#2002-08
June 2002

Three States' Approaches to Pharmaceutical Assistance: A Guide for the Perplexed

by

Stephen Crystal, Kimberley Fox, Mina Silberberg, Tom Trail, Susan Reinhard, and Joel Cantor

Center for State Health Policy Institute for Health, Health Care Policy, and Aging Research
Rutgers University

The AARP Public Policy Institute, formed in 1985, is part of the Policy and Strategy Group at AARP. One of the missions of the Institute is to foster research and analysis on public policy issues of importance to mid-life and older Americans. This publication represents part of that effort.

The views expressed herein are for information, debate, and discussion, and do not necessarily represent formal policies of the AARP.

AARP, 601 E Street, N.W., Washington, DC 20049

ACKNOWLEDGMENTS

The authors of this paper would like to give special thanks to David Gross and John Luehrs at AARP for their invaluable input in thinking through the issues in this report. Dr. Gross, project officer at AARP Public Policy Institute for this study, provided useful suggestions and comments on successive versions of the manuscript and shared his broad perspective on these issues, as did Mr. Luehrs. The paper also benefited from the contributions of other internal and external AARP reviewers. At the Rutgers Center for State Health Policy, Joann Donatiello, Information Specialist, provided invaluable research assistance.

This study drew on work conducted as part of a related study funded by the Commonwealth Fund, whose support we acknowledge. We thank AARP for its assistance in facilitating a study design that permitted the AARP and Commonwealth projects to go forward in a complementary fashion.

This study would not have been possible without the cooperation of the many state officials and other key stakeholders. Key informants interviewed for the study are listed in Appendix A. We are grateful to all of these individuals for their help.

FOREWORD

In the absence of a federal Medicare prescription drug benefit, many states—over 30 at this time—have instituted programs that provide some form of assistance to older and disabled residents who lack drug coverage. These programs differ substantially from state to state. Some offer direct benefits, while others seek only to reduce prices. Some are targeted to lower-income beneficiaries, while others reach up to more moderate income levels. Some provide unlimited benefits, while others impose annual benefit caps on enrollees or restrict coverage to certain classes of drugs. What each has in common, however, is an attempt to address the growing disparity between prescription drug needs among Medicare beneficiaries and their ability to pay for those drugs.

The growing importance of state prescription drug assistance programs has led to substantial interest in how different types of programs have been designed, the experience of different states in implementing their programs, how programs adapt to address changing needs and the lessons that particular states have drawn from their own experiences. This study, by Professor Stephen Crystal and his colleagues from Rutgers University's Center for State Health Policy, provides insight into these issues through a detailed examination of pharmacy benefit programs in three states. Their case studies of the development and implementation of New Jersey's direct benefit program, California's price discount program, and Maine's efforts to provide both direct benefits and drug price discounts offer valuable insights into the experiences of each state's vastly different approach to providing pharmaceutical assistance to Medicare beneficiaries. Their analysis provides valuable information to policymakers, consumer and patient advocates, policy researchers, and officials in states that are considering developing new programs or modifying existing programs.

David J. Gross, Ph.D.
Senior Policy Advisor
Public Policy Institute

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

EXECUTIVE SUMMARY

The affordability of prescription drugs for older and disabled persons recently has emerged as an urgent and high-profile state health policy issue. The first state programs to make prescription drugs more affordable for state residents date back to the mid-1970s, but many states are currently implementing or considering new programs and program expansions. Given the magnitude of the human, financial, operational, and political issues at stake, it is important that policymakers and policy analysts in states that are considering changes have information on the experiences of other state pharmacy assistance programs.

In late 2000, we conducted case studies of pharmacy assistance initiatives in three states—New Jersey, California, and Maine. We selected these states for study because their pharmacy assistance initiatives represent two of the broad approaches most commonly used by states to make prescription drugs more affordable for their residents: (1) pharmacy assistance subsidy programs that provide state-funded prescription drug insurance coverage (direct benefit programs); and (2) pharmacy assistance discount programs that do not insure individuals against the cost of drugs but give members a discount on their prescription drug purchases (discount programs).[1] This report presents our findings from the case studies regarding the history and features of the state pharmacy assistance programs in the three states, along with lessons that may be of interest to other states contemplating or operating similar initiatives.

Methodology

Our case studies of state pharmacy assistance initiatives were based on reviews of relevant documents and key informant interviews. In each of the three states, we interviewed people in a wide variety of positions, including representatives of the state legislature, state executive branch agencies involved with prescription drug initiatives, pharmacy groups, prescription drug manufacturers, consumer groups, and a wide variety of other stakeholders. As noted above, the report is based on case studies conducted in 2000 and unless stated otherwise, information on programs has not been updated beyond March of 2001. Appendix A provides a list of key informants in each state.

Findings

New Jersey: A Mature Direct Benefit Program

New Jersey's operates one of the oldest pharmacy assistance subsidy programs in the country: the Pharmacy Assistance for the Aged and Disabled (PAAD) program for lower income Medicare beneficiaries. In 2000, about 187,000 elderly and disabled residents were enrolled in the program. Since the PAAD program's inception in 1975, several changes have been made to its income eligibility requirements. As of 2000, the program was open to elderly and disabled New Jersey residents whose incomes do not exceed $19,238 (single person) or $23,589 (couple). PAAD enrollees pay a $5 copayment per prescription.

[1] Approaches not represented here include the tax credit approach taken by Missouri and Michigan (but later replaced by direct subsidy programs) and the private insurance subsidy approach taken by Nevada.

In 2001, using funds from the state's 1998 settlement with tobacco manufacturers, the New Jersey Legislature enacted a law creating a new pharmacy assistance subsidy program, called Senior Gold. This program is open to elderly and disabled individuals with incomes up to $10,000 above the PAAD eligibility limits, and the income limits are adjusted upward each year to account for increases in the cost of living. For each prescription drug, Senior Gold enrollees pay a $15 copayment plus 50 percent of the remaining price paid by Medicaid. Once Senior Gold participants' annual out-of-pocket expenses reach a certain level ($2,000 for singles, $3,000 for couples), they pay only $15 per prescription.

New Jersey's PAAD program enjoys wide support among older and disabled residents in the state, as well as among public officials. Many sources we interviewed in the state indicated that a key to the PAAD program's success in providing drug coverage for so many low-income and disabled individuals has been the state's ability to identify funding sources other than state general funds. In 2000, casino gambling revenues were the source of funds for two-thirds of PAAD's $331 million expenditures. Senior Gold, which the sponsors projected would cost the state no more than $86 million in the first year, is funded in part with the state's tobacco settlement funds. Rebates from drug manufacturers are another source of revenue for the PAAD and Senior Gold programs.

The PAAD program's success is also attributable to strong management. Nearly every person we interviewed reported having respect for and trust in PAAD's program director, who has been running the program for more than 20 years. Management has repeatedly demonstrated a capacity to initiate innovative solutions to a number of programmatic issues, such as how to deal with the PAAD program's rapidly rising costs.

Nonetheless, constraining the rapidly escalating costs of New Jersey's pharmacy assistance programs is likely to remain a continuing challenge for the foreseeable future.

California: A Broad-Based Discount Approach

In February 2000, California began implementing a pharmacy assistance discount program that has drawn considerable interest from other states: the Prescription Drug Discount Program for Medicare beneficiaries. The statute establishing the program was enacted in October 1999.

The program's design is simple. Pharmacies participating in California's Medicaid program (Medi-Cal)—about 95 percent of the pharmacies in the state—are required, as a condition of Medi-Cal participation to charge California Medicare beneficiaries no more than the Medi-Cal payment rate for a particular prescription plus a 15-cent processing fee for each prescription. To receive the Medi-Cal discount, a Medicare beneficiary need only walk into a Medi-Cal participating pharmacy and present his or her Medicare card to the pharmacy. The pharmacy gets a Medi-Cal price quote for the drug, using the same computer system that it uses to handle prescriptions reimbursed by Medi-Cal, and the Medicare beneficiary pays that amount plus the processing fee directly to the pharmacy. (The 15-cent processing fee is intended to cover the pharmacy's cost of getting a Medi-Cal price quote on the drug from the state.)

The intended population for the discount program is cash-paying California Medicare beneficiaries—that is, Medicare beneficiaries who do not have prescription drug coverage under

Medicare+ Choice plans, Medigap, or other health plans. In addition, some California Medicare beneficiaries *with* prescription drug coverage may also benefit from the discount program (e.g., if they have reached their annual or monthly drug benefit cap, if their insurer does not cover the drug they need, or if they are paying off a deductible before coverage begins).

In 2000, costs to the state for the discount program were only about $544,000. This figure includes one-time costs (i.e., for the Medi-Cal claims processing software to allow pharmacies to access a Medi-Cal price quote without actually submitting a claim, and for the development of an interactive Web site that allows consumers to identify the Medi-Cal price for the most commonly requested drugs) and ongoing costs (i.e., salaries for two full-time equivalent California Department of Health personnel for administrative support and 2 cents paid to a private contractor for every price quote requested for Medicare beneficiaries).

The simplicity of California's Prescription Drug Discount Program is a source both of strengths and limitations. By designing the discount program to include all Medicare beneficiaries, the California state legislature averted the need for administratively costly eligibility determination, application, and enrollment procedures. The program requires very little funding from the state. Furthermore, the program's simple design makes the program easy for consumers to use. All Medicare beneficiaries have to do to get the discount is to present their Medicare card to a pharmacist. There is no application or enrollment process.

The tradeoff for these advantages is that there is little accountability or capacity to evaluate the program's effectiveness. The fact that there is no formal enrollment process means there is no mechanism for the state to count how many people are using the program. Few funds are available for education and outreach to ensure that consumers are informed of this benefit on an ongoing basis. There is little enforcement to ensure that pharmacies are actually offering and correctly charging the price to which beneficiaries are entitled.

The impact of the program on consumer savings is difficult to assess. Clearly, however, the program offers at least some cash-paying Medicare consumers a significant discount on their prescription drugs. The amount of savings to the consumer depends upon the pharmacy where prescriptions are purchased and the existing senior discounts available. In the past, pharmacies have been able to charge cash-paying customers whatever they like for any drug. A Medicare beneficiary will save money under the discount program only if his or her particular pharmacy had been charging a higher price for a prescription drug than the Medi-Cal price.

Finally, it is important to note that while California's pharmacy assistance discount program provides marginal benefits to cash-paying Medicare beneficiaries by reducing markups at the pharmacy level, it does not generate reductions at the level of drug manufacturers' prices. As legislative staff in California acknowledged, manufacturers' prices account for 70 percent of the cost of a prescription drug. Since retail pharmacy markups typically only account for 25 to 30 percent of the price of a drug, price reductions or discounts imposed at the pharmacy level can go only so far in lowering consumers' prescription drug costs.

Maine: Addressing Affordability on Multiple Fronts

Maine historically has been a front-runner in improving access to prescription drugs and has a multifaceted approach that includes several important initiatives intended to make prescription drugs more affordable for state residents. These include a pharmacy assistance subsidy program and two pharmacy discount programs.

Maine Low-Cost Drugs for the Elderly and Disabled (DEL) Program**.** Maine's pharmacy assistance subsidy program—the Low-Cost Drugs for the Elderly and Disabled (DEL) program—was established in 1975. From 1997 to 2000, an upturn in the economy and the availability of tobacco settlement funds allowed Maine to expand eligibility for the DEL program and broaden the program's benefits.

Maine's DEL program provides prescription drug coverage for low-income Maine residents age 62 and over and disabled residents age 19. The income eligibility limit for the DEL program in 2000 was 185 percent of the federal poverty level, or $1,279/month for singles and $1,705/month for couples. However, for individuals who spend more than 40 percent of their income on prescription drugs, the limit was 210 percent of the federal poverty level.

The DEL Basic Program pays up to 80 percent of the cost of drugs used for 14 medical conditions; the DEL enrollee pays $2 or 20 percent of the drug cost (whichever is greater). A Supplemental Plan, created in 1999, provides enrollees a $2 discount off the Medicaid rate for all medically necessary drugs not covered under the Basic Program that are supplied by participating manufacturers. Maine recently created a catastrophic benefit that operates within the Supplemental Program. Once a DEL enrollee has spent $1,000 on prescription drugs, the DEL program pays up to 80 percent of the cost of additional prescription drugs; the enrollee pays $2 or 20 percent of the drug cost (whichever is greater).

As measured by current enrollment levels, recent expansions in eligibility and coverage, and the broad support for its growth, Maine's DEL program is popular and effective. Most of the people we interviewed in Maine reported that the DEL program is well publicized and that state residents are highly aware of it. On the other hand, while expanding the benefits under the DEL program, the state of Maine has struggled with the rising costs of the program.

Maine Rx Program. In the late 1990s, Maine state officials began looking for ways to achieve discounts for a broader population than those covered by the DEL program, but without committing significant public expenditures. In May 2000, the Maine Legislature passed a law establishing the Maine Rx program.

Maine Rx is open to all Maine residents regardless of age or income. The legislation incorporated a combination of mandated retail pharmacy discounts and negotiated rebates with drug manufacturers to make prescription drugs more affordable. Because the Maine Rx statute authorizes the state of Maine to use the state's profiteering statute and Medicaid purchasing power to induce manufacturers to participate in negotiations, the pharmaceutical industry strongly opposes the Maine Rx program and has challenged the program in court. The final outcome of this challenge remained to be determined at the time of writing.

Maine's leaders have shown considerable commitment to making prescription drugs more affordable, continuing to fight for Maine Rx despite legal challenges and to design other strategies for achieving price reductions. Whatever the outcome, Maine Rx remains a noteworthy story of grassroots support for affordable drugs, and an important innovation whose progress should continue to be watched.

Healthy Maine Prescription Program (HMPP). HMPP is a Medicaid waiver program that allows Maine residents with incomes up to 300 percent of the federal poverty level to purchase prescription drugs at the Medicaid discounted price (minus the manufacturer's rebate). In February 2002, by which time it had enrolled approximately 110,000 participants, HMPP was upheld in federal district court in a decision that rejected a challenge to the program by the Pharmaceutical Research and Manufacturers of America (PhRMA).

Maine's brief experience with Maine Rx and HMPP suggests that finding an effective strategy for cost control in pharmacy assistance programs is not easy. Although a powerful grassroots campaign in support of prescription drug affordability—involving seniors, labor, women's groups, and religious organizations—was successful in securing the enactment of strong pharmacy assistance legislation in Maine, it remains to be seen which of the state's new programs will be able to withstand legal challenges from the pharmaceutical industry.

Lessons Learned from the Three States

The experiences of New Jersey, California, and Maine offer several broad lessons that may be of particular interest to other states:

- ***Influence of state environments on policy responses***. Each state's approach to prescription drug affordability for older and disabled people is in some respects unique. Different political environments, programmatic history, and financial resources in each state lead to very different approaches to addressing the issue of prescription drug affordability.
- ***The importance of political leadership***. In each of the study states, a commitment to the issue of making prescription drugs more affordable, on the part of key individuals in leadership positions who were able to build strong coalitions, was a critical element in the success of legislative initiatives.
- ***Tapping grassroots consumer support.*** There was strong grassroots public support for making prescription drugs more affordable in every one of the study states. In each case, advocates for state pharmacy assistance programs recognized and used this as an impetus for legislative initiatives to address the problem.
- ***Deciding on the target population***. In developing pharmacy assistance programs, states must decide which population or populations the program should cover. For example, should the pharmacy assistance program cover only the lowest income older and disabled persons? Should it cover older and disabled persons with moderate incomes? Or should it cover a broader population, such as state residents who lack health insurance? Such decisions may require making tradeoffs between offering a small population a broad benefit and offering a broad population a more limited benefit. In some cases, a state may decide, as Maine has done, to adopt a multi-

pronged approach that addresses the prescription drug needs of various populations. Decisions about which populations should be covered by state pharmacy assistance programs are complicated by the lack of good state-level data, particularly on the proportion of specific populations with adequate prescription drug coverage.

- ***Determining the scope of the benefit***. The scope of the benefit to be offered by a pharmacy assistance program is a key program decision. One question is what types of health conditions and drugs are to be covered. Other important decisions include the structure of copayments, benefit ceilings, and deductibles. Finally, states need to consider whether—and if so, to what degree—the program will address the needs of persons with catastrophic prescription expenses. Whatever program design is chosen, program advocates are naturally motivated to stress the benefits of the program and minimize likely program costs. It is important for them to recognize, however, that the public will be disappointed if their expectations of a program exceed what the program can realistically offer.
- ***Importance of finding a stable and permanent funding source***. A critical challenge for direct benefit pharmacy assistance programs is to find a stable and permanent funding source. Direct benefit programs are expensive if they are made available to more than a narrowly defined group of beneficiaries or offer substantial economic benefits. Furthermore, per capita pharmacy expenditures have been increasing far faster than incomes—and indeed faster than other health care expenditures—so program costs can outstrip targeted revenues even if enrollment does not rise. New Jersey has successfully used casino revenue funds for its direct benefit program, but the program's costs are rising faster than casino revenue funds.
- ***Controlling program costs.*** Managing the costs of state pharmacy assistance programs is a challenging task, because growth in per-person pharmacy expenditures is likely to lead to escalating costs. Furthermore, pressures to expand income eligibility and the scope of benefits under a program are likely to expand over time. In the case of pharmacy assistance subsidy programs initially established only for very low-income people, for example, a common pattern has been the creation of a strong constituency for the program and a growing perception that there is a need to expand eligibility to individuals with modest to moderate incomes who find the cost of prescription drugs increasingly burdensome. There are several approaches to controlling program costs: changing eligibility criteria, modifying the scope of benefits, modifying the level of consumer cost-sharing, leveraging market share to negotiate or mandate pharmacy discounts and manufacturer rebates, and tightly administering a program.
- ***Approach to reducing prescription drug costs for a broader population***. An important issue in promoting prescription drug discount programs is what approach should be used to reduce costs for consumers. The California approach essentially exercises control over pharmacies' markups but not the much larger markup over marginal costs at the manufacturer level. Maine's efforts to secure better prices for its residents rely on a combination of pharmacy discounts and rebates from drug manufacturers, but these efforts have met with considerable resistance from drug manufacturers.

