not proven that Maine Rx "severely curtail[s] Medicaid recipients' access to prescription drugs."<sup>89</sup> In a separate opinion, Justice Breyer agreed with much of this analysis, but appeared willing to deny the preliminary injunction—even in the ab-

<sup>82.</sup> Id. at 76–77.

<sup>83.</sup> Id. at 82.

<sup>84.</sup> Brief for the United States as Amicus Curiae Supporting Reversal, Pharm. Research & Mfrs. of Amer. v. Walsh, 123 S. Ct. 1855 (2003) (No. 01-188).

<sup>85.</sup> Id. at 15–18.

<sup>86.</sup> Walsh, 123 S. Ct. at 1855.

<sup>87.</sup> Id. at 1867.

<sup>88.</sup> Id.

<sup>89.</sup> Id. at 1868.

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sence of a showing of Medicaid-related benefit—because PhRMA had not shown sufficient harm to Medicaid beneficiaries.<sup>90</sup>

In two separate opinions, Justices Scalia and Thomas provided the fifth and sixth votes for lifting the preliminary injunction, but their reasoning differed greatly from the plurality's and Justice Breyer's. Justice Scalia took the view that the sole remedy for Maine's alleged violation of its obligations under Medicaid is the Secretary's termination of federal funding, subject to judicial review for abuse of discretion. Hence, PhRMA has no cause of action to claim that Maine Rx is pre-empted by the Medicaid statute.<sup>91</sup> By contrast, Justice Thomas appears to believe that PhRMA is entitled to bring such an action, but he wrote clearly, in disagreement with the plurality and Justice Breyer, that no further factual development is necessary in the case and that PhRMA cannot be entitled to relief.92 In his view, the Medicaid statute unambiguously gives Maine the authority to impose a prior authorization requirement so long as it meets the statutorily prescribed steps in establishing that requirement; Maine's purpose in creating that requirement is irrelevant; and courts have no authority to engage in the sort of balancing of Medicaid-related benefits and harms that the plurality, Justice Breyer, and the dissenters rely upon.<sup>93</sup> Rather, in his view, the Medicaid statute leaves such balancing solely to the discretion of the Secretary.<sup>94</sup> Although he left the point implicit, apparently Justice Thomas would rule that PhRMA's sole recourse would be to challenge the Secretary's action on the ground that it is arbitrary and capricious.

Finally, writing for herself and for Chief Justice Rehnquist and Justice Kennedy, Justice O'Connor agreed with the plurality and Justice Breyer that the pre-emption question could be answered only by judicial balancing of harms and benefits, but believed that the District Court had not abused its discretion in granting a preliminary injunction.<sup>95</sup> While the plurality and Justice Breyer clearly ruled that PhRMA could prevail only by negating the existence of a Medicaid-related benefit, the three dissenters found that Maine bore the burden of affirmatively showing the existence of that benefit.<sup>96</sup> In the dissenters' view, the plurality merely "speculates about

<sup>90.</sup> *Id.* at 1872.

<sup>91.</sup> *Id.* at 1874.

<sup>92.</sup> Id. at 1874–78.

<sup>93.</sup> Id. at 1874–75.

<sup>94.</sup> *Id.* at 1874–78.

<sup>95.</sup> Id. at 1878–82.

<sup>96.</sup> Id.

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three 'Medicaid-related interests that will be served if the [Maine Rx] program is successful.'"<sup>97</sup> The dissenters' view of the record was that Maine had not proven any benefit, and therefore the grant of a preliminary injunction was proper.

It is obvious that these five opinions present great difficulties of interpretation. In part this difficulty arises from the procedural posture of the case. Usually the Supreme Court will review a case only after facts have been fully developed, but in this instance the Court granted certiorari although very little evidence existed with regard to the program's benefits to Medicaid beneficiaries and non-Medicaid populations, the impact of prior authorization on beneficiaries' access to prescriptions, and the actual manner in which Maine Rx would be implemented. Moreover, because Medicaid is a program jointly administered by the states and the federal government, courts will usually interpret the Medicaid statute with the benefit of the Secretary's interpretation of relevant facts and law; the merits of a case are inextricably intertwined with questions of proper process for obtaining the Secretary's views. However, in this case, while the Secretary's views were expressed to some degree in briefs and letters, no formal process to obtain the Secretary's interpretation of fact or law had been invoked.