- ***Importance of strong program administration.*** Many sources we interviewed in the three case states stressed the importance of strong pharmacy assistance program administration. They highlighted, in particular, the importance of (1) a skilled program administrator; (2) advisory structures that solicit participation in program development from key stakeholders; (3) developing application and eligibility procedures to minimize stigma; (4) linking state pharmacy assistance program eligibility determination processes with those for other programs; (5) conducting program outreach; (6) effective data and claims processing systems; (7) appropriate use of drug utilization review procedures; (8) timely payment to pharmacies; and (9) developing good systems for recovering funds from Medicare and other third-party payers.

Concluding Observations

The experiences of New Jersey, California, and Maine—each of which has taken its own approach to the issue of prescription drug affordability, reflecting different political, economic, historical, and health policy environments—are well worth consideration by other states contemplating new or expanded approaches to prescription drug assistance. States will face great uncertainty in the next several years. Federal actions, such as new Medicare benefits or possible subsidies for state pharmaceutical assistance programs, may reshape the environment. Judicial decisions (such as those related to Maine's initiatives) may redefine the boundaries of viable state action. Market developments may affect the nature of the underlying problem of the lack of prescription drug coverage. Finally, changes in the economy or in states' revenue pictures may affect their ability to undertake new initiatives. As events unfold over the next several years, it will be important to continue to exchange information among states in this policy area.

1. INTRODUCTION AND OVERVIEW

The affordability of prescription drugs has emerged as a crucial and high-profile issue of state health policy. While state prescription drug programs date back to the mid-1970s, there is clearly a heightened level of attention and sense of urgency across the country, with new programs and program expansions being considered or implemented in many states. The primary focus of these initiatives has been on older adults and, in some cases, persons with disabilities whose income and/or assets disqualify them for prescription drug benefits through state Medicaid programs. The problem of prescription drug affordability is not limited to older persons and persons with disabilities, however, and several states (e.g., Maine) are seeking to address prescription drug affordability for broader populations.

Given the magnitude of the human, financial, operational, and political issues at stake, it is important for information on the experience of states that have pharmacy assistance programs to be available to those in other states who are considering program implementation or changes. In late 2000, we conducted case studies of pharmacy assistance initiatives in three states—New Jersey, California, and Maine. This report presents our findings regarding pharmacy assistance programs in these three states, along with lessons that may be of interest to other states contemplating or operating similar initiatives. The method of the study is described below. Also provided below is an overview of the organization of the report.

Method of the Study

The pharmacy assistance programs in New Jersey, California, and Maine were selected for study because they represent the dominant approaches taken by states to provide pharmacy assistance.[2]

- New Jersey sponsors one of the oldest state pharmacy assistance subsidy programs (direct benefit programs). This program, along with a program in Pennsylvania, has served as a model for similar programs in other states. The state is currently implementing a program expansion to cover elderly and disabled individuals with more moderate income levels.
- California recently established a state pharmacy assistance discount program (discount program) that operates at substantially less expense to the state than a direct benefit program and has been of considerable interest to other states. California's discount program requires pharmacies that participate in the state's Medicaid program (Medi-Cal), about 95 percent of pharmacies in the state, to offer elderly and disabled Medicare beneficiaries prescription drugs at prices that do not exceed discounted price paid by Medi-Cal.
- Maine operates a well-established direct-benefit program that is more limited in scope than New Jersey's program. In addition, the state has recently drawn national attention with a program that relies on a combination of mandated retail discounts and negotiated rebates with participating drug manufacturers to reduce the price of prescription drugs for all Maine residents—especially those who are uninsured or underinsured—regardless of age or income.

[2] Approaches not represented here include the tax credit approach taken by Missouri and Michigan (but later replaced by direct subsidy programs) and the private insurance subsidy approach taken by Nevada.

The case studies were based on reviews of relevant documents and key informant interviews in the three study states. For the New Jersey case study, conducted in November/December 2000, we interviewed representatives of the New Jersey Legislature, New Jersey Department of Health and Senior Services, PAAD Advisory Committee, New Jersey pharmacists associations, Pharmaceutical Research and Manufacturers of America (PhRMA), and consumer advocates. In California, in September 2000, we interviewed representatives of the California Legislature, California Department of Health Services, California Pharmacists Association, California State Board of Pharmacy, California State Office of AARP, Congress of California Seniors, Older Women's League, California Health Advocates, the California Health Insurance Counseling and Advocacy Program Association, and PhRMA. For the Maine case study, conducted in October 2000, we spoke with representatives of the Maine Legislature, Maine Department of Human Services, state pharmacy associations, PhRMA, and consumer advocacy groups. As noted above, unless stated otherwise, information on programs has not been updated beyond March of 2001. Appendix A provides a list of key informants interviewed in each of the three states.

Organization of the Report

The chapters that follow present the detailed findings regarding the context for the development of the pharmacy assistance programs in each state, the features of each program, funding sources and costs, administration, program impact, and lessons learned:

- ***New Jersey: A Mature Direct Benefit Program***. This chapter describes the features of New Jersey's PAAD pharmacy assistance subsidy program for elderly and disabled Medicare beneficiaries with low incomes, as well as the recent Senior Gold program expansion, which is open to elderly and disabled individuals with somewhat higher incomes.
- ***California: A Broad Discount Approach.*** In this chapter, the focus is on California's recently implemented Prescription Drug Discount Program for Medicare beneficiaries.
- ***Maine: Addressing Affordability on Multiple Fronts.*** This chapter describes Maine's direct benefit program, the Maine Low-Cost Drugs for the Elderly and Disabled (DEL) program, as well as the state's two more recently enacted pharmacy assistance discount programs: Maine Rx and the Healthy Maine Prescription Program (HMPP).
- ***Lessons Learned from the Three States.*** The final chapter of this report outlines lessons learned from New Jersey, California, and Maine's experiences with pharmacy assistance programs that might be of interest to states operating or contemplating similar programs.

2. NEW JERSEY: A MATURE DIRECT BENEFIT PROGRAM

Overview

New Jersey's Pharmaceutical Assistance to the Aged and Disabled (PAAD) program for low-income state residents was created in 1975 (see Table 2-1). With more than 180,000 enrollees, this program is one of the oldest direct benefit prescription drug programs in the country.[3] The Senior Gold program, signed into law in May 2001, offers a somewhat more limited prescription drug benefit to moderate-income elderly and disabled state residents – those with incomes up to $10,000 higher than those of state residents eligible for the PAAD program. Senior Gold also offers some catastrophic protection for its enrollees.

New Jersey's PAAD program enjoys wide support among older and disabled residents in the state, as well as among public officials. Other states that are contemplating either expanding or implementing a direct benefit program can learn from New Jersey's long history and experience managing a large and popular direct benefit program.

This case study explores the context for the development of New Jersey's PAAD program, along with the program design, funding sources, administration, and program impact. This case study also discusses the Senior Gold program, but much of the discussion only refers to plans for implementation as the program only began enrollment in June 2001.

Table 2-1: New Jersey's Pharmacy Coverage Initiatives

Initiative	Description	Status
Prescription Assistance to the Aged and Disabled (PAAD) Program—Created 1975	A state pharmacy assistance subsidy program that provides a direct prescription drug benefit to elderly and disabled persons who meet specified income criteria and lack prescription drug coverage or have exhausted their coverage.	Operational
Senior Gold Program—Enacted May 2001	A state pharmacy assistance subsidy program that offers a more limited benefit than the PAAD program for elderly and disabled people with moderate incomes—i.e., incomes up to $10,000 higher than the income eligibility limits for the PAAD program. It also includes a catastrophic provision that waives coinsurance requirements once enrollees' annual expenditures reach a certain level.	Operational as of June 2001

[3] US General Accounting Office, State Pharmacy Programs; Assistance Designed to Target Coverage and Stretch Budgets, GAO/HEHS-00-162, Sept 2000, p.9.

Context

PAAD Program. New Jersey established the PAAD program in 1975, long before the need to address the rising cost of pharmaceuticals was on the national agenda. Legislative sources we interviewed emphasized the size of New Jersey's elderly population and the state's historic emphasis on programs for older persons as important reasons for the creation of a pharmacy benefit for low-income older residents. The percentage of New Jersey's population age 65 and over (13.3 percent in 1999) somewhat exceeds the national average (12.7 percent in 1999).[4] New Jersey has one of the highest median family income levels in the nation ($55,572 in 1995-97), giving it more fiscal capacity to address social needs than many other states. Even so, the state has many elderly people with very low incomes. In the period 1996-98, for example, some 17.8 percent of New Jersey residents aged 65 and older had incomes at or below 135 percent of the federal poverty level, slightly less than the national average of 20.6 percent.[5] The PAAD program was designed to address the needs of such individuals.

The sources we interviewed in New Jersey widely acknowledged that New Jersey's PAAD program has played an important role in addressing the needs of the state's low-income elderly and disabled residents for affordable prescription drugs. The program has received consistent, broad bipartisan support among legislators and regulators since its enactment and is strongly supported by both consumer advocates and older persons in the state.

Senior Gold. The New Jersey Legislature created the Senior Gold program with a bill that was signed into law in May 2001. There were several reasons for the creation of this program, including pressure from constituents who were concerned that people with low and moderate incomes who were not eligible for the PAAD program were unable to afford needed prescription drugs. The primary impetus for the Senior Gold program, according to sources we interviewed, was the availability of a new revenue stream through the state's settlement with tobacco manufacturers in 1999. For further background on the political history and evolution of this program and the PAAD program in New Jersey, see Appendix B.

Program Design

Eligibility

PAAD Program. The PAAD program was originally designed to help near-poor elderly New Jersey residents whose incomes were just above Medicaid eligibility and who could not afford the cost of needed prescription drugs. Since the program's inception in 1975, there have been several changes to PAAD's eligibility criteria, as shown in Table 2-2. In particular, the program was opened to disabled persons in 1983. Most amendments to the PAAD program have raised the program's income eligibility limits, often in response to strong advocacy by elderly New Jersey residents.

[4] Normandy Brangan, Kelly Griffin, and Cathy McDougall, *Reforming the Health Care System: State Profiles 2000.* Washington: AARP Public Policy Institute, 2000.

[5] Ibid.

Table 2-2: New Jersey's PAAD Program and Senior Gold Program: Changes in Eligibility Criteria, 1976-2001

Year Enacted and Program Change
1976: PAAD program annual income limit changed from $9,000 single/$9,000 couple to $9,000 single/$12,000 couple
1982: Eligibility expanded to include disabled persons; and raised income limits (using casino revenue funds) to $12,000 single/$15,000 couple
1985: Income limits raised to $13,250 single/$16,250 couple
1987: Income limits raised to $13,650 single/$16,750 couple
1989: Income earned through sale of house excluded from income limits
1991: Income limits raised to $15,700 single/$19,250 couple
1992: Income from reparations for interned Japanese excluded from income limits
1993: Income limits raised to $16,171 single/$19,828 couple
1995: Income eligibility tied to annual Social Security cost of living adjustments (COLAs)
2001: Senior Gold program established using tobacco settlement funds for persons with incomes $10,000 above PAAD income limits

Source: Rutgers Center for State Health Policy Survey of State Pharmaceutical Assistance Programs, December 2000, and key informant interviews.

As of 2000, New Jersey's PAAD program was open to elderly or disabled single persons with incomes under $19,238 (230 percent of the federal poverty level in 2000) and married couples with incomes under $23,589 (210 percent of the federal poverty level in 2000). The income thresholds for PAAD eligibility are now higher than those set for the majority of other state direct-benefit pharmacy assistance programs.[6]

New Jersey's PAAD program has no asset test. In 1994, the governor proposed adding an asset test in order to limit enrollment by persons with considerable assets, such as people with dual residences in Florida and New Jersey. This initiative was vigorously opposed by older persons in the state and was not pursued by the state legislature.

Since 1995, PAAD income eligibility limits have been linked to the Social Security cost of living adjustments (COLAs). Thus, PAAD income limits are automatically raised every year by two to three percentage points. Although program administrators had expected that an automatic annual

[6] In 1999, the average income eligibility requirement for 17 state pharmacy assistance programs surveyed by the General Accounting Office was approximately 173 percent of the federal poverty level, ranging from 100 percent of the federal poverty level in Wyoming to 225 percent of the federal poverty level in New York and Vermont. Note that the 225 percent of the federal poverty level income limits in New York and Vermont were for programs with much higher consumer cost-sharing requirements than New Jersey's. U.S. General Accounting Office, *State Pharmacy Assistance Programs: Assistance Designed to Target Coverage and Stretch Budgets,* Report # GAO/HEHS-00-162, September 2000. Similarly, newer program expansions to moderate-income individuals, such as the insurance-model program in Massachusetts, involve substantially higher cost-sharing than does PAAD.

increase in income limits would increase enrollment and program costs, enrollment in the PAAD program has actually declined since this change was implemented.

Senior Gold. The Senior Gold program is targeted to older and disabled persons earning up to $10,000 more per year than the PAAD limits. It was enacted to address state residents' concern that many low- and moderate-income older and disabled people whose incomes only slightly exceeded PAAD's income limits were unable to afford prescription drugs.

According to several sources we interviewed in New Jersey, the income eligibility criteria for the Senior Gold Program were derived on the basis of the funds that were available. Specifically, legislators used utilization rates in the existing PAAD program to calculate how many additional people could be covered in the Senior Gold program using the anticipated funds to be allotted to the program from the state tobacco settlement funds.

Benefits and Consumer Cost-Sharing

PAAD Program. PAAD allows eligible New Jersey residents to purchase prescription drugs, insulin, insulin syringes and needles, and certain diabetic testing materials. PAAD covers only drugs purchased in New Jersey that are approved by the Food and Drug Administration and produced by manufacturers that have entered into a Medicaid and PAAD rebate[7] agreement. Initially, the PAAD program's design was similar to that of a major medical policy in that enrollees were required to pay a deductible and submit claims for retroactive reimbursement after meeting their specified deductible. According to PAAD program officials, this design posed a barrier to participation. Consequently, PAAD enrollment was much lower than predicted at first, and the program significantly underspent what the state had budgeted.

In 1978, New Jersey changed the PAAD program's design to its current form. Upon enrollment, PAAD participants receive a card that they present to pharmacies to receive drugs; when they receive the drugs, they pay only a small copayment. The copayment was originally set at $1 and has subsequently been raised to $2 in 1978 and to $5 in 1992 due to escalating program costs. Raising copayments has met with considerable objections from consumers, according to most sources we interviewed.

Senior Gold. Senior Gold covers the same drugs as the PAAD program, but Senior Gold enrollees are charged a $15 copayment plus 50 percent of the remainder of the Medicaid discounted price. Thus, for example, for a drug with a Medicaid price of $100, a Senior Gold enrollee would pay $57.50—i.e., a $15 copayment plus 0.5×($100 minus $15 copayment).

The Senior Gold program waives the 50 percent coinsurance requirement for single enrollees who have spent more than $2,000 out-of-pocket on prescription drugs annually, or couples who spend more than $3,000 annually.[8] New Jersey consumer representatives strongly advocated for this feature of the program.

[7] A.E. Cook, "Strategies for Containing Drug Costs: Implications for a Medicare Benefit," *Health Care Financing Review* 20(3):29-37, Spring 1999.

[8] Costs incurred prior to program enrollment do not count toward the catastrophic cap.

Neither the PAAD program nor the Senior Gold program provides coverage to persons whose income exceeds eligibility limits but who have prescription needs that consume large portions of their income.

Funding Sources and Costs

Many sources we interviewed in the state indicated that a key to the PAAD program's success in providing drug coverage for so many low-income and disabled individuals has been the state's ability to identify funding sources other than state general funds. As discussed below, state casino gambling revenues were the source of funds for two-thirds of PAAD's $331 million expenditures in 2000. Nonetheless, state general revenue funds appropriated for the PAAD program more than doubled between 1999 and 2001. New Jersey's Senior Gold program, which was projected to cost about $86 million in the first year of its implementation, is being funded by New Jersey's 1998 settlement with tobacco manufacturers. The PAAD and Senior Gold programs are also supported by rebates from drug manufacturers.

Over time, the cost of the PAAD program and Senior Gold expansion will depend on trends in prescription drug utilization, pricing, and availability of other coverage, among other factors, many of which are difficult to project. If prescription drug coverage from Medicare+Choice and employer-sponsored plans continues to erode while the amount and cost of pharmaceuticals used by older and disabled persons continues its recent sharp increase, New Jersey's PAAD and Senior Gold programs will require additional money from the state's general funds.

PAAD Program

Table 2-3 shows PAAD expenditures and revenues for the years 1999 to 2001. PAAD program expenditures in fiscal year 2000 were about $331 million, and are expected to rise to about $375 million in 2001. Sources of revenues for New Jersey's PAAD program include casino revenues, state general funds, drug manufacturer rebates, and recoveries from other third-party payers. PAAD also receives discounts from pharmacies that lower program costs.

Casino Revenue Funds and State General Funds. According to many of the people we interviewed, the state's decision to allow casino gambling in the early 1980s was a critical contributor to the PAAD program's stable support and expansion. Legislative sources note that there was considerable debate at the time about finding a permanent funding source for the PAAD program. As a condition for allowing casinos to come into New Jersey, the state formed a casino revenue fund that was dedicated to programs for older and disabled New Jersey residents.

In 1982, New Jersey casino revenue funds were earmarked to pay for a significant PAAD program expansion including coverage of the disabled. State general revenue funds were used to pay for older persons eligible under the original PAAD income limits ($9,000/single person; $12,000/couple).

Table 2-3: New Jersey's PAAD Program Expenditures and Revenues, FY 1999-2001

	FY 1999	FY 2000	FY 2001 (projected)	Percent change, 1999-2001
TOTAL PAAD EXPENDITURES*	**$293,320,043**	**$331,272,398**	**$375,502,346**	**28%**
PAAD REVENUES BY SOURCE:				
Casino revenues	$204,099,000	$218,811,000	$229,918,000	13%
State general revenues	$39,820,000	$61,119,000	$90,306,000	127%
Manufacturer rebates	$37,882,004	$40,400,000	$50,000,000	32%
Recoveries from other third-party payers**	$11,532,093	$10,943,000	$10,943,000	- 5%
TOTAL REVENUES	**$293,333,097**	**$331,273,000**	**$369,067,000**	**26%**

* Includes administrative costs

** These are funds recovered retrospectively from third-party payers that cover programs for which PAAD program participants are also eligible, such as retirement health benefits programs.

Source: Rutgers Center for State Health Policy, Survey of State Pharmaceutical Assistance Programs, December 2000.

As shown in Table 2-3 above, casino revenue funds remain the primary revenue source for the PAAD program, accounting for two-thirds of program expenditures in fiscal year 2000. Increasingly, however, the PAAD program has had to rely on state general revenues. State general revenue funds appropriated for the PAAD program more than doubled between 1999 and 2001, increasing from $40 million to $90 million.

Furthermore, the burden of New Jersey's PAAD program on the state's casino revenue fund has been greater than originally expected. In the early 1990s, only 30 percent of the state's casino revenues were dedicated to the PAAD program, and the other 70 percent were used to support other programs for older persons, such as respite care. As the PAAD program has grown, however, it has taken a larger and larger share of casino revenues. At the time this case study was conducted, the PAAD program was projected to account for about 65 percent of casino revenues for 2001.

Manufacturer Rebates. The term manufacturer's rebate refers to a monetary payment that a prescription drug manufacturer pays a final purchaser (e.g., a state pharmacy program) based on the volume of drugs purchased over a given period.[9]

Currently, about 12 to 13 percent of gross PAAD program expenditures are recovered through rebates from prescription drug manufacturers. Although New Jersey's Medicaid program began securing prescription drug rebates from manufacturers for its Medicaid program in 1990, the PAAD program did not begin securing manufacturer rebates until 1992. The PAAD rebate, as

[9] A.E. Cook, "Strategies for Containing Drug Costs: Implications for a Medicare Benefit," *Health Care Financing Review* 20(3):29-37, Spring 1999.

well as the Senior Gold rebate which is similarly designed, does not include the Consumer Price Index component of the Medicaid rebate. Under the Social Security Act (42 U.S.C., Title XIX, §1927 subsection (c)(1)(C)), a state Medicaid program can seek an additional rebate from a company that raises the Average Manufacturer Price of a single source or innovator multiple source drug in the previous month in excess of the Consumer Price Index CPI-Urban increase since September 1990.[10] According to some sources, program administrators argued to include the CPI adjustment in order to offset growing program costs, but prescription drug manufacturers opposed its inclusion and lobbied against it intensively.

Pharmacy Reimbursement. In addition to manufacturer rebates, PAAD is also subsidized in part by pharmacy discounts. Pharmacy reimbursement is currently based on the Medicaid discounted price (average wholesale price [AWP[11]] minus 10 percent), plus a dispensing fee that ranges from $3.73 to $4.07, depending on whether the pharmacy provides supplemental services, such as 24-hour delivery service. Pharmacists support the variable dispensing fee, but argue that all fees are low and should be increased.[12]

Prior to 1996, the ingredient cost reimbursement rate paid to a pharmacy varied depending upon the pharmacy's total prescription volume during the previous year. There were six levels of reimbursement rates ranging from the full AWP rate for pharmacies with prescription volumes less than 14,999 prescriptions a year, to AWP minus 6 percent for pharmacies with prescription volumes of more than 50,000 prescriptions a year. The reimbursement rate for all pharmacies was changed to AWP minus 10 percent in 1996 to control program costs. More recently, program administrators have proposed to reduce ingredient cost reimbursement to pharmacies once more, from AWP minus 10 percent to AWP minus 12 percent, mirroring the rate paid to pharmacies in the state employees' health program. However, pharmacy associations strongly objected to such a change, arguing that the cost of doing business has increased, and that the reimbursement rate has not kept up with costs. As of the time this case study was conducted, the proposed change to pharmacy reimbursement rates had not been approved by the legislature. Note that reductions in ingredient cost reimbursement reduce the payment to pharmacies without affecting manufacturers, since they do not change the price that the pharmacy or its wholesaler pays for the drugs. Reimbursement rates for Senior Gold were expected to be the same as for the PAAD program.

Fund Recoveries from Insurers. New Jersey has adopted several approaches to recover funds for its state pharmacy assistance subsidy programs from other insurers. As a payer of last resort, the PAAD program has moved aggressively to recover funds from third-party payers that provide partial coverage for PAAD enrollees. It has used two systems very successfully.

---

[10] Social Security Act (Title 19, Section 1927), According to drug manufacturers, the CPI adjustment is pegged to price increases since 1990 or from the date the drug was introduced and is cumulative in nature. If a company increases the price of a drug more than the CPI, the manufacturer continues to pay a penalty until the initial increase falls below the CPI.

[11] The *average wholesale price* (AWP) is the price that prescription drug manufacturers suggest that wholesalers charge retail pharmacies. Drug manufacturers generally offer lower prices or rebates to favored purchasers, such as large insurance companies or governments, meaning that those customers pay significantly less than the AWP. Source: Families USA, Glossary of Terms, available at http://www.familiesusa.org/media/pdf/18_Glossary.pdf.

[12] In 1999, the legislature passed a bill to increase the dispensing fees by $1.00, but this bill was vetoed by the Governor. According to several interview respondents, the Governor argued that New Jersey dispensing fees were comparable to those in other states, and she did not support raising New Jersey's fees to be much higher than other neighboring states.

- PAAD program managers have found that most PAAD applicants do not know the name of their retirement health plan, and many do not even know that they have other third-party coverage. In addition to asking PAAD applicants the name of their health plan, therefore, the PAAD program application also asks applicants who report either pension or salary income to provide the name of their employer. PAAD program administrators then cross-reference the names of PAAD applicants' employers with a Medicaid-generated list of all health plans with drug coverage that contract with those employers. If a PAAD enrollee is found to have other prescription drug coverage, the PAAD program enters an insurance code on the person's file and sends batch billings to the insurer in an effort to recover funds.
- New Jersey's Department of Health and Senior Services has a contract with Health Management Systems—the company that manages the data system for many New Jersey managed care plans (including Medicare HMOs and some retirement benefit plans)—to match PAAD enrollees' and managed care enrollees' files using Social Security numbers. For every duplicate identified, Health Management Systems bills the insurer and gets a commission or finder's fee.

These two third-party recovery systems have enabled the PAAD program to achieve greater recoveries than the state's Medicaid program (which later adopted the PAAD program's approach). As shown in Table 2-3 above, the PAAD program's third-party recovery systems produced approximately $10 million dollars per year in 1999 and 2000. The recovery systems were initially implemented in the mid-1990s, when there was a steady growth in third-party revenues. According to PAAD program officials, however, over the last several years, recoveries from third-party payers have plateaued and even declined slightly, because many employers and pension plans are no longer covering prescription drugs.

Efforts to Recover Funds from Medicare. The state of New Jersey has been negotiating with the Centers for Medicare and Medicaid Services (CMS)—formerly known as the Health Care Financing Administration (HCFA)—to recover funds from Medicare for certain prescription drugs used by PAAD enrollees that are Medicare-covered (e.g., diabetic supplies and immunosuppressive agents used to prevent the rejection of organ transplants). At the time of this case study, New Jersey had still not recovered any funds through this process. As of June 2001, there were still unresolved issues. Although both sides have attempted to respond within the limitations of existing Medicare statute, the process has not been easy. This experience highlights the need to build coordination of benefits procedures into a Medicare prescription drug benefit, if such a benefit is enacted and is more limited than PAAD.

The PAAD program could simply exclude diabetic supplies and immunosuppressive agents covered by Medicare, but PAAD administrators believed that this would put a significant burden on consumers who have become accustomed to purchasing these items over the counter with only a $5 copayment. Exclusion of these items from the PAAD program would mean that elderly and disabled individuals either would have to pay the full amount of the item at the counter and submit paperwork subsequently to CMS to get retroactively reimbursed by Medicare, or would have to seek out a Medicare-participating pharmacy.[13] Furthermore, New

[13] Officials at CMS said there should not be additional paperwork burden for the beneficiary. If beneficiaries purchased prescriptions at a pharmacy with Medicare assignment, that pharmacy is required to submit the claim. Even if they went to a

Jersey's pharmacies were resistant to billing Medicare directly because Medicare payment often takes six to eight weeks, longer than they had to wait for payment from the PAAD program.

Rather than put more burden on consumers or pharmacies, the PAAD program has been trying to coordinate its efforts with CMS and pharmacies in order to develop a more seamless system. At first, New Jersey proposed an arrangement under which the PAAD program would pay the pharmacy for a PAAD enrollee's diabetic supplies and/or immunosuppressives at point of purchase, and the enrollee would pay the usual $5 copayment as in the past. The PAAD program, acting as the Medicare billing agent for New Jersey pharmacies, would then submit a bill for the cost of the enrollees' diabetic supplies and/or immunosuppressives to CMS. The problem with this proposed arrangement turned out to be the lack of explicit authority in the Medicare statute for a state government to be considered a provider and paid directly.

Under another proposed arrangement, therefore, CMS would make direct payments to individual pharmacies as Medicare providers (the pharmacies would have to obtain a Medicare provider number). CMS would then send New Jersey a list of all payments made to New Jersey pharmacies for PAAD enrollees' diabetic supplies and immunosuppressives. Every month, the PAAD program would debit the pharmacy for the cost of these items, so that the pharmacy would receive only one payment

According to officials at New Jersey's Department of Health and Senior Services, if the latter proposed process is implemented, the state would be able to recover $4 million from Medicare through this program in the first half-year of operation—annual recoveries might amount to $8 million. However, these recoveries from Medicare would primarily be for future purchases of covered drugs or purchases made subsequent to the pharmacies' enrollment in the Medicare program. In correspondence to the New Jersey Commissioner of Health and Senior Services, CMS has stipulated that retroactive billing is not permitted for pharmacies newly enrolled as Medicare providers, which may only bill for drugs purchased after the date that the pharmacy is issued a Medicare supplier billing number. Since most pharmacies were not previously enrolled as Medicare providers, recoveries can only be prospective.

Senior Gold

The primary impetus for the Senior Gold expansion, according to sources we interviewed in the state, was the availability of a new revenue stream from New Jersey's 1998 settlement from tobacco companies. The governor's office had originally earmarked tobacco settlement funds to maintain the existing PAAD program, but consumer advocates vigorously lobbied to have these funds set aside for new benefits rather than for existing state commitments. The Senior Gold program will benefit from prescription drug manufacturer rebates similar to those negotiated for the PAAD program. The program also plans to use third-party recovery systems.

The sponsors of the law establishing New Jersey's Senior Gold program estimated that the program would cost about $86 million in 2001, the first year of its implementation, $96 million the second year, and $107 million the third year.

---

pharmacy without assignment, Section 1848 (g)(4)(a) requires physicians and suppliers to file a claim for services on behalf of a beneficiary.

Administration

PAAD Program

One of the strengths of New Jersey's PAAD program is its strong administration. PAAD is administered by New Jersey's Department of Health and Senior Services, which began performing eligibility determination, enrollment, claims processing, and benefit administrations for the program in 1996. New Jersey's PAAD program works closely with the state's Medicaid pharmacy unit in coordinating pharmacy policies and reimbursements. Prior to 1996, the program was administered by the same state agency that administers New Jersey's Medicaid program (the Division of Medical Assistance and Health Services of the New Jersey Department of Human Services). The program has always been maintained as a separate program from Medicaid in order to avoid the stigma that is often associated with Medicaid.

Respondents in New Jersey generally praised the administration of the PAAD program. The program's administrator at the time of the case study, they noted, had been in the position for nearly 20 years and had developed a strong, collaborative relationship with all stakeholders. Furthermore, an advisory board made up of consumers, medical providers, and pharmacy and manufacturer representatives advises the PAAD program on programmatic changes. Advisory board members interviewed for this study reported that the PAAD program is fairly administered by New Jersey's Department of Health and Senior Services and that the staff running the program and the program director are easy to work with, knowledgeable, and responsive. In general, advisory board members reported that their feedback on PAAD programmatic changes is heard and incorporated into new initiatives. PAAD program managers have repeatedly demonstrated a capacity to develop innovative solutions to programmatic issues that have arisen over the years.

Application Process. Elderly and disabled New Jersey applicants seeking to enroll in PAAD submit their applications to PAAD by mail. Applicants must submit proof of age/disability and residence and a copy of their income tax return to verify income eligibility. Applications for the PAAD program are made available through pharmacies, county Offices on Aging, legislators, and the Internet. Referrals to the PAAD program are integrated with the county-level networks through New Jersey's Easy Access, Single Entry (NJ EASE) program. The NJ EASE program—a comprehensive information and referral program designed to link older residents to needed services for which they might be eligible—became operational early in 2000, after some implementation delays. Although there is no tracking of how people acquire PAAD applications, program administrators believe that the pharmacies distribute the greatest number of applications.

PAAD applicants must submit proof of age/disability and residence and a copy of their income tax return to verify income eligibility as part of their applications. The state operates a hotline for applicants to provide basic assistance in filling out the form; operators refer applicants to their county Office on Aging should they require additional help. PAAD Administrators report receiving few complaints about difficulties in filling out the application.

Under an interagency agreement between the New Jersey Department of Health and Senior Services (DHSS) and the Department of Taxation, the Department of Taxation verifies self-

reported income tax information on the PAAD application by matching applicants' social security numbers with tax records, for which the applicant gives permission. To increase program visibility and minimize application burden, New Jersey has merged the application for the Lifeline utility assistance program and the Hearing Aid Assistance Program with the PAAD program. Lifeline provides gas and electric assistance for low-income older persons who qualify. Applicants fill out only one form to enroll in any or all of these programs. To inform residents of Lifeline, the PAAD program, and the Hearing Aid Assistance Program, DHSS also sends an annual insert in utility bills.

The reapplication period for the PAAD program is based on income. Enrollees with lower incomes need only reapply once every two years, because it is less likely that they will become ineligible. Enrollees with higher incomes must apply once a year. Although DHSS has no mechanism in place to track or remind individuals previously enrolled who do not reapply, the state permits a 90-day grace period for eligibility lapses. If eligibility lapses for fewer than 90 days, the state will back-date coverage to cover bills retroactively for that 90 day period. If eligibility lapses for more than 90 days, the enrollee bears the risk for the lapsed period and the PAAD program pays for drugs purchased from the renewed date of enrollment forward.

Coordination with Medicaid and Other Public Benefit Programs The PAAD program works closely with the Medicaid pharmacy unit in coordinating pharmacy policies and reimbursements. The PAAD program uses the same discounts as Medicaid, as well as the same drug utilization review (DUR) and fraud/abuse detection procedures.

Claims for PAAD enrollees are processed through the Medicaid Management Information System (MMIS). The state Medicaid program administers the PAAD rebate program. The procedures used for claims processing and payment to pharmacies are the same for the PAAD program as for Medicaid.