As a result, the different opinions' expressions of the propriety of a preliminary injunction rest on differing views of the relevance of the inadequate factual development, the proper relationship between the state and federal governments, the appropriate process for sorting out that relationship, and the range of discretion which the states and the Secretary have in administering Medicaid both in terms of the program alone or within the context of a state's more general health care program and policies. In most of the opinions these issues are just swirling around, and in very few of them are these different elements clearly identified, separated, and adequately addressed.

Hence, even after *Walsh*, the future of Maine Rx remains unclear. While the decision clearly holds that the grant of a preliminary injunction was inappropriate, four Justices are of the view that further factual development is needed to obtain a final disposition of the case; two believe that PhRMA cannot prevail under any circumstances; and three maintain that PhRMA already has shown a probability of prevailing. Necessarily the decision's implications for other types of state discount programs are even less clear.

<sup>97.</sup> Id. at 1880.

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Nonetheless, we offer some predictions and an analysis of the relevant lines of inquiry on the question of what type of state program is permissible. Given how the Justices decided *Walsh*, we organize our discussion around two questions: to what extent must states proceed with only the Secretary's acquiescence and what is the scope of the Secretary's authority?

#### A. The State and the Secretary Agree on a Plan Amendment or Waiver

In our first situation, suppose that a state (like Maine) files a plan amendment or a waiver request, and the state and the Secretary reach an agreement on the proper form of the state program.<sup>98</sup> We are relatively certain that PhRMA or another plaintiff with standing could successfully challenge this program only in limited circumstances.<sup>99</sup> So long as the Secretary finds that there is a Medicaid-related benefit and that there is not substantial (or severe) harm to Medicaid beneficiaries,<sup>100</sup> and so long as these findings are not arbitrary, the plurality and Justice Breyer would find that there is no pre-emption. Justice Thomas would agree with this result, given the range of discretion he accords to the Secretary, and Justice Scalia would reach this conclusion because his view is that the sole remedy to a state's violation of its Medicaid obligation lies with the Secretary. In this situation, the Secretary and the state's extension of Medicaid mechanisms such as discounts, rebates, and prior authorization requirements would be valid.

#### B. The Secretary Imposes a Condition Opposed by the State

In this situation, suppose again that a state files a plan amendment or a waiver request, but the Secretary approves the plan subject to a condition, such as a requirement that beneficiaries must be limited to a certain percentage of FPL. This issue, as discussed above, separated Maine and the United States in *Walsh* because the

<sup>98.</sup> It is possible that a waiver request would raise different issues than a plan amendment because of the different statutory basis for a waiver. Space limitations preclude discussion of this question.

<sup>99.</sup> It is not clear that PhRMA would have such standing, but this issue remains outside the scope of this paper.

<sup>100.</sup> The opinions do not clearly state the nature of harm necessary for a state's program to be invalid. Would it be sufficient that 95% of Medicaid beneficiaries are not harmed even though 5% of beneficiaries suffer severe hardship? What if a lesser degree of hardship is spread more widely? What if it is shown that overall funding is a zero-sum game and that dollars, if any, devoted to non-Medicaid beneficiaries are therefore taken from Medicaid beneficiaries? None of these questions can be answered now because the Court gave no indication of what it meant by harm.

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United States took the position in its brief that Maine's program violated the Medicaid statute in the absence of some limitation to low-income persons. Suppose the Secretary's restriction is then the subject of litigation.<sup>101</sup> The relevant question is what does *Walsh* tell us about the range of the Secretary's discretion?

The members of the plurality were quite careful in pointing out that this issue was not before the Court.<sup>102</sup> However, its opinion might be interpreted to mean that the Secretary must approve a state program if the program on its face or as factually proven by the state provides Medicaid-related benefit, while not causing sufficient harm to Medicaid beneficiaries. This interpretation flows from the structure of their analysis, in which they find implicit in the Medicaid statute a principle that a state program is consistent with Medicaid so long as the program creates a Medicaid-related benefit without causing severe harm to Medicaid beneficiaries. Indeed, as Justice Thomas points out in attacking both the plurality and dissent,<sup>103</sup> the three dissenting Justices find the same principle to be immanent in the federal statute, while disagreeing with the plurality concerning what balance the record shows.