The PAAD program coordinates its eligibility-related procedures with those of other public benefit programs, specifically the Medicaid program, the Qualified Medicare Beneficiary (QMB) Program, or the Specified Low Income Medicare Beneficiary (SLMB) Program. Under the QMB Program, Medicaid pays Medicare premiums and cost-sharing for Medicare beneficiaries living below the federal poverty threshold but who are not eligible for full Medicaid benefits. Under the SLMB Program, Medicaid pays the Part B premium for Medicare beneficiaries with incomes between 100 and 120 percent of the federal poverty threshold.

To assess whether PAAD applicants might be Medicaid eligible or eligible for the Qualified Medicare Beneficiary (QMB) or Specified Low-income Medicare Beneficiary (SLMB) programs, PAAD program administrators use the interest and dividends reported in the income section of the PAAD application to estimate applicants' assets.[14] If a PAAD applicant appears to be eligible for Medicaid the PAAD program informs the Medicaid office and also notifies the applicant and suggests that he or she follow up with the local Board of Social Services.

[14] Normandy Brangan, *The Medicare Program*, AARP Public Policy Institute, Data Digest #64 (Washington, DC: AARP. August 2001).

Coordination with the SLMB program is more straightforward because the director for the PAAD program also oversees the SLMB program. In cases where projected assets of a PAAD applicants are close to SLMB levels, the PAAD program sends the applicant an SLMB application, so that the applicant can certify his or her actual income and assets. The probable reason for separating the application for SLMB from the PAAD application is that the state did not want to include any asset information on the PAAD application. Through this coordination, New Jersey has enrolled around 16,000 PAAD participants in SLMB in 2000, and another 7,000 enrolled in two other Medicare premium assistance programs (QI1 and QI2). This accomplishment, according to the PAAD program administrator, far exceeds the success of many other states in program linkage. In fact, New Jersey's PAAD program received an award from CMS for enrolling so many applicants in SLMB.

Most PAAD enrollees would not qualify for a Medicare prescription drug benefit if the benefit had an asset test that was comparable to that required for QMB/SLMB, according to New Jersey state officials. They base this statement on the state's projections of enrollees' assets for QMB/SLMB eligibility.

Monitoring Prescription Use and Medication Error (Drug Utilization Review). To address the issues of appropriateness of care and potential medication error, in the 1997-98 session the New Jersey Legislature strengthened the state's Medicaid and PAAD program drug utilization review (DUR). Although some Medicaid DUR had existed since the early 1990s as required by federal law, its primary focus had been on reviewing claims retrospectively for fraud and abuse.

New Jersey's strengthened DUR program is more proactive in its approach, focusing on standardizing medication practices to reduce medication error. Under this DUR program, New Jersey's Drug Utilization Review Board, appointed by the governor and made up of pharmacists and physicians, determines standards for appropriate prescribing. These standards are then incorporated into the point-of-sale PAAD/Medicaid data system to flag pharmacists when the prescription submitted does not comply with these standards.

Although the strengthened DUR program was approved by the state legislature in 1998, the program has had a long startup period, due to delays in appointing Drug Utilization Review Board members, identifying a subcontractor, and modifying the software to flag edits (that is, messages to pharmacists regarding potentially inappropriate prescribing). The program finally became operational in December 1999 and is being phased in, starting with simple edits at first and slowly adding more flags for error and duplication.

As of 2001, the PAAD/Medicaid data system incorporated prescribing standards that addressed possible life-threatening drug-to-drug interactions, contraindications, excessive duration of therapy, excessive dosage, therapeutic duplication, and early refills. If the prescriptions requested could cause a life-threatening drug interaction, the claim is denied, but for all other problems, the pharmacist can call First Health (the DUR subcontracting agency) to get prior authorization for a 30-day supply. First Health then follows up with the prescribing doctor to determine medical necessity. According to state officials, this approach takes the burden off the patient and the pharmacy.

New Jersey modeled its DUR system on a system used by Pennsylvania's Pharmaceutical Assistance Contract for the Elderly (PACE) program, the state pharmaceutical assistance program with the largest number of enrollees in the country. In the nine months of operation between December 1999 and September 2000, 5,632 PAAD claims required follow-up by First Health due to a potential error. Of these, 1,182 PAAD claims, totaling $149,000, were denied.[15]

The DUR program, which was implemented in response to a study commissioned by the New Jersey Council of Chain Drug Stores,[16] was strongly supported by pharmacy associations and manufacturers who were also involved in its design. The New Jersey Council of Chain Drug Stores had commissioned the study, in part, in reaction to other proposed state initiatives to cut PAAD program costs.

There seems to be general support for the program—and the program seems to be working effectively for the most part, although several respondents suggested that many prescribers are not aware of the DUR program. One respondent did note that there is some concern within the pharmaceutical industry that New Jersey may begin to use DUR as a tool to limit drug use based on cost rather than on clinical criteria. State officials we interviewed, however, did not report any plans to extend DUR to limit dispensing of expensive drugs.

In addition to implementing the DUR program, New Jersey has implemented a generic substitution program that requires pharmacies to dispense the generic alternative of a prescribed drug for PAAD enrollees unless the physician specifically indicates medical necessity for the brand prescribed. Generic substitution information is built into the PAAD point-of-sale software system, automatically signaling the pharmacist that a lower cost generic alternative is available. The pharmacists strongly support this program. Pharmacies generally are able to negotiate lower prices with manufacturers for generic drugs, due to the number of companies competing to sell them, and therefore they tend to get higher margins on generic drugs than on brand name medications. Pharmaceutical manufacturer representatives indicated that brand-name manufacturers have resigned themselves to generic substitution as long as physicians are given the authority to deny substitution when they believe that the brand drug is medically necessary.

Senior Gold

The Senior Gold program began enrolling eligible individuals in June 2001. Like PAAD, the Senior Gold program is administered by New Jersey's Department of Health and Senior Services. Given PAAD's generally positive experience with its application process, a similar approach has been used for the Senior Gold program.

[15] Michele Guhl, Christine Grant, Edward Vaccaro, *New Jersey State Drug Utilization Review Board Annual Report: October 1, 1999 through September 30, 2000,* Trenton, NJ, 2001

[16] Zachary Dyckman, Center for Health Policy Studies, *Proposed Enhancement to the PAAD Program to Improve Program Cost-Effectiveness,* prepared for the New Jersey Council of Chain Drug Stores, Trenton, NJ January 1996.

Program Impact

Awareness

PAAD Program. There are no data available to measure awareness of the PAAD program among New Jersey residents, but most of the sources we interviewed in the state thought that older residents were well aware of the PAAD program. Certainly the number of PAAD enrollees—about 187,000 in 2000—is an indicator that many people know of the program's existence. Nonetheless, at least one consumer respondent said that PAAD program outreach and public education is insufficient, particularly in minority communities. Other respondents indicated that outreach and education varies by county.

Senior Gold. At the time we conducted our fieldwork for this case study, the Senior Gold program was too new to evaluate New Jersey residents' awareness of the program.

Enrollment

PAAD Program. The takeup rates for PAAD are difficult to measure because estimates of the number of persons eligible for the current PAAD program — lower income elderly and disabled New Jersey residents who lack prescription coverage — are not available. Such estimates are difficult to construct because of the scarcity of current information on the prevalence of other prescription drug coverage among older and disabled persons on a state level. What is known is that New Jersey has a higher coverage rate (proportion of Medicare beneficiaries enrolled) than most states with SPAPs. The nearly 200,000 PAAD enrollees in 2000 represent 16 percent of all Medicare beneficiaries in the state,[17] the second highest coverage rate for a state pharmacy assistance program in the country. By comparison, coverage rates for other state pharmaceutical assistance programs range from 0.2 percent in Minnesota to 18 percent in Rhode Island. In 2000, New Jersey, Pennsylvania and New York together accounted for about two-thirds of all state pharmacy assistance enrollees in the country.[18]

Throughout the program's history, enrollment has fluctuated. In the late 1970s, New Jersey changed the program's benefit design from a deductible and retrospective reimbursement system to the current design, which requires the beneficiary to make a small copayment at the time he or she purchases the prescription. In the wake of these changes, according to one respondent, the PAAD program was inundated with applications and had to hire new staff to meet the demand. For a period, the program was understaffed and unable to keep up with the influx of applications. Thus, in the initial design, fewer people than expected enrolled, while in the redesign, many more enrolled than had been anticipated.

Despite the growth in program costs, enrollment in the PAAD program actually declined somewhat since 1999, counter to the expectation of program officials that increases in enrollment would follow the 1995 decision to link adjustments in PAAD income eligibility criteria to the Social Security COLA (see Table 2-4). In 1999, the PAAD program had nearly about 195,000

[17] U.S. General Accounting Office, *State Pharmacy Assistance Programs: Assistance Designed to Target Coverage and Stretch Budgets*. Report # GAO/HEHS-00-162, September 2000..

[18] Rutgers Center for State Health Policy, *Survey of State Pharmaceutical Assistance Programs,* December 2000.

enrollees. By 2000, enrollment in the PAAD program had declined to 187,358, and the projected enrollment for 2001 was 179,825.

Table 2-4: Enrollment in New Jersey's PAAD Program, FY 1999-2001

Enrollees	FY 1999	FY 2000	FY 2001 (Projected)	Percentage Change 1999-2001
Over age 65	172,258	163,958	155,774	-10%
Disabled	22,747	23,400	24,051	6%
TOTAL	**195,005**	**187,358**	**179,825**	**- 8%**

Source: Rutgers Center for State Health Policy, *Survey of State Pharmaceutical Assistance Programs*, December 2000.

PAAD program officials report that the recent decline in PAAD program enrollment has been largely concentrated among people ages of 65 to 75. In contrast, while enrollment of older persons has been declining in recent years, the number of disabled persons enrolled in the program has shown a modest increase.

The reasons for the decline in PAAD enrollment among people in ages 65 to 75 are unclear. Some sources we interviewed suggested that an increasing number of people in the state may be working past age 65, making them ineligible under the PAAD income limits; however, there are no data available to substantiate this theory. Enrollment in Medicaid by older persons has also declined in the past few years.

Senior Gold

Prior to enactment, New Jersey's Office of Legislative Services estimated that approximately 190,000 persons would be eligible and 114,000 to 142,000 would enroll. Sources interviewed suggested that it is difficult to estimate the exact number of eligibles given the limited state-level information available on existing prescription insurance coverage.

Consumer Savings

PAAD Program. Overall, most sources we interviewed in New Jersey believe that PAAD is an excellent program that helps to pay for drugs for low-income persons that they otherwise would not be able to afford. According to program officials, the PAAD program provides large savings to elderly and disabled enrollees—averaging $1,553 annually for the program's approximately 170,000 older enrollees and $3,219 for the program's approximately 30,000 disabled participants.

Senior Gold. Since the Senior Gold program only began in June 2001, it is too early to measure the cost savings to consumers. However, some consumer respondents expressed concern that consumer savings from the Senior Gold program would be more limited than consumer savings in the PAAD program. These respondents did not support providing a more limited benefit to a larger group of elderly people with moderate incomes, preferring programs that provide a more generous benefit with less consumer cost-sharing to a smaller group of persons with the lower incomes.

Impact on Pharmacies and Manufacturers

PAAD Program. From the outset, the PAAD program has been supported by representatives of the pharmaceutical industry and pharmacists. This support is fairly important in a state that, economically, relies heavily on the pharmaceutical industry. When the program was first introduced, the state had turned to the pharmacist associations to help design the program, and the associations were instrumental in its passage. Respondents from the pharmacist associations said that they supported the program, because it provided a definitive source of funding for a population thought likely to be delaying or avoiding purchasing needed prescriptions.

According to industry representatives, while participation in the PAAD program is voluntary, all pharmacies and manufacturers participate. In general, most respondents reported that the PAAD program has been good for pharmacies and manufacturers. Pharmacy representatives indicated that, compared to reimbursement rates from insurance programs, the PAAD rate is not unreasonable. But pharmacy respondents are still pushing for an in-depth study of the cost of filling a prescription so that the reimbursement rate and dispensing fee can be set to reflect the findings from such a study.

Despite claims that the PAAD program might increase other sales in pharmacies, one pharmacy representative did not think this had proven to be true, commenting that "PAAD participants do not buy as much other merchandise in the stores as do other customers. They have lower incomes and can't afford to buy that much."

Senior Gold. Since Senior Gold is a relatively new program, it is too early to assess the impact on pharmacies and manufacturers. Pharmacists interviewed prior to the program's enactment expressed support for an expansion of the existing PAAD program rather than the development of an entirely new benefit program such as Senior Gold that they suggested may be more difficult to administer and less generous than PAAD in what it covers.

Impact on State Budget

PAAD Program. New Jersey has aggressively pursued a myriad of cost-containment strategies to minimize the impact of the growing cost of the PAAD program. Despite these efforts, which have resulted in some savings, program costs continue to outpace the growth in revenue sources.

The specific reasons for escalating costs in the PAAD program are varied but generally reflect many of the same factors that are driving increased per capita prescription drug spending in general. One industry official cited a recent national study by the Kaiser Family Foundation indicating that these general increases in prescription drug spending from 1993 to 1998 were due to a combination of increased drug utilization, changes in the types of drugs used (with newer, higher priced drugs replacing older, less expensive ones), and, to a lesser extent, increases in existing drug prices.[19] Now that the program is increasingly relying on state general revenue funds to supplement casino revenues, it may come under even greater scrutiny. Nonetheless, the state's commitment of tobacco settlement funds toward an expansion of the program to Senior Gold, rather than for a "trust fund" to maintain the existing PAAD program over time, suggests

[19] The Kaiser Family Foundation, *Prescription Drug Trends Fact Sheet,* September 2000.

that the state believes that it can continue to commit state general funds to this politically popular program.

Senior Gold. As noted earlier, the sponsors of the law establishing Senior Gold estimated that the total costs to the state for Senior Gold would be no more than $86 million in the first year of its implementation.

Lessons from New Jersey

Many respondents indicated that the key to the New Jersey PAAD program's success in providing drug coverage for so many low-income older and disabled persons has been the ability to identify funding sources other than general revenues. New Jersey capitalized on a new industry in the state (casino gambling) to support this popular benefit program, which had an insignificant impact on general revenues until recently. Similarly, the state later used the influx of dollars from the tobacco settlement for the Senior Gold expansion. This reliance on dedicated funding streams contributed to the fiscal viability and popularity of the direct benefit approach and its continued expansion, as did the strong support from advocacy groups representing older residents. New Jersey's experience suggests that state pharmacy assistance program programs with dedicated revenues may find it easier to maintain bipartisan support and minimize controversy over their budgetary requirements, compared to programs for which substantial amounts of general revenues need to be reappropriated each year.

The PAAD program's success can also be attributed to strong program management. Nearly every person interviewed indicated respect and trust in the long-serving program director. Based on key informant interviews, PAAD management has repeatedly demonstrated a capacity to come up with innovative solutions to a number of programmatic issues, particularly in developing mechanisms to recoup program costs. The state has also developed an inclusive process, seeking guidance from consumers as well as manufacturers in program design issues.

A particular challenge which New Jersey program administrators have addressed in program operations—and which deserves careful attention in other states—concerns coordination of benefits with other payers including Medicare. If a new Medicare benefit provided a more limited benefit than the state program, the state might want to supplement the Medicare benefit to maintain the current benefit level with minimal burden to the consumer. To do this, states would need to develop an administrative process for having Medicare pay first with states "wrapping around" the benefit, which would require information sharing and benefit coordination between Medicare and state programs. The lengthy and complicated coordination between the PAAD program and CMS in order for New Jersey to recover Medicare reimbursement for diabetic supplies and some immunosuppressives indicates that, even with the passage of a Medicare drug benefit, significant administrative coordination issues will need to be resolved between Medicare and states with pre-existing direct benefit programs.

Few concerns were raised by respondents about the design and administration of the PAAD program, but escalating costs, despite efforts to control them, were cited by many as an ongoing issue. Program officials have tried to minimize program costs by instituting aggressive third-party reimbursement recovery from Medicare and private insurers. While these initiatives have

helped to reduce costs marginally, PAAD program costs continue to increase by more than 13 percent annually, which is likely to be an ongoing challenge for the state.

3. CALIFORNIA: A BROAD DISCOUNT APPROACH

Overview

California's Prescription Drug Discount Program was enacted by the state legislature in 1999 and became operational in February 2000 (see Table 3-1). The program is open to all Medicare beneficiaries, regardless of age or income.

The discount program has drawn considerable interest from other states as a way in which costs to the general population of elderly and disabled consumers can be reduced, at least to some extent, at minimal cost to the state. The program achieves discounts in the prices paid by Medicare beneficiaries through mandated discounts at pharmacies. Thus, California's experience can be instructive to other states interested in pursuing a pharmacy assistance discount program that relies on discounts at the level of the pharmacy.

This case study explores the context for the development of California's program, along with the program design, funding sources, administration, and program impact. At the time of fieldwork for this case study in September 2000, the program had only been in place for eight months.

Table 3-1: California's Initiative to Make Prescription Drugs More Affordable

Initiative	Description	Status
Prescription Drug Discount Program—Enacted 1999, became operational February 2000	A state pharmacy assistance discount program that requires all pharmacies participating in California's Medicaid program (Medi-Cal) to charge California's elderly and disabled Medicare beneficiaries no more than the Medi-Cal payment rate for that prescription plus a 15-cent processing fee.	Operational as of February 2000

Source: Rutgers Center for State Health Policy, *Survey of State Pharmaceutical Assistance Programs*, December 2000.