Perhaps inconsistently, as Justice Thomas points out,<sup>104</sup> the plurality also stresses that the Secretary's interpretation of Medicaid's requirements is needed.<sup>105</sup> If the federal statute itself provides a principle that courts can apply in deciding whether a state program is consistent with federal law, then upon what is the Secretary's discretion to operate? Justice Thomas is clear that the Secretary has the authority to determine whether the relevant burdens and benefits render a state program invalid,<sup>106</sup> and it is therefore clear that he would uphold the Secretary's action in this situation unless it is arbitrary, as would Justice Scalia.<sup>107</sup> However, it is possi-

<sup>101.</sup> The issue of how procedurally this question is properly placed before a court turns on the nature of the agency action required. Because this is very complicated, it remains beyond the scope of this discussion.

<sup>102.</sup> Walsh, 123 S. Ct. at 1866–67, 1870.

<sup>103.</sup> Id. at 1874.

<sup>104.</sup> Id. at 1876.

<sup>105.</sup> Id. at 1866–67, 1870.

<sup>106.</sup> Id. at 1876–77.

<sup>107.</sup> Justice Thomas's opinion also appears to be internally inconsistent. In part I.A., he finds that the Medicaid statute does not unambiguously preclude Maine Rx because there are few limitations placed on a state's use of a prior authorization requirement, and no explicit mandate that the prior authorization requirement serve a particular purpose. *Walsh*, 123 S. Ct. at 1875–76. This analysis suggests that the Secretary is without discretion because all that is required is a ministerial act to ensure that the state's prior authorization requirement does or does not satisfy the federal statute. However, part I.B. of his opinion stresses the

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ble that the plurality, Justice Breyer, and the dissenters would accord the Secretary deference with regard to whether benefits or harms exist, but not with regard to the legal conclusion flowing therefrom.<sup>108</sup> All three opinions might be read as standing for the proposition that a state program is legal if the Secretary finds that there exists any Medicaid-related benefit and no severe harm to Medicaid beneficiaries.<sup>109</sup> In that case, the Secretary would not have authority to impose further conditions.

In sum, subject to all the caveats discussed above, we conclude that it is possible that there are seven votes in the current Court for the proposition that the Secretary must approve the state's program in the situation we pose here if the Secretary finds that there exists Medicaid-related benefit without countervailing severe harm to Medicaid beneficiaries. Given the high degree of uncertainty, this issue is ripe for much litigation and divergent results in lower courts.

# C. The Secretary Refuses to Approve an Amendment or Grant a Waiver to Benefit Non-Medicaid Populations

Suppose that a state submits a plan amendment or a waiver request, and the Secretary responds that states have no authority to use Medicaid mechanisms like rebates, prior authorization requirements, or discounts to benefit non-Medicaid populations. The Bush Administration is currently not taking this position, but in different political or budgetary circumstances, such a stance is possible.<sup>110</sup> Does the Secretary have such authority?

108. The dissenters do not explicitly state that they find the Secretary's interpretation to be relevant, but this silence is explicable given that they find that Maine was required but had failed to satisfy the requirement that it prove Medicare benefit. However, Justice Thomas appropriately considers the structure of the plurality's and the dissenters' opinions to be the same in that both distill a general principle from the Medicaid statute without considering the implications of that principle for the Secretary's role. *Id.* at 1876–78.

109. In places Justice Breyer seems to treat the Secretary's view as more determinative than does the plurality. *Id.* at 1872–73. Because our analysis is already complicated enough, we will ignore this further complication.

110. Courts usually defer to an agency's interpretation of the statute it administers, but sometimes hold that such deference is unwarranted when an agency changes that interpretation. *See, e.g.*, CHARLES H. KOCH, JR., ADMINISTRATIVE LAW AND PRACTICE § 11.26 (2d ed. Supp. 2003). We do not address that issue here, nor

Secretary's authority to approve or disapprove the state's requirement depending on the Secretary's view of the relevant impact on the state's overall program. *Id.* at 1876–77. While Justice Thomas is clear that his discussion is limited to the question of whether PhRMA has a cause of action, *Id.* at 1877, it is not clear how these two parts can be reconciled.