Context

In the two years prior to the passage of this program, several Medicare+Choice plans had withdrawn from service areas within the state, leaving nearly 60,000 California Medicare beneficiaries without the drug coverage they had received through these programs. While some Medicare beneficiaries who lost their Medicare+Choice coverage lived in areas where they could switch to another Medicare+Choice plan with prescription drug benefits, many Medicare beneficiaries had no other option for obtaining prescription drug coverage.[20] The federal requirement for specified Medigap plans to be open to Medicare beneficiaries forced to leave a Medicare+Choice plan did not include Medigap plans with prescription drug coverage.[21]

[20] Respondents did not indicate how many of the 60,000 California Medicare beneficiaries had no other option, but the number appeared to be large enough to make this problem an important political issue.

[21] After this case study was conducted, California passed a law to extend open enrollment to include at least one supplemental Medigap plan that covers prescription drugs. It also extends open enrollment to disabled persons who were previously ineligible.

Compounding this problem, older persons in the remaining California M+C plans were also faced with increasing premiums and reductions in their drug benefits.

Meanwhile, the national press was drawing attention to the escalating costs of pharmaceuticals and the fact that cash-paying prescription drug customers—that is, people without prescription drug coverage—are charged substantially higher prices for prescription drugs than are people with prescription drug coverage. Medicare beneficiaries with no prescription drug coverage under the traditional Medicare program were among those paying the most for their prescriptions.

With little expectation that the affordability of prescription drugs would be addressed through a Medicare prescription drug benefit at the national level until at least after the 2000 presidential election, several California state legislators introduced bills in 1999 to provide some relief to Medicare beneficiaries without prescription drug coverage in California. The only bill that passed was Senate Bill 393, which established the California Prescription Drug Discount Program. The program became operational on February 1, 2000. For further background on the political history and evolution of the California's discount program, see Appendix B.

Program Design

The design of California's Prescription Drug Discount Program is simple. Pharmacies participating in California's Medicaid program (Medi-Cal) are required to charge Medicare beneficiaries no more than the Medi-Cal payment rate for that prescription plus a 15-cent processing fee (to cover the pharmacy's cost of obtaining Medi-Cal price quotes from the state). The program covers all prescription drugs and is open to all Medicare beneficiaries, regardless of age or income. Thus, there are no complicated and administratively costly procedures for eligibility determination, application, and enrollment. Any elderly or disabled person with a Medicare card can walk into any Medi-Cal participating pharmacy and purchase a prescription at a price that does not exceed the Medi-Cal price plus the small processing fee.

The discount program required few changes by the state other than revising the Medi-Cal claims processing data system at pharmacies to allow pharmacists to access the Medi-Cal price for a prescription drug without submitting a claim. The costs to the state for the pharmacy assistance discount program are minimal.

The Medicare beneficiary will save money if his or her pharmacy had been charging a higher rate than the Medi-Cal rate. Complexity arises from the fact that pharmacies can charge cash-paying customers whatever they like for any drug. They could be charging more—or less—than the Medi-Cal rate for any given drug. Therefore, a Medicare beneficiary may or may not save money on any given prescription depending on what had been previously charged in that particular pharmacy.

Eligibility

California's Prescription Drug Discount Program is open to all Medicare beneficiaries in the state, regardless of age, income, or insurance status; however, the intended population for the discount program is all cash-paying Medicare beneficiaries—that is, Medicare beneficiaries who do not have prescription drug coverage under Medicare+Choice plans, Medigap, Medi-Cal, or

other health plans. The state has estimated that 1.3 million cash-paying Medicare beneficiaries will use the program, basing that estimate on the number of California Medicare beneficiaries (3.8 million) and national estimates of the percentage of older persons without prescription drug coverage (35 percent). [22] In addition, some sources said, California Medicare beneficiaries *with* prescription drug coverage may also benefit from the discount program (e.g., if they have reached their annual or monthly drug benefit cap, if their insurer does not cover the drug they need, or if they are paying off a deductible before coverage begins). Beneficiaries with Medigap drug coverage are also likely to benefit because, typically, their coverage requires that they first pay retail prices and then send in their claims for reimbursement.

One consumer advocate noted that some disabled Medicare beneficiaries have been denied the discount at pharmacies. Some pharmacists apparently were unaware that the discount applies to *all* California Medicare beneficiaries, including disabled beneficiaries as well as elderly beneficiaries.

Benefits

California's Prescription Drug Discount Program offers all Medicare beneficiaries in California an opportunity to obtain virtually any prescription drug at the Medi-Cal payment rate for that prescription—plus the 15 cent processing fee. These rates are available at any pharmacy that participates in the Medi-Cal program. The Medi-Cal payment rate for a prescription varies, but on average, it is equal to the *average wholesale price* (AWP)[23] minus 5 percent, according to officials at California's Department of Health Services (DHS), the agency responsible for running the Medi-Cal program. The processing fee paid by the beneficiary covers the pharmacy's cost of contacting Medi-Cal for pricing information on the drug.

Virtually every prescription medication is covered under the program.[24] There is no restricted formulary. There are no forms to fill out, and there is no prior authorization. To receive the Medi-Cal discount, all a California Medicare beneficiary has to do is show the pharmacist his or her Medicare card when purchasing a prescription drug, then pay for the prescription.
The discount offered does not include the Medicaid drug manufacturer rebate.[25] The rebates earned by the California Medicaid program total nearly $700 million annually, according to DHS officials. As reported by legislative staff and DHS respondents, the discount program did not attempt to also extract a rebate, because this was thought to increase implementation costs and to

[22] The state utilized national estimates from a 2000 study by Poisal and Chulis of the percent of older persons without prescription drug coverage because no reliable state estimates are available (J.A. Poisal and G.S. Chulis, "Medicare Beneficiaries and Drug Coverage," *Health Affairs* 19, No. 2, 2000). Other studies report that about half of older persons lack coverage at some point in the year (see B. Stuart, D. Shea, and B. Briesacher, "Prescription Drug Costs for Medicare Beneficiaries: Coverage and Health Status Matter," The Future of Medicare—Issue Brief, The Commonwealth Fund, New York, January 2000). Note that the number of older persons without drug coverage may be smaller in California because of the higher managed care penetration in that state.

[23] The *average wholesale price* (AWP) is the price that prescription drug manufacturers suggest that wholesalers charge retail pharmacies. Drug manufacturers generally offer lower prices or rebates to favored purchasers, such as large insurance companies or governments, meaning that those customers pay significantly less than the AWP. Source: Families USA, Glossary of Terms, available at http://www.familiesusa.org/media/pdf/18_Glossary.pdf

[24] The discount program includes all prescriptions covered by the Medi-Cal program.

[25] On October 10, 2001, California enacted Senate Bill 696, which authorizes the California DHS to negotiate voluntary rebates from manufacturers for the Prescription Drug Discount Program. The resulting rebates will be passed along to program participants as additional savings. See Chapter 696, Statutes of 2001. *An act to amend Section 4426 of the Business and Professions Code, and to add Division 111 (commencing with Section 130400) to the Health and Safety Code, relating to health, and making an appropriation therefor*. October 10, 2001

add political complications that could obstruct the bill's passage. Officials at DHS did not indicate how the Medicaid rebate might affect the discount if it had been included, but since the total amount of rebates offsets about 25 percent of the state's total Medicaid drug expenditures, including the value of a rebate could significantly lower the price for consumers.[26]

Funding Sources and Costs

The costs of California's Prescription Drug Discount Program are borne primarily by the pharmacies that participate in Medi-Cal, which includes 95 percent of California pharmacies. The state-mandated discounts under the program reduce Medi-Cal participating pharmacies' profit margin for cash-paying Medicare beneficiaries. Because California's Prescription Drug Discount Program is a discount program rather than a subsidy program, the state does not have to allocate any funding for benefits. The estimated and actual costs to the state of the discount program in 2000 are shown in Table 3-2.

Table 3-2: California's Prescription Drug Discount Program: Estimated vs. Actual Costs to the State, 2000

Item	Estimated Cost	Actual Cost*
Software development costs**	$200,000	$200,000
Personnel: 2 full-time equivalent (FTEs)	$200,000	$200,000
Costs paid to contractor for Medi-Cal price quotes provided to pharmacies for Medicare beneficiaries	$1,300,000	$144,000
TOTAL	**$1,700,000**	**$544,000**

* Actual costs are annualized based on expenditures as of December 2000.

** Software development is a one-time cost. The cost of software development to revise the Medi-Cal claims system and develop an interactive Web site

Source: Interviews with Kevin Gorospe and Len Terra, California Department of Health Services, September 2000.

California's DHS originally estimated that ongoing administration of the discount program would cost the state $1.7 million annually, an amount that was to come from DHS's existing budget. This estimate was apparently too high, because the actual costs of the discount program in 2000 were expected to be only about $544,000. This figure includes $200,000 for software development (a one-time cost); $200,000 for two full-time equivalent personnel; and $144,000 paid to Electronic Data Systems, the subcontractor for claims processing in the Medi-Cal program, for every Medi-Cal price quote requested by pharmacies for Medicare beneficiaries.

The actual cost to revise the Medi-Cal claims processing software to allow pharmacies to access a Medi-Cal price quote without submitting a claim, and to develop an interactive Web site for state residents listing Medi-Cal prices for prescription drugs, was about $200,000, as DHS originally estimated. The Web site that will allow individuals to identify the Medi-Cal price for

[26] This 25 percent proportion is based on projections for FY 2000-2001 provided by the California Department of Health Services. Medicaid rebates were projected at approximately $700 million while total Medicaid pharmacy expenditures were projected at $2.8 billion. Personal communication, Kevin Gorospe, California Department of Health Services, December 2000.

most commonly requested drugs and is being developed by DHS in response to complaints by elderly state residents in public forums and in complaint calls to legislators and DHS that they were receiving inaccurate price quotes from the pharmacies. According to interviews with key stakeholders, many of these complaints were the result of consumers' misinterpretation of the law or misunderstanding about the "benefit". Their misunderstanding was complicated by both the complexities of Medi-Cal pricing and the fact that the Medi-Cal discount was not as large as many of them may have expected. Nonetheless, to stem the increasing frustration of older residents, the DHS has agreed to develop a website that will allow individuals to identify the Medi-Cal price for most commonly requested drugs. At the time of this case study, DHS officials planned to include all 70,000 Medi-Cal prices (representing combinations of drug, strength, dosage, and manufacturer) on the Web site. Since then, however, DHS has amended this plan. In November 2000, California's DHS publicly released the unit Medi-Cal prices of the 50 most requested drugs in the discount program.[27] A broader interactive Web site to include the top 200 drugs is under development.

For two full-time equivalent personnel for California's Prescription Drug Discount Program in 2000, the DHS estimate was $200,000, which corresponds to actual costs. Legislative staff contend that the cost is actually lower than this, because two full-time equivalent personnel are not working exclusively on the discount program.

The costs of Medi-Cal price quotes provided to pharmacies for Medicare beneficiaries were originally estimated by DHS at about $1.3 million in 2000. When the case study was conducted, the number of Medi-Cal price quotes requested for Medicare beneficiaries was substantially lower than had been projected, as the state had been processing about 600,000 price quotes per month, or an estimated 7.2 million annually, at an annual cost of only $144,000. In arriving at the $1.3 million estimate for price quotes, DHS had based its estimate of volume of price quotes on 1999 Medi-Cal prescription claims data indicating that Medi-Cal enrollees age 65 and over fill an average of about four prescriptions per month (although DHS acknowledged that Medi-Cal beneficiaries might use more prescriptions than Medicare beneficiaries). Assuming that Medicare beneficiaries similarly fill four prescriptions a month, DHS calculated, there would be 60 million price quotes in the first year (1.3 million cash-paying Medicare beneficiaries x 4 prescriptions/month x 12 months/year). Given the 2-cent processing fee per price quote, DHS calculated that this volume of price quotes would cost the state $1.3 million a year. (The bill's sponsor's lower estimate of the volume of price quotes, which came closer to the actual volume, was based on estimates in testimony to the U.S. Congress that elderly Medicare beneficiaries use an average of only 2.3 prescriptions every three months.)

To minimize the costs of the program, no money was specifically allocated for outreach and education to consumers about the California Prescription Drug Discount Program. The California State Board of Pharmacy has invested some time in informing pharmacists about the discount program and in responding to calls from them. This expense is probably minimal. Initially, the bill's sponsor installed a toll-free number in her office to take consumer calls. The calls on the toll-free number were later transferred to the state's Health Insurance Counseling and Advocacy Program (HICAP). No new funds were allocated to respond to these calls.

[27] http://www.dhs.ca.gov/mcs/mcpd/MBB/contracting/sb393/index.htm

Administration

Application and Outreach

There is no application process for California's Prescription Drug Discount Program. Any person with a California Medicare card is entitled to the discounts at Medi-Cal participating pharmacies.

When California's pharmacy assistance discount program was announced in late 1999, it generated press coverage that created visibility and awareness about the program. According to California's DHS, the agency's initial outreach efforts included providing multiple announcements to Medi-Cal pharmacy providers, sending information to federal Medicare officials and the California State Board of Pharmacy, and contacting HICAP for assistance in educating Medicare beneficiaries about the new program. Notification was also provided through the California State Board of Pharmacy quarterly newsletter (published in April 2000), in guidelines for pharmacies, and in a consumer brochure.

The Drug Discount Program was implemented in only three months, in part because consumer advocates and legislators were eager to provide relief to Medicare beneficiaries as soon as possible. The statute did not specify plans for continued consumer education and outreach. Thus, community-based advocacy groups such as HICAP have taken on much of the responsibility for outreach. These organizations, which according to a HICAP representative and several consumer groups were already under-funded for their existing insurance counseling mandate, absorbed the costs of outreach and education, which particularly at the outset of the program were sizeable.

Officials from state agencies thought that a three-month implementation period was too short to fully inform pharmacies and providers of the program or to get the Medi-Cal pricing software in place. In fact, according to the California State Board of Pharmacy, some pharmacies did not have the pricing software in place on the February 2000 start date of the program and many pharmacists did not understand what their obligations were to provide the discount. Their obligations were later clarified in the Board of Pharmacy's April newsletter, but pharmacists' lack of knowledge at the outset of the program resulted in some confusion and frustration on the part of consumers.

While many of the sources we interviewed in California believed that the Prescription Drug Discount Program had been well publicized through the extensive press coverage at the outset of the program, consumer advocates said that outreach could have been much better, particularly in rural communities. They suggested that the Medicare beneficiaries who need the program the most—the low-income and uninsured—are the ones who probably know the least about it. As one advocate commented:

> "[Such individuals] have no access to computers and are less likely to have access to the state or HICAP programs. People in some kind of network are likely to have information on the program, but 81 percent of older persons never set foot in a senior center. That's the group that is hardest to reach."

To reach everyone who could benefit, advocates suggested that the Drug Discount Program could have benefited from the same level of outreach funding (about $1 million) that was appropriated to inform low-income families about California's Healthy Families program. Legislative staff acknowledged that if they had to do it again, they might have put some money in for outreach. In fact, after this case study, the bill's sponsor indicated that she would be seeking funds for outreach in 2001.

Publicity through the press also had its downside. The overall impression from those interviewed was that there was a fair amount of misinformation about the program going out to the public initially, which further contributed to consumer confusion and frustration. In particular, overly optimistic expectations of the savings to consumers may have resulted in disillusionment on the part of some Medicare beneficiaries.

Monitoring Prescription Use and Medication Error (Drug Utilization Review)

California's Prescription Drug Discount Program does not use the kinds of monitoring for inappropriate prescribing patterns that have been included in the drug utilization review programs of pharmacy assistance subsidy programs such as the Pharmaceutical Assistance to the Aged and Disabled (PAAD) program in New Jersey or the Low-Cost Drugs for the Elderly Disabled Program (DEL) in Maine.

Although California's DHS modified the Medi-Cal claims database to provide price quotes to pharmacies, it did not tie the price quotes to the drug utilization review (DUR) system used by the Medi-Cal program. In the Medi-Cal program, the claims data system rejects some claims submitted by pharmacists at the point-of-sale for duplicate doses, early refills, therapeutic duplication, and other cost and safety issues.

A representative from the California State Board of Pharmacy asserted that the new Prescription Drug Discount Program might inadvertently contribute to concerns about inappropriate drug utilization. While the Medi-Cal price for brand-name drugs is uniform across pharmacies, prices for generic equivalents vary by manufacturer—and different pharmacies buy from different manufacturers. If a Medicare beneficiary opted to "shop around" at different pharmacies to get the best prices on prescription drugs, then no single pharmacy would have the information on all drugs that the beneficiary was taking in order to assess drug interactions—and this situation could increase the likelihood of medication errors. According to legislative staff, however, the expectation was that the price ceiling created by the discount program, by tending to level prices, might very well reduce "shopping around." One of the anticipated benefits of the discount program, they say, was that if prices were more consistent, Medicare beneficiaries would be less likely to shop around at different pharmacies. The improved continuity of services would reduce the opportunity for medication errors.

Pharmacy Participation and Enforcement

California's Prescription Drug Discount Program requires discounts to be provided by all Medi-Cal participating pharmacies, including retail pharmacies in the community, mail order facilities, and pharmacies located in long-term care facilities operating in the state. Pharmacies just over the California border in Nevada and other states that participate in the Medi-Cal program are also required to provide the Medi-Cal discount to California Medicare beneficiaries. California

pharmacies that do not participate in Medi-Cal do not have to provide discounts to Medicare beneficiaries, but DHS extended access to the price quote system to such pharmacies, both to encourage greater participation in the pharmacy assistance discount program and to avoid restraint-of-trade issues.

There are few mechanisms for monitoring or enforcing pharmacies' compliance with the program. According to legislative staff, the law was not intended to be punitive toward pharmacies and therefore did not include any enforcement component. Legislative staff believed that pharmacies would voluntarily comply with the law, both for competitive reasons and to benefit their clients. Furthermore, the program was intended to have little or no cost to the state, and DHS officials acknowledged that enforcing compliance would be expensive.

DHS has established a complaint telephone hotline and e-mail address to help monitor pharmacies' compliance with the law and answer questions from the public. Consumer advocates were not sure that the complaint process was sufficient for monitoring pharmacies' compliance, but hoped that since several large chain pharmacies have been advertising the pharmacy assistance discount program, competition would help enforce compliance.

As of mid-2001, DHS's telephone hotline had received an average of 30 calls per month with questions or complaints about the Prescription Drug Discount Program—relatively few, given the number of persons eligible for the program. The number of calls to the DHS telephone hotline, however, does not reflect the calls to California legislators, to the California State Board of Pharmacy, or to the HICAP regional offices—all of whom, by most accounts, were inundated with calls in the early stages of the program. Given that the DHS telephone hotline is not toll-free, and that some of the information available on the program does not specifically cite the DHS number (at least one brochure actually cites the California State Board of Pharmacy number), the low call rate may reflect consumers' lack of knowledge or access to the complaint line more than pharmacies' compliance with the law.

About half of the complaints to DHS's hotline have involved an issue not anticipated in the program's development--apparently, some pharmacies were refusing to provide price quotes to consumers over the phone. Since every price quote costs the pharmacy 15 cents to process through the Medi-Cal claims processor Electronic Data Systems, pharmacies do not want to incur that cost unless the consumer actually purchases the drug (in which case the customer pays the processing fee).

DHS claims that the statute establishing the Prescription Drug Discount Program did not authorize the agency to monitor pharmacies to ensure that price quotes were supplied to consumers. However, the California State Board of Pharmacy requires pharmacies licensed in the state to provide up to five free retail price quotes for prescriptions if customers request them in person or over the phone. This potentially obligates the State Board of Pharmacy to enforce the Medi-Cal discount price. According to one representative from the California State Board of Pharmacy, this lack of attention to existing licensure requirements was an unexpected flaw in the bill. The existing licensure requirement that pharmacies provide free price quotes was imposed at a time when providing price quotes had no financial costs to pharmacies; this is not the case in providing Medi-Cal price quotes. The State Board of Pharmacy has informed their membership that it expects pharmacies to provide price quotes for drugs, but they have neither the staff nor

resources to enforce this rule. They also believe having Medi-Cal prices available on-line for easy pharmacy and consumer reference (as the state has done) may reduce this problem.

According to DHS, California's pharmacies are, by and large, complying with the new law. DHS interprets as a sign of pharmacy compliance the fact that an average of 3,600 out of 5,000 Medi-Cal pharmacies, plus 70 non-Medi-Cal pharmacies, access Medi-Cal price quotes each month. Noting that some pharmacies may not be accessing the price quote system each month, DHS considers this a conservative estimate of participation. In January 2001, for example, 3,907 Medi-Cal pharmacies and 103 non-Medi-Cal pharmacies submitted price inquiries. The California Pharmacists Association concurred that most pharmacies are complying.

Program Impact

Awareness

California's Prescription Drug Discount Program does not require enrollment, so there is no mechanism for the state to know exactly how many people are using the program. All the state knows is that pharmacists requested a total of 6,147,905 Medi-Cal price quotes for Medicare beneficiaries (a rough measure of program use) from February 2000 through January 2001—approximately 500,000 price quotes every month—and that the number of price quotes for Medicare beneficiaries is rising. In January 2001, pharmacies submitted 747,549 Medi-Cal price quotes for Medicare beneficiaries—up from an average of 660,194 per month from October to December, and an average of 427,472 per month from February through September. There is also no mechanism for the state to know how many Medicare beneficiaries sought these price quotes or the number of discounted purchases made by Medicare beneficiaries once the quote is requested. The current system allows state officials to see only the number of price quotes requested and the pharmacy's usual and customary price.

The number of Medi-Cal price quotes for Medicare beneficiaries under the discount program is far lower than DHS had originally anticipated, as discussed earlier. On the other hand, pharmacies are not obligated to access the Medi-Cal price quote system each time someone purchases a drug if they already know the Medi-Cal price from quotes given earlier or if they calculate the price differences based on published drug prices. California law only requires Medi-Cal participating pharmacies to charge Medicare beneficiaries no more than the Medi-Cal price; it does not mandate that pharmacists check the Medi-Cal price for every prescription (even though DHS does suggest that pharmacies check Medi-Cal prices regularly since drug prices can change). Thus, Medi-Cal price quotes could substantially underrepresent how many purchases are being made with the discount. If Medicare beneficiaries are requesting several price quotes before they buy a drug, however, the number of price quotes could overestimate the number of purchases.

Consumer Savings

In 1999, at the time the bill establishing the Prescription Drug Discount Program was enacted, the bill's sponsor said that consumer savings of an estimated 20 to 40 percent would result from

the program.[28] This estimate of consumer savings, cited in numerous media reports, was calculated using an example of one consumer's actual market basket of drugs. Legislative staff compared the usual and customary charge for these drugs at one pharmacy with the Medi-Cal rates for these drugs and found a range of savings of 20 to 40 percent.

Most of the sources we interviewed in California felt that the estimated savings of 20 to 40 percent were high. The sponsor's staff did not supply the exact market basket analysis used for the initial cost savings estimate, so it is difficult to assess why the estimate was so high. It may have been because the market basket included a high percentage of generic drugs, which have bigger percentage discounts than brand-name drugs, or because they did not factor in the existing discounts available to older persons through large discount houses (such as Costco or Wal-Mart), mail order companies, or local community pharmacy discount programs.

The people we interviewed highlighted complaints more than praise for the size of the discount. "The discount has not proven to be as much as hoped—the Medi-Cal price is not as low as they thought for specific drugs they are purchasing," commented one community advocate. "This program educated us (consumers) about the limitations of the state's discounts," commented a HICAP representative. It is difficult to determine if these anecdotal complaints represent the broader experience of all cash-paying Medicare beneficiaries or only a vocal minority.

According to the California Pharmacists Association, many pharmacies already offered older adults generous discounts as loss leaders to attract them into the pharmacies to purchase other goods before the program's enactment. In fact, in complaints to legislative staff, some elderly California Medicare beneficiaries expressed surprise and disappointment that they were already paying less than the Medi-Cal rate. DHS suggests that an unexpected consequence of the state's discount program may be that some pharmacies will eliminate their existing discount programs, potentially *raising* prices for Medicare beneficiaries to the Medi-Cal rate. At the time we conducted our interviews, DHS was aware of at least one chain drugstore that had eliminated its discount program and raised its prices.

Some recent analyses, however, suggest that the savings to California Medicare beneficiaries under the Prescription Drug Discount Program may be significant. DHS analyzed Medi-Cal price quote data for 300 to 400 commonly used drugs (those with more than 100 queries), comparing the average retail price entered by the pharmacists with the Medi-Cal price. Based on this analysis, DHS derived an average savings of 24 percent per prescription, with savings ranging from 0 to 70 percent. DHS was only able to provide a copy of an internal e-mail with general information about the analytic approach. As a result, it is difficult to assess the accuracy of this estimate; the number of queries included; the breakdown of drugs included by brand or generic name; and the accuracy of self-reported retail prices. The California Pharmacists Association also conducted an e-mail survey of 75 of its members, comparing the usual and customary charge with the Medi-Cal rate for a market basket of commonly used drugs; they estimated the savings to the discount program to be 10 percent.

[28] "Speier Bill to Cut Prescription Drug Costs," press release from California Senator Jackie Speier's office, October 11, 1999.

Medicare beneficiaries using the Prescription Drug Discount Program are not benefiting from the same net cost savings on prescription drug prices as the Medi-Cal program is able to obtain. Medi-Cal gets a discount on prescription drugs not only in the form of discounts at the level of the retail pharmacy but also in the form of rebates from prescription drug manufacturers based on the volume of drug purchases. The discount on prescription drugs offered to Medicare beneficiaries under California's Prescription Drug Discount Program does not include rebates from drug manufacturers.[29]

Impact on Pharmacies

Pharmacies ultimately bear the costs of California's Prescription Drug Discount, because the program reduces their profit margin for cash-paying Medicare customers. Concerns were raised about the impact the program would have on pharmacies before the law establishing the program was passed. The California Legislature, in response to the pharmacy industry's concerns, passed a separate law phasing out a pharmacy tax of 50 cents per prescription that had been deducted from Medi-Cal dispensing fee payments. The 1999 law establishing the Prescription Drug Discount Program allows pharmacies to charge Medicare beneficiaries the processing fee (15 cents) that pharmacies must pay to get a Medi-Cal price quote from the state. Another provision of the 1999 law, incorporated at the urging of at least one association, mandates that DHS conduct a study to assess the appropriateness of Medi-Cal payment rates to pharmacies for prescription drugs. The pharmacy associations are hopeful that such a study will reveal the inadequacy of the Medi-Cal rate in covering pharmacies' costs and result in higher Medi-Cal reimbursement in the future.

The impact of the mandated retail discounts on pharmacy profit margins is difficult to assess, because it depends on several factors: (1) wholesale prices actually paid by pharmacies; (2) how much pharmacies were previously marking up the prices of prescription drugs for cash-paying Medicare beneficiaries: (3) what share of pharmacies' sales were going to cash-paying Medicare beneficiaries; and (4) the actual Medi-Cal discounted price paid per drug.

Tying the price for Medicare beneficiaries to Medi-Cal pharmacy discounted prices has highlighted the sometimes obscure topic of just what Medi-Cal pays per drug. Medi-Cal discounted prices are typically benchmarked to the AWP. In California, AWP minus 5% is used as a ceiling price for Medicaid drug purchases, and this figure has sometimes been used to characterize the level of the Medicaid discount. However, for products of 11 large manufacturers that account for 60 percent of drugs purchased by Medi-Cal, reimbursement is limited to the *direct manufacturer wholesale price*[30], which corresponds to approximately AWP minus 16.7 percent. Taking this into account, the California Pharmacists Association estimates that the average size of the average Medi-Cal discount is closer to the AWP minus 12 percent.

There is little evidence that the discount program has increased or decreased total revenues to pharmacies. If, as suggested by sponsors of the bill establishing the program, more individuals are increasing the frequency of their retail pharmacy visits as opposed to the frequency of their use of mail order pharmacies, retail pharmacies could be gaining market share from mail order

[29] As noted above, subsequent legislation (Senate Bill 696) authorizes the California DHS to negotiate voluntary rebates from manufacturers for the Prescription Drug Discount Program, with the resulting rebate to be passed along to program participants as additional savings.

[30] The direct manufacturer wholesale price is lower than the AWP paid by pharmacies.

pharmacies and getting more dispensing fees and greater purchase of non-drug items to offset the losses from the pharmacy discount. There has been no evidence thus far that pharmacies have gone out of business as a result of the program, but the program only became operational in February 2000, so it is premature to assess the long-term impact on the pharmacy business.

Impact on Manufacturers

The Drug Discount Program has had no discernible impact on prescription drug manufacturers. As noted earlier, the discount to Medicare beneficiaries under the program is based on mandated discounts at the pharmacy level. Manufacturers took no position on the bill establishing the program, because the cost was intended to be borne largely by pharmacies and there was no discussion by the California Legislature of seeking rebates from drug manufacturers. As footnoted above, the rebate issue was addressed in subsequent legislation that authorizes the California DHS to negotiate voluntary rebates from manufacturers for the Drug Discount Program.

Impact on the Medi-Cal Program

According to legislative staff and one contact within DHS, DHS was concerned prior to the program's enactment that California's Prescription Drug Discount Program could discourage pharmacy participation in the Medi-Cal program and thus possibly limit access to drugs for Medi-Cal beneficiaries. In particular, DHS feared that some pharmacies might decide to stop participating in Medi-Cal rather than suffer the losses of extending the Medi-Cal discount on prescription drugs to Medicare beneficiaries.

As of mid-2001, there were no reports that any California pharmacies have terminated their Medi-Cal participation because of the pharmacy discount program. DHS is hoping to have a clearer picture of the Medi-Cal pricing structure after they complete the pricing study, which is expected to be released in 2002.

Possibility of Crowdout

California's Prescription Drug Discount Program was designed primarily to benefit Medicare beneficiaries without prescription drug coverage—referred to as cash-paying Medicare beneficiaries—rather than Medicare beneficiaries with prescription drug coverage under Medigap, Medicare+Choice, or other retirement health coverage. Since the prices cash-paying Medicare beneficiaries pay for prescription drugs under the discount program are not likely to be as low as the copayments that insured persons pay for drugs, there is probably little likelihood that the program will crowd out existing insurance coverage.

According to at least two sources we interviewed in California, however, some indemnity insurers are trying to use the discount to their advantage and to the advantage of their policyholders by advising their policyholders to ask for the Medi-Cal discount and then submit the discounted bill for reimbursement by the insurer. Other sources we interviewed thought that this practice was rare.

Lessons from California

Although the impact of California's program is difficult to assess, it clearly offers at least some cash-paying Medicare consumers a price reduction on their drugs, at minimal cost to the state. Further research is needed to determine the extent of the savings.

The simplicity of the California program is a source both of strengths and limitations. By creating a program that had minimal apparent costs to the state, advocates were able to get broad bipartisan support to pass the bill. In addition, the simple design reduces burden on consumers and requires very little administrative support. Beneficiaries are automatically eligible and do not have to complete an application to enroll or submit to a means test. They need only to present their Medicare card to a pharmacist to get the discount.

The tradeoff for these advantages is that there is little accountability or capacity to evaluate the program's effectiveness. Almost no funds are available for education and outreach to ensure that consumers are informed of this benefit on an ongoing basis, or for enforcement to assure that pharmacies are actually offering and correctly charging the lower price. The complexities of the Medi-Cal pricing structure in California make this a particular concern. Even once the Web site of prices is made public, it may not be useful to many low-income beneficiaries who do not have computer access. Even those who do have computer access may still have difficulty understanding how to identify the correct manufacturer, dose, and strength to match their prescription.

The original legislation for the Drug Discount Program did not attempt to extract rebates from prescription drug manufacturers, according to state legislative staff and DHS sources interviewed in California, because they thought that doing so would increase program implementation costs and add political complications that could obstruct the bill's passage. Officials at DHS did not indicate how the Medicaid rebate from drug manufacturers might affect Medicare beneficiaries' discount if it had been included in California's Prescription Drug Discount Program. Such a rebate could probably have lowered the price of prescription drugs for California Medicare beneficiaries, however, given that the drug manufacturer rebates were expected to offset about 25 percent of Medi-Cal's projected $2.8 billion expenditures for FY 2000-2001. [31]

As legislative staff in California acknowledged, manufacturer prices account for 70 percent of the cost of a prescription drug. Since retail pharmacy markups typically only account for 25 to 30 percent of the price of a drug, price reductions or discounts imposed at the pharmacy level can go only so far in lowering consumers' prescription drug costs.[32]

---

[31] This 25 percent proportion is based on projections for FY 2000-2001 provided by the California Department of Health Services. Medicaid rebates were projected at approximately $700 million while total Medicaid pharmacy expenditures were projected at $2.8 billion. Kevin Gorospe, California Department of Health Services, personal communication, December 2000.

[32] A pharmacy assistance discount program in Florida requires pharmacies to provide a prescription drug discount to Medicare beneficiaries as a condition of participation in the Medicaid program. Florida's program was challenged in federal court by the National Association of Chain Drug Stores, which argued that the use of Medicaid requires a waiver from the Centers for Medicare and Medicaid Services (CMS)— formerly known as the Health Care Financing Administration (HCFA). Subsequently, the state of Florida agreed to file for a waiver to operate its discount program. The National Association of Chain Drug Stores is continuing to negotiate with the state. Pink Sheet, June 11, 2001.

4. MAINE: ADDRESSING AFFORDABILITY ON MULTIPLE FRONTS

Overview

Maine historically has been a front-runner in improving access to prescription drugs, and continues to be so. In 1975, Maine was one of the first states to establish its own direct benefit pharmaceutical assistance program – the Low-Cost Drugs for the Elderly and Disabled Program (DEL) – which, after a long period of stability, has been expanded several times in recent years. The state is currently employing a multi-pronged approach to prescription drug affordability. This case study discusses the features of Maine's initiatives and draws lessons for other states. An overview of these initiatives is presented in Table 4-1.