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This situation would seem analogous to the one previously discussed. Subject to all the caveats indicated above, the opinions by the plurality, Justice Breyer, and the three dissenters could be interpreted to mean that the Secretary must approve the state's program if there exists a Medicaid-related benefit in the absence of severe harm to Medicaid beneficiaries. The plurality opinion explicitly seems to state that such an overbreadth—that there is benefit to non-Medicaid state programs and populations in addition to the Medicaid program—is irrelevant:

[Maine Rx] will provide medical benefits to persons who can be described as "medically needy" even if they do not qualify for [Aid to Families with Dependent Children] or [Supplemental Security Income] benefits. There is some factual dispute concerning the extent to which the program will also benefit non-needy persons, but even if the program is more inclusive than the Secretary thinks it should be, the potential benefits for non-needy persons would not nullify the benefits that would be provided to the neediest segment of the uninsured population.<sup>111</sup>

In sum, subject to the caveats stated above, while Justices Scalia and Thomas would probably find that the Secretary has the discretion to restrict the use of Medicaid mechanisms to benefit Medicaid populations, it is possible that seven Justices on the current composition of the Court would find that the Secretary has no authority to use such non-Medicaid benefit as the basis for rejecting a state's plan amendment or waiver request.

# D. A State Seeks to Implement a Program Using Medicaid Mechanisms Without Seeking a Plan Amendment or Requesting a Waiver

In this situation, suppose that a state seeks to implement a pharmacy discount program that uses rebates, prior authorization requirements, or discounts without seeking federal approval. This situation is that presented by Maine Rx, which was created by the state legislature without contemplation that its implementation was contingent on federal approval. May a state do so?

the somewhat related question of how a change in interpretation would affect previously granted waivers like those for Pharmacy Plus programs.

<sup>111.</sup> Walsh, 123 S. Ct. at 1867. This passage has its own ambiguity. If the plurality used the words "medically needy" as Medicaid terms of art, then arguably the "extra" benefit it discussed would inure not to non-Medicaid populations but to such other Medicaid populations as states, at their option, may include in their programs.

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One might very broadly interpret the plurality opinion and those by Justice Breyer and the dissenters as answering affirmatively, but this conclusion is certainly not compelled by the prior discussion. Remember that a result on the merits turns both on questions relating to the states' and Secretary's discretion and on questions involving the proper process by which the range and proper exercise of that discretion can be exercised. Therefore, it would be possible for the Court to conclude that in given factual circumstances the Secretary, after full consideration, has no authority to disapprove a state program, while also concluding, in a consistent fashion, that states must still submit such a program for the Secretary's view, including relevant factual determinations. Indeed, the plurality opinion contemplates the possibility that the Secretary would rightly contend that his or her review is necessary. After noting that the Supreme Court's determination with regard to the grant of a preliminary injunction will not determine the final validity of Maine Rx because further factual development is necessary, the plurality stated: "Moreover, there is also a possibility that the Secretary may view the Maine Rx Program as an amendment to its Medicaid Plan that requires his approval before it becomes effective."112 Given the importance that Justices Thomas and Scalia accord to Medicaid procedures, we think that they would probably rule that the Secretary's approval must be sought.

In sum, we think it a strong possibility that the Court would accord great deference to an interpretation by the Secretary that a state might use Medicaid mechanisms only if the state first seeks federal approval.

We may summarize these points together as follows. Most likely, a state and the Secretary, acting together, have the discretion to use Medicaid mechanisms like discounts, rebates and prior authorization requirements to create discount programs for non-Medicaid populations. To challenge such a program successfully, a private litigant would have to show that in approving the program, the Secretary's finding of Medicaid-related benefit or insufficient harm to Medicaid beneficiaries was arbitrary and capricious (VIII.A above). Possibly the Secretary must approve the state's program if the Secretary finds that the program creates Medicaid-related benefit and/or insufficient harm to Medicaid beneficiaries (VIII.B above), regardless of the fact that the program benefits non-Medicaid populations (VIII.C above). Finally, possibly a state discount program using Medicaid mechanisms need not be submitted for

<sup>112.</sup> Id. at 1866.

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the Secretary's approval so long as it achieves Medicaid-related benefit without causing severe hardship to Medicaid beneficiaries, but more than likely the state must at least invoke formal processes to obtain the Secretary's approval (VIII.D above).

## IX.

# CONCLUSION

All state discount programs are still in their initial phases of implementation. Of the three types of discounts states have pursued—extending Medicaid discounts and/or rebates to non-Medicaid eligible persons, the state acting as a pharmacy benefit manager using Medicaid prior authorization as leverage for negotiating rebates, and contracting with private sector PBMs—those that seek to include manufacturer rebates can yield the most savings.

Extending Medicaid rebates to non-Medicaid eligible persons or using Medicaid prior authorization are strategies that are more difficult to implement, are likely to require federal waivers, and will definitely face continued legal challenge by the manufacturers. As of June 2003, none of these programs were operating. Private PBM models and those that seek voluntary rebates from manufacturers have so far been unsuccessful in persuading manufacturers to participate. In traditional insurance-type programs, PBMs are able to gain manufacturer rebates by promising increases in market share or utilization of a manufacturer's drug through the use of formularies, tiered co-pays, or prior authorization. However, none of these methods can be used to their full effect in discount programs, because discount programs are not attached to an insurance benefit. Since the consumer is still responsible for actually purchasing the drugs, PBMs cannot guarantee that they will be able to transfer purchases to less expensive medications. The savings to the consumer of choosing a drug with a marginally higher discount from a rebate would neither be easy to explain nor would it necessarily convince the consumer to switch from the drug that was prescribed by his or her physician, unless the discount was significant. Without the incentive of increased utilization of their products, it is unclear what benefit manufacturers would realize by providing rebates for discount programs. This casts some uncertainty on the ability of a national Medicare endorsed discount program administered through PBMs to obtain and pass along rebates to consumers, thus limiting the size of the discounts potentially available through this avenue.

Whether or not discounts incorporate manufacturer rebates, state pharmacy discount programs are not a substitute for direct

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subsidies, particularly for low-income seniors. While state pharmacy discount programs provide some relief to cash-paying seniors, the estimated price reductions are marginal compared to the benefit offered in most state pharmacy assistance programs. Even with estimated consumer savings of 12–25% off of retail prices, many of the lowest-income seniors or those with catastrophic drug costs may be unable to afford the drugs they need. Still, there are some benefits for consumers from such programs, particularly if the program model includes manufacturer rebates in the discount. In particular, moderate and higher income seniors could benefit from the discounts, but unless states invest funds for outreach or enforcement of the discounts, there is little guarantee that consumers will be aware of the discounts or that pharmacists will offer the discounts at the counter.

The marginal benefit of these discount programs and/or the lack of awareness of the benefit are reflected in low participation rates. For programs that are able to track utilization by discount card enrollees, the proportion of enrollees that actually use the discount card was relatively low, ranging from 5% to 35%. Participation was particularly low in the PBM programs, where an average of 8% of enrollees actually used the discount.

Pharmacy participation also can limit consumers' access, particularly in state programs that rely on PBMs. With the exception of Iowa, the state-sponsored PBM discount programs have confronted significant challenges in getting pharmacies to participate, with participation rates averaging 68%. In contrast, states that mandate Medicaid discounts to Medicare beneficiaries as a condition of participation in the state Medicaid program have a much greater proportion of pharmacies participating, because the risk of not participating is much higher. While some state officials were initially concerned that a Medicare discount requirement might drive pharmacies out of the state Medicaid program, this has not proven to be the case. Low participation rates in PBM-administered state discount programs are potentially an issue for Medicare-endorsed privately administered discount cards as well. Since private entities negotiate lower prices with pharmacists by promising a competitive advantage for that book of business, privately administered cards, by definition, are unlikely to have the universal pharmacy involvement that many Medicare beneficiaries are likely to expect.

As for those discount programs that mandate manufacturer rebates, their future viability depends on their ability to withstand legal challenges brought by pharmaceutical manufacturers. Indeed, several states have indicated that they were waiting to see the out-

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come of the challenge to Maine Rx before proceeding to develop similar programs. The Supreme Court Maine Rx decision, while somewhat ambiguous, has left the door open for states to leverage their Medicaid market share to negotiate rebates for non-Medicaid eligible persons. The opinions by the majority of the justices suggest that, so long as the Secretary finds that there is a Medicaidrelated benefit and that there is not substantial (or severe) harm to Medicaid beneficiaries, the states' extension of Medicaid mechanisms like discounts, rebates and prior authorization requirements is valid. However, it is still unclear whether the HMPP and the Vermont programs can go forward. These programs were enjoined based on the interpretation of Medicaid law that said that the Secretary had no authority to grant the waiver without a state contribution. The Supreme Court ruling in *Walsh* does not address the state contribution issue.