Maine is a relatively low-income state, ranking 36th in the nation in per capita income (approximately $20,366 in 1998),[33] a fact that likely contributed to widespread concern about prescription drug affordability while constraining the state revenues available to address the problem, even during periods of national economic expansion. Thus, its experience is of particular interest to other states that have recently faced the combination of flat or declining state revenues and growing prescription drug affordability problems for their citizens. Maine state government, as one of the primary insurers in the state through its Medicaid and state employees benefit programs, has been particularly affected by the increasing cost of providing prescription drug coverage. In 2000, the state found that per capita drug expenditures in the state's Medicaid program had been the highest in the country for two consecutive years, and, by October 2000, weekly Medicaid drug expenditures surpassed $4 million.[34] With some drug prices significantly lower in Canada, Maine residents and officials have also been acutely aware of the cross-national disparities in drug prices.

The design and evolution of Maine's initiatives illustrate the tension between efforts to expand the population covered and to control program costs. Maine's experience also illustrates how manufacturer rebates, widely seen as a critical tool for affordability initiatives, can become the locus of conflict between states and the pharmaceutical industry. This conflict became particularly heated in the year 2000 with the enactment of Maine Rx, Maine's ambitious effort to address the problem of prescription drug affordability broadly -- not only for older and disabled persons, but for all of the estimated 325,000 Maine residents who lack prescription coverage or have inadequate coverage. Faced with unmet need for affordable drugs but wary of expanding state-subsidized pharmacy assistance to populations beyond the low-income elderly and disabled because of its experience with spiraling Medicaid drug costs, the state moved from a strategy of covering costs to one of reducing costs without direct public expenditure. Maine Rx was designed to reduce drug prices at no cost to the state, through a combination of mandated retail discounts at participating pharmacies and negotiated rebates with participating manufacturers. [35]

---

[33] U.S. Census Bureau. *Statistical Abstract of the United States.* 1999. http://www.census.gov/statab/www/states/me.txt

[34] A further indicator of rising Medicaid costs is that Maine's Medicaid program currently finds itself in a financial crisis. The state proposed cutbacks in a number of Medicaid program components, including prescription drug coverage; for now, this proposal was rejected (Kaiser Daily Health Policy Report. *Maine Governor Signs Emergency Appropriations Bill; Medicaid Funding Still in Question.* http://www.kaisernetwork.org/daily_reports/rep_hpolicy.cfm February 6, 2001).

[35] The discussion of Maine Rx is based on review of the legislation and other relevant documentation, as well as key informant interviews. However, the regulations for the program had not been released as of June 2001, so that all descriptions of the details of program design and operations constitute descriptions of *planned* design and operations.

At the time of writing, Maine was awaiting the final outcome of a federal court challenge against Maine Rx by the Pharmaceutical Research and Manufacturers of America (PhRMA).

Table 4-1: Maine's Policy Initiatives for Improving Access to Affordable Drugs

Initiative	Description	Status (as of June 2001)
Low-Cost Drugs for the Elderly and Disabled Program [DEL] (established 1975, expanded 1997-2000)	State pharmacy assistance program covering low-income persons aged 62 and over and all adult disabled persons. This program has recently expanded eligibility, covered conditions, and covered drugs.	Operational
DEL-Related Medicaid Waiver (submitted 2000)	Application to HCFA to extend Medicaid eligibility for the elderly and disabled up to 185 percent of the federal poverty level to give the DEL population Medicaid coverage for all prescription drugs.	Awaiting waiver from CMS
Maine Rx (2001)	Program to reduce prescription drug prices for Maine residents. Combines mandated discounts at participating pharmacies with negotiated rebates from the manufacturers.	Operational, but undergoing court challenge
Medicaid Waiver: Healthy Maine Prescription Program (2001)	Entitles those with incomes up to 300 percent of FPL to purchase drugs at the Medicaid discounted price less the manufacturers' rebate.	Operational
Tri-State Coalition (*Request for Proposals* issued 2000)	Coalition among Maine, New Hampshire, and Vermont to jointly contract with a Pharmacy Benefit Manager to control costs through aggregate purchasing.	Expected to be operational in early 2002
Northeast Legislative Association on Drug Prices	Coalition of legislators from eight states seeking ways to jointly reduce drug costs.	Coalition under development

In December 2000, Maine's Department of Human Services — concerned about legal challenges to Maine Rx and still determined to serve a larger population while containing state costs — applied for a Medicaid waiver to provide Medicaid discounted prices (including manufacturer rebates) to a significant portion of the Maine Rx target population. That waiver was granted on January 19, 2001, and created the Healthy Maine Prescription Program (HMPP). In February 2002, by which time it had enrolled approximately 110,000 participants, HMPP was upheld in federal district court in a decision that rejected a challenge to the program by PhRMA.

Finally, as shown in Table 4-1, Maine is engaged in other approaches to reduce prescription drug prices as well. In 2000, the state applied for a Medicaid waiver to provide Medicaid prescription drug coverage to the state's elderly and disabled up to 185 percent of the federal poverty level. As of February 2002, they were still awaiting word on this waiver application. Maine also entered into a bulk purchasing agreement with Vermont and New Hampshire, and is working

with a group of eight states to find ways to jointly reduce drug costs. The three-state collaboration was promoted by the executive branches of the states, while the eight-state initiative is being coordinated by state legislators. Maine has also recently considerably expanded its use of prior authorization in the Medicaid program in an effort to reduce prescription drug costs in that program.

This case study of Maine focuses on the three recent developments of greatest importance — the DEL expansions between 1997 and 2000; the enactment of Maine Rx; and the HMPP waiver program.

Low-Cost Drugs for the Elderly and Disabled (DEL)

DEL was one of the first state pharmacy assistance programs, and in its original incarnation was limited both in terms of the population served and the drugs covered. DEL is a popular and effective program, as measured by current enrollment levels, high manufacturer and pharmacy participation, the recent expansions in eligibility and coverage, and the broad support for its growth. However, its design and evolution also illustrates the tension between the impetus to expand the population covered and the push to control program costs.

Eligibility

As of this writing, all older and disabled persons with incomes less than 185 percent of the federal poverty level are eligible for the DEL Basic Program. For Maine residents who spend more than 40 percent of their income on prescription drugs, the income threshold is raised to 210 percent of the federal poverty level (see Table 4-2). When a DEL enrollee has third-party coverage for prescription drugs, the DEL program is the payer of last resort. DEL's current eligibility requirements are significantly different from those in place only a few years earlier and for much of the program's history (see Table 4-3). The DEL program originally offered state assistance to help poor older residents age 62 and over and disabled persons age 55 and over to pay for drugs for cardiovascular and respiratory diseases. Income eligibility was set by statute; it was not referenced to the FPL but in 1975 approximated 130 percent of the federal poverty level for a person living alone and 120 percent of the federal poverty level for a household of two. With minor adjustments to income levels, these eligibility criteria remained in place until the last few years, when eligibility was extended to include low-income disabled adults over the age of 19 (enacted in 1997 and implemented in 1999), and the income eligibility threshold was increased to 185 percent of the federal poverty level (added in 1999).

Benefits and Consumer Cost-Sharing

Since January 2000, DEL has had two benefit programs that vary by the degree of consumer cost-sharing (see Table 4-4). The Basic Program covers up to 80 percent of the cost of generic drugs for all conditions and name brand drugs for 14 disease conditions, with the consumer paying either $2.00 or the remaining 20 percent (whichever is greater). Under the Supplemental plan, drugs that are not available through the Basic Program, but that are deemed medically necessary, are sold to DEL enrollees at the Medicaid rate, with the state paying $2.00 of the cost. Both programs will only pay for drugs from manufacturers that agree to provide a rebate.

Table 4-2: Eligibility Criteria for Maine's Pharmacy Assistance Programs

Program	Eligibility Criteria
Low-Cost Drugs for the Elderly and Disabled Program (DEL)	Age: 62 and over 19 and over if disabled Income: Up to 185 percent of the federal poverty level Up to 210 percent of the federal poverty level for persons who spend more than 40 percent of their income on prescription drugs Coverage: Payer of last resort
Maine Rx	Open to all Maine residents
Healthy Maine Prescription Program (HMPP)	Age: No age limits Income: Up to 300 percent of the federal poverty level Coverage: Must lack prescription drug coverage, with the exception that those in DEL can use for "wrap-around"

Table 4-3: Recent Changes in DEL Program Features

Program Change	Year Enacted/ Month and Year Implemented
Eligibility Program Changes	
Lowered minimum eligibility age for disabled persons from age 55 to age 19.	1997/ August 1999
Raised income limits from approximately 130 percent of FPL to 185 percent of FPL; income limit is 25 percent higher if prescription drug out-of-pocket costs exceed 40 percent of household income.	1999/ August 1999
Benefit Changes	
Expanded Basic Program coverage from drug treatments for four chronic conditions to treatments for 14 conditions; enrollee pays $2 or 20 percent of drug cost, whichever is greater.	1999/ August 1999
Created a Supplemental Program, which provides a $2 discount off the Medicaid rate for all medically necessary drugs not covered under the Basic Program that are supplied by participating manufacturers.	1999/ August 1999
Added coverage of all generic drugs to the Basic Program at a $2 or 20 percent copayment.	1999/ August 2000
Created a Catastrophic Coverage Program that covers all prescriptions at a $2 or 20 percent copayment (whichever is greater) after an enrollee has spent $1,000 out of pocket in a year.	1999/ August 2000

Source: Rutgers Center for State Health Policy Survey of State Pharmaceutical Assistance Programs, December 2000 and key informant interviews.

The program also has a catastrophic benefit. Once an enrollee has reached an annual out-of-pocket spending limit of $1,000, the program will pay up to 80 percent of the costs of all medically necessary drugs supplied by participating manufacturers, regardless of disease state. The consumer pays $2.00 or the remaining 20 percent (whichever is greater).

This benefit is considerably more comprehensive than what was available through DEL for most of the program's history. The original program paid only for drugs for respiratory and circulatory conditions. Before 1999, only two other conditions had been added, but in that year the number of fully covered conditions was increased from 4 to 14 conditions[36] and the Supplemental plan was added to provide coverage for other conditions. To contain costs, however, this coverage was more limited than for the Basic program, with the state contributing only $2 towards the cost of each prescription. In 2000, all generic drugs were added to the Basic Plan. Despite these expansions, some consumer advocates cite the restriction of full coverage to 14 conditions in the Basic Plan as a serious limitation, as costly brand name drugs for some conditions, such as cancer, are covered only by the Supplemental program.[37] Catastrophic coverage was added in 2000.

In an attempt to restrain program costs, DEL was changed in the early 1990s, constituting the one major change in program design before the recent expansions. The co-pay was changed from $10 to the current level (the greater of 20% or $2), and generic substitution was mandated, unless the prescribing physician writes "dispense as written" on the prescription.

Funding Sources and Costs

The DEL program is financed entirely through state funds and manufacturer rebates (see Table 4-5). The state contribution, which comes from both general revenues and, since 1999, tobacco settlement funds, amounted to $17 million in fiscal year 2000, a $10 million increase from the year before.

Increases in expenditures prior to the expansion were relatively modest, with expenditures totaling $3,643,259 in FY 1996, $3,453,484 in FY 1997 and $3,994,328 in FY 1998 — a 10 percent increase from 1996 to 1998. However, a number of observers stated that increasing state costs and the potential for further increases were a source of concern in the DEL program. This was one of the reasons that policymakers created Maine Rx, rather than further expanding DEL, and was the state's motivation in applying for a Medicaid waiver. The increase in state expenditures from 1999 to 2000 may be due for the most part to the increase in enrollees and enhanced benefits. It remains to be seen what the actual rate of expenditure increase will be with an even more expanded range of drugs included in the program. One observer believes that covering program costs will become difficult in the near future.

---

[36] These conditions are diabetes; heart disease; high blood pressure; chronic lung disease (including emphysema and asthma); arthritis; anticoagulation; high cholesterol; incontinence; thyroid disease; osteoporosis; Parkinson's Disease; glaucoma; multiple sclerosis; and ALS (Lou Gehrig's Disease). Maine Department of Human Services, Bureau of Elder and Adult Services, *Prescription Drug Assistance: A Guide to Maine Elders and Adults With Disabilities*, March 2000. http://www.state.me.us/dhs/beas/medbook.htm#lowcost.

[37] As of June 2001, there was a bill before the Maine legislature to add coverage of brand name cancer drugs to the DEL program (LD1303, An Act to Increase Access to Health Care).

Table 4-4: Benefits Offered by Maine's Pharmacy Assistance Programs

Program	Features
Low-Cost Drugs for the Elderly and Disabled Program (DEL)	• **Basic Program:** Pays up to 80 percent of costs of drugs used for 14 disease conditions, and all generic drugs. Enrollee pays either $2 or 20 percent, whichever is greater. • **Supplemental Plan:** Provides coverage for medically necessary drugs not covered under the Basic Program. Enrollee pays Medicaid price minus $2. State pays $2.
Maine Rx	• Price reduction for drugs for which state has negotiated a rebate with drug manufacturers. • Mandatory price discounts for all drugs by 2003, if prices have not been reduced sufficiently. • No direct subsidy from the state.
Healthy Maine Prescription Program (HMPP)	• Price reduction for drugs for which state has negotiated a rebate with drug manufacturers, equal to price that state Medicaid program pays to pharmacies, less the average manufacturer rebate. • No direct subsidy from the state.

According to officials at DHS, manufacturer rebates for the DEL program are identical to those of Medicaid, approximating 15 percent of Average Manufacturer Price.[38] Rebates offset about 20 percent of total costs in 1999. This figure includes rebate collections that the state recovers from manufacturers for drugs covered through the Supplemental Program, even though the state pays only $2.00 per prescription toward their cost (compared to 80 percent for drugs covered under the Basic Program).

Manufacturer rebates in DEL have been the source of some conflict. A legislative initiative in the 1996-97 session to increase the DEL rebate to 21 percent of AMP drew considerable opposition from manufacturers. Representatives of PhRMA contended that providing a higher rebate to DEL could have a ripple effect, since federal Medicaid law requires manufacturers to provide Medicaid rebates of AMP minus 15 percent or "best price",[39] whichever is lower. PhRMA contended that if the DEL rebate were increased, manufacturers would have to extend DEL's "best price" to Medicaid programs nationwide (although Title XIX of the Social Security Act explicitly excludes the FSS and state pharmacy rebates from the "best price" requirement).[40] As a result of manufacturer opposition, the legislation that was passed called for the Department to solicit voluntary rebates, which by most accounts had little impact. However, the inability of the state to reach an agreement with the pharmaceutical manufacturers helped set the stage for the introduction of the Maine Rx bill two years later.

---

[39] "Best Price" refers to the lowest price offered by a drug manufacturer to any other customer, excluding Federal Supply Schedule prices, prices to state pharmaceutical assistance programs, and prices that are nominal in amount. See National Pharmaceutical Council, 1999.

[40] Social Security Act, 42 U.S.C, Title XIX, §1927 subsection (c)(1)(C)

Table 4-5: Funding Sources for Maine's Pharmacy Assistance Programs

Program	Features
Low-Cost Drugs for the Elderly and Disabled Program (DEL)	• State funds – General revenues – Tobacco settlement funds • Drug manufacturer rebates
Maine Rx	• State funds – Tobacco settlement funds used for start-up costs only • Drug manufacturer rebates – Sole revenue source for operational costs – Used to reimburse pharmacies for part of discount that they provide to enrollees
Healthy Maine Prescription Program (HMPP)	• $25 enrollment fee – Used to finance administrative costs • Drug manufacturer rebates – Used to reimburse pharmacies for part of discount that they provide to enrollees – Same as Medicaid rebate

Administration

Application, Eligibility Determination, and Outreach

The Bureau of Medical Services, which administers Medicaid in Maine, is also responsible for overall administration of the DEL program, the Maine Rx program, and HMPP (see Table 4-6). For the DEL program, eligibility determination is assigned to Maine Revenue Services, the state's tax agency, in order to reduce the potential stigma of applying for public assistance. Maine has also worked to make the application process as seamless as possible by merging it with the rental/property tax refund that is available annually through the Bureau. Those who apply for the rental/property tax refund and are eligible for DEL will automatically be sent a DEL card. Reapplication is required every 18 months, and those who are already in the program are automatically sent an application to renew.

Prior to the DEL expansion, the Governor's 1997 Task Force on Improving Access to Prescription Drugs for the Elderly, concerned about program takeup, had advocated expanded public education efforts. In response, the DEL expansion was accompanied by increased efforts at outreach, and included an allocation of $100,000 for program marketing over the next three years.

DHS now conducts extensive outreach for DEL. The Bureau of Elder and Adult Services has worked closely with local agencies such as the Area Agencies on Aging (AAA), the State Health Insurance Assistance Program (SHIP), and Community Action Agencies (that provide low-

income of all ages with heating assistance) to promote the DEL program. DHS conducts ongoing pharmacist education programs. Physician education was carried out initially, although not on a continuous basis. Finally, the Commissioner makes a public service announcement on television every year to remind the public about the DEL program.

Table 4-6: Application, Eligibility Determination, and Outreach for Maine's Pharmacy Assistance Programs

Program	Eligibility Criteria
Low-Cost Drugs for the Elderly and Disabled Program (DEL)	• Overall administration by Maine's Bureau of Medical Services (agency that administers Maine's Medicaid program) • Eligibility determined by Maine Revenue Service (state tax agency) • Outreach conducted by Maine's Department of Human Services (DHS)
Maine Rx	• Eligibility (i.e., Maine residency) determined by Maine's Department of Human Services. • Outreach conducted by Maine's Bureau of Medical Services
Healthy Maine Prescription Program (HMPP)	• Eligibility coordinated by Maine's Bureau of Family Independence (which determines Medicaid eligibility) and the Maine Revenue Service • Outreach conducted by Bureau of Medical Services

Monitoring Prescription Use and Medication Error (Drug Utilization Review)

DEL, Maine Rx, and HMPP all participate in Medicaid's drug utilization review (DUR) process. The programs employ tracking of adverse reactions and point-of-sale monitoring for possible drug-drug interactions, therapeutic duplication, high or low doses, early refills, and generic equivalents. The system also steers patients to generics. Beginning January 1, 2001, three key changes were instituted: (1) more prescriptions require prior authorization; (2) name-brand drugs can only be prescribed in 34-day supplies vs. 90 days for generics; and (3) some medications known to become ineffective after long use now have supply limitations. While pharmacists and physicians argue that prior authorization could create harmful delays and otherwise impede patient access to needed drugs, DHS has argued that all prescription requests will be addressed in 72 hours or less, and that physicians can insist on drugs that are medically necessary for their patients.[41]

Pharmacy and Manufacturer Participation

Pharmacy participation in the DEL program is voluntary. However, according to both DHS and pharmacy representatives, all of Maine's 300 pharmacies have chosen to participate. Pharmacy groups have some concerns about DEL, but have generally supported it, as well as participating in it. Some attributed pharmacists' favorable stance towards the program in part to their concern for their clients. Furthermore, according to state officials and pharmacy representatives, pharmacies benefit from DEL because it provides a reliable payment source at a more reasonable

[41] Michael O'D. Moore, "Medicaid to require cheaper drugs." *Bangor Daily News*, December 5, 2000.

reimbursement rate (Average Wholesale Price (AWP) minus 10 percent plus the standard $3.35 dispensing fee) than many other payment sources. An important issue in program implementation and impact, however, is the ability of the state to reimburse pharmacies in a timely fashion. Pharmacy representatives and officials from DHS noted that the state was significantly delayed in reimbursing the pharmacies for DEL prescriptions filled last year, and one respondent claimed that payment delays have occurred fairly regularly.

There was a difference of opinion among those we interviewed about the reasons for and length of the delays. Pharmacy officials said that the program ran out of money in February 2000, and that pharmacies were not reimbursed by the state until the new budget year started in August. They claim that the state had not appropriated enough money to cover the expansion in eligibility, although pharmacy groups had asked the legislature to make a special effort to provide additional funding for overdue reimbursements. DHS officials said the delays were much shorter — only three months — and were due to temporary cash flow problems resulting from delays in recovering rebate monies from manufacturers. Whichever is true, as program costs continue to grow and as Maine Rx is added to the roster of state programs, payment delays could be a serious ongoing problem, particularly when added to current pressures placed on small independent pharmacies by market forces. As in other states, the number of small pharmacies in the state has declined, although the number of chain pharmacies remains stable.

As do pharmacies, virtually all prescription drug manufacturers choose to participate in DEL. Overall, manufacturers — like pharmacy groups —perceive that they benefit from this program because it provides a reliable source of payment for a pool of people who might not otherwise be able to purchase these drugs. In interviews, manufacturers, like pharmacy groups, expressed their support for the DEL program.

Maine Rx[42]

Enacted in May 2000,[43] the Maine Rx legislation represented an ambitious attempt to meet the state's twin goals of expanding coverage and containing state costs. Maine Rx aimed to address the problem of prescription drug affordability not only for older and disabled persons, but for all of the estimated 325,000 Maine residents who lack prescription coverage or have inadequate coverage. Maine Rx has aimed, however, to do this without the state subsidies of prescription drug purchases that characterize direct benefit programs. The originally proposed legislation for Maine Rx pegged manufacturer drug prices to the Canadian market. However, this bill was revised, due to concerns about a constitutional challenge to that provision. As passed, Maine Rx is designed to reduce drug prices through a combination of mandated retail discounts at participating pharmacies and state-negotiated rebates with participating manufacturers. The program's history thus far, however, reflects the potential impact of legal constraints on the program's goals, as well as exemplifying the struggle over manufacturer rebates.

[42] Note again that Maine Rx remains under legal challenge and that it is unclear to what extent its provisions will ultimately be upheld. As with the litigation over HMPP, outcomes of this litigation will help to define the parameters of permissible state action in the area of drug pricing.

[43] The discussion of Maine Rx is based on review of the legislation and other relevant documentation, as well as key informant interviews. However, the regulations for the program had not been released as of June 2001, making all descriptions of the details of program design and operations descriptions of *planned* design and operations.

Eligibility

Maine Rx, unlike DEL, has no age, disability, or income requirements (see Table 4-2). While the program is technically intended for residents who are not currently insured or are underinsured, anyone who is a resident may enroll. The assumption behind this design is that Maine Rx will never be used in place of other coverage that residents might be able to obtain because the program offers price discounts, not coverage. The target population of uninsured and underinsured Maine residents is estimated to be 325,000.

Benefits and Consumer Cost-Sharing

Unlike the DEL program, Maine Rx provides no direct subsidy to consumers, but rather requires that participating pharmacies provide drugs from participating manufacturers at a discount to be set by the state (see Table 4-4). To be eligible for these price reductions, consumers must apply for a card from the state, and present their Maine Rx card to the pharmacist at the point of sale. The only drugs covered under Maine Rx are those for which the state has negotiated a rebate with manufacturers. According to drug manufacturer respondents, the state originally required drug manufacturers to include all of its drug products in rebate negotiations in order to be deemed participating. However, in an effort to get more manufacturers to participate, the state has provided more latitude, allowing manufacturers to enter into rebate negotiations for specified products.

The initial discounted price for drugs purchased in 2001 under Maine Rx was set in the legislation at the AWP minus 6 percent, plus a $3.35 dispensing fee. In addition, to encourage pharmacy participation, the state pays pharmacies an extra $3.00 processing fee for each transaction. The Maine Rx program was designed to be implemented in three phases, with secondary lower discounts starting in 2002. These further discounts were to be determined by a program advisory commission based on the amount of rebates negotiated.

The stated objective of the Maine Rx program is to bring pharmaceutical prices for participants down to the level in the Federal Supply Schedule (FSS).[44] The law states that if prices have not been sufficiently reduced by the year 2003 (or if there is insufficient manufacturer participation), the third phase of the program — mandatory retail discounts for all pharmaceuticals — will go into effect. Some respondents suggested, however, that the state did not intend to use the FSS — the lowest price nationally — as the standard by which to activate this trigger, but would accept a smaller reduction.

Funding Sources and Costs

Figure 4-1 is a flow chart of the reimbursement process envisioned under Maine Rx. The Maine Rx program is intended to be supported wholly by negotiated manufacturer rebates once fully implemented (see Table 4-5 above). A portion of the negotiated rebates is for reimbursing the

[44] The Federal Supply Schedule for pharmaceuticals is a price catalog currently containing almost 23,000 pharmaceutical products available to federal agencies and institutions and several other purchasers, such as the District of Columbia, U.S. territorial governments, and many Indian tribal governments" (GAO 1997, p. 4). The Department of Veterans Affairs (VA) negotiates with manufacturers to establish the prices for drugs on the schedule, seeking to establish a price that is equal to the best price manufacturers give to nonfederal customers. U.S. General Accounting Office, *Drug Prices: Effects of Opening Federal Supply Schedule for Pharmaceuticals are Uncertain*. GAO/HEHS-97-60, June 1997. The Federal Supply Schedule price for drugs is not referenced to the AWP set by manufacturers. The Federal Supply Schedule price for drugs is not referenced to the AWP.

pharmacies, although the exact amount to be allotted to pharmacies is to be determined by the advisory commission. The statute includes an initial $4.5 million allocation from the tobacco settlement funds to the program to cover the initial costs of administration, legal challenges, and the additional $3.00 transaction fee. This allocation is considered a loan, to be paid back within five years from the rebate collections.

The initial cost of the discount was designed to be borne by participating pharmacies, who were required to offer Maine Rx cardholders the discount set by the state and would be retrospectively reimbursed by the state for a portion of the discount provided from rebates negotiated with manufacturers. Participation by drug manufacturers in Maine Rx would be essential to the program's success (at least until the imposition of mandatory price-setting in 2003, an eventuality which all respondents, including state officials, hoped would not occur), and the legislation includes powerful sanctions to promote manufacturer participation. The legislation sets the Federal Supply Schedule[45] price as the ultimate goal for the retail price, a level significantly lower than Medicaid prices, and authorizes the state to impose mandatory retail price controls in 2003 if that goal is not reached. The legislation provides the state with two powerful tools to promote manufacturer participation. The first is the requirement that drugs lacking a manufacturer rebate agreement with the state, and therefore not covered by Maine Rx, will be subject to prior authorization in the state's Medicaid program (prior authorization is a new initiative in Maine's Medicaid drug program). Prior authorization does not eliminate dispensing of a particular drug— it can still be dispensed if desired by a physician after consultation with Medicaid -- but it can decrease the volume of sales significantly. Second, the Maine Rx legislation authorizes the state, as a measure of last resort, to invoke Maine's profiteering statute, which makes it illegal to demand an "unreasonable" price when basic human needs are at stake.

Application, Eligibility Determination, and Outreach

Because Maine Rx has no income, age, or disease status eligibility requirements (see Table 4-6), it provided for those wishing to obtain a Maine Rx card to submit applications to DHS providing provide only proof of residency. Outreach for Maine Rx is the responsibility of the Bureau of Medical Services.

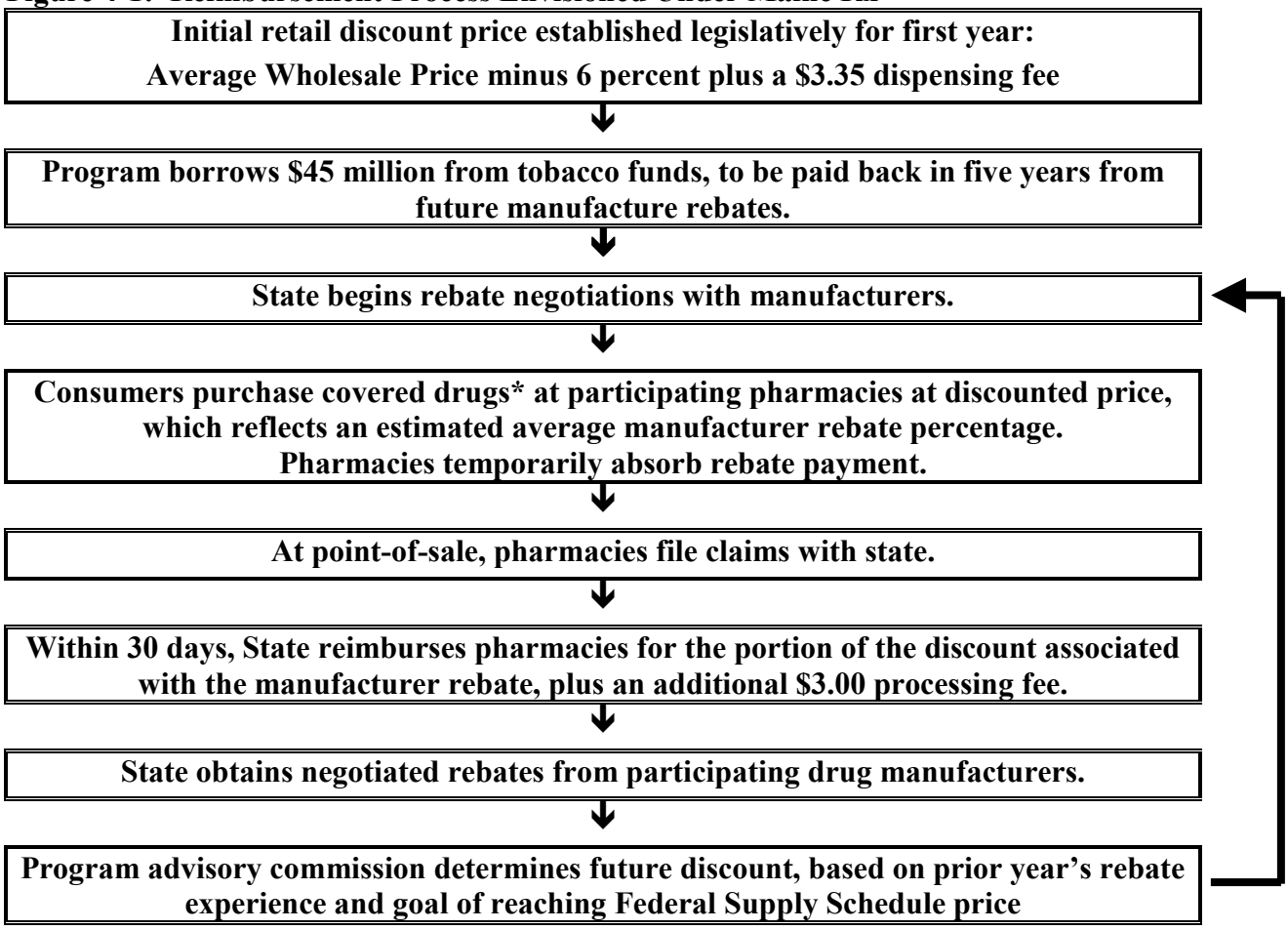
Pharmacy and Manufacturer Participation

Because of the uncertainty created by litigation over Maine Rx, it is difficult to determine what participation would be like if it were fully implemented. Initial response to a state request in 2000 for manufacturers to participate on a voluntary basis was limited, but it is unclear what the response would be if legal uncertainties were resolved. With respect to pharmacy participation, the Maine Rx legislation provided that until 2003, pharmacy participation in Maine Rx would be voluntary. Names of participating pharmacies would be publicized by DHS, thereby creating a public relations inducement for participation. Finally, the state saw the $3.00 additional per

[45] "The federal supply schedule (FSS) for pharmaceuticals is a price catalog currently containing almost 23,000 pharmaceutical products available to federal agencies and institutions and several other purchasers, such as the District of Columbia, U.S. territorial governments, and many Indian tribal governments" (GAO 1997, p. 4). The Department of Veterans Affairs (VA) negotiates with manufacturers to establish the prices for drugs on the schedule. The VA seeks to establish a price that is equal to the best price manufacturers give to nonfederal customers. United States General Accounting Office. *Drug Prices: Effects of Opening Federal Supply Schedule for Pharmaceuticals are Uncertain*. GAO/HEHS-97-60, June 1997.

transaction professional fee as an incentive to participate and, in general, considered current payments to pharmacies under the program to be quite reasonable.

Figure 4-1: Reimbursement Process Envisioned Under Maine Rx



* Covered drugs are those from manufacturers that have agreed to provide rebates. Manufacturers may limit rebates to certain labels.

Status of Maine Rx

After the passage of Maine Rx, PhRMA filed suit against the state, claiming that the program interferes with interstate commerce and violates the supremacy clause of the U.S. Constitution. PhRMA sought an injunction against certain aspects of the program.[46] On October 26, 2000, the U.S. District Court in Maine granted the injunction because of two key provisions of Maine Rx, both designed to influence manufacturer participation: the requirement that drugs not covered in Maine Rx be subject to prior authorization in the Medicaid program, and the authority granted to the state to invoke Maine's profiteering statute against the drug companies.[47] The use of the profiteering statute was viewed as likely to be found unconstitutional because it would be

[46] *PhRMA vs. Commissioner, Maine Department of Human Services et al*. Civil No. 00-157-B-H (United States District Court, District of Maine).

[47] *PhRMA v. Commissioner, Maine Department of Human Services*, 2000 U.S. District Court LEXIS 17363 (D. Me. October 26, 2000).

invoked in regard to manufacturer-distributor transactions, the vast majority of which occur outside the state and therefore are constitutionally beyond the state government's jurisdiction. Use of Medicaid prior authorization to pressure manufacturers for rebates was viewed by the court as an exercise of regulatory power, probably in violation of Medicaid's preemptive requirement that state action "assure that care and services…will be provided in a manner consistent with the best interest of Medicaid's requirements."[48] This injunction created delays in program implementation. However, that decision was overturned by the U.S. First Circuit Court of Appeals in May 2001 on the grounds that Maine Rx regulates in-state activity only and that there was no conflict between the Maine law and the Medicaid statute[49]. This decision was appealed by PhRMA to the United States Supreme Court, and in October 2001, the court delayed the program's implementation, asking the U.S. Solicitor