Since the Supreme Court's decision in *Walsh*, the state of Maine passed a new program—known as Maine Rx Plus—which was implemented in January 2004 and is a hybrid of the Healthy Maine Prescription program and Maine Rx. To forestall legal challenge, Maine Rx Plus limits eligibility to Maine residents who earn up to 350% of the federal poverty level or to those residents who have higher incomes but spend more than 5% of their income on prescription drugs.<sup>113</sup> However, like Maine Rx, Maine Rx Plus uses Medicaid's prior authorization requirement as a lever to encourage manufacturers to participate, even though Maine did not seek the Secretary's approval. It is unclear whether this new discount program will withstand legal challenge or extend meaningful price discounts to consumers.

While the Supreme Court ruling in *Walsh* does not address the state contribution issue, Medicaid waivers in Florida and Maryland that have been approved by CMS but were not operational at the time of our case studies include a discount for persons earning as much as 175–200% of the federal poverty level. These discount programs have some state contribution, much of which is likely to be retrospectively recouped through mandated Medicaid manufacturer rebates and federal matching funds. At this writing, their legality has not been tested, and it is possible that the states' contributions, though still relatively nominal, may enable them to withstand legal challenge.

<sup>113.</sup> Meg Haskell, *Baldacci Signs Revised Rx Plus Bill*, BANGOR DAILY NEWS, June 25, 2003, at A1.

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The passage of the Medicare drug benefit<sup>114</sup> and the initiation of the interim Medicare-endorsed drug discount cards effective June 2004 changes the political dynamic for state discount programs and makes prediction of their future difficult. Beginning in June 2004, a series of Medicare-endorsed discounts cards will provide prescription drug discounts estimated to be between 10% and 25% to those Medicare beneficiaries who choose to enroll and pay an enrollment fee. For people with annual incomes at or below 135% of the federal poverty standard, Medicare will pay their enrollment fee and also provide a \$600 credit on their Medicare-endorsed discount card programs. Endorsed discount cards must be administered by private, non-governmental entities. Thus, enrollees in state-sponsored discount card programs will not be eligible for the \$600 credit. As a result, some states may opt to end their programs when the new Medicare benefit becomes available. Others may wait to see how deep the discounts really are and whether consumers participate. In light of the states' experience with low participation rates when only one card was available, participation in the Medicare-endorsed discount card programs could be even lower due to the complexities of choosing among the various drug cards that will be available. As of March 1, 2004, all state discount programs in operation remain in effect.<sup>115</sup>

Nonetheless, if drug prices continue to rise, states will continue to face pressure to develop new strategies for lowering the purchase price for other uninsured consumers, particularly those with low incomes. Some of these programs may continue to target the elderly because the interim Medicare discounts and the full Medicare benefit in 2006 are unlikely to be deep and are not broad. First, while the new Medicare Part D drug benefit will offer significant subsidies in 2006 for the lowest-income seniors that earn below 135% FPL and moderate subsidies for those earning between 135%and 150% FPL, seniors above these income limits will still incur significant costs, particularly those who fall within the Medicare bill's "doughnut hole". Second, while the interim discount program does extend a \$600 subsidy to persons earning up to 135% FPL, this is a much narrower target population than the state programs that have attempted to extend the Medicaid discount to other low-income persons. On the other hand, because the new Medicare benefit does provide some relief to the elderly, states may be able to

<sup>114.</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

<sup>115.</sup> NCSL Summary at http://www.ncsl.org/programs/health/drugaid.htm(last visited Apr. 6, 2004).

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focus more on providing discounts to their non-elderly citizens, and there may be more programs like Maine Rx and Rx Plus that include the non-elderly as beneficiaries.

While state discount programs have thus far only yielded marginal price discounts and may not be broadly available at all pharmacies, they nonetheless still offer some price discounts that were not available in the past. Despite the limited success of state-sponsored discount cards, the old adage "it's better than nothing" suggests that more state-sponsored discount card programs will be developed in the foreseeable future. States are also likely to continue to explore other types of programs, like purchasing cooperatives and re-importation programs, because, faced with continued budget deficits, the amount of state funds available to lower consumers' costs will remain limited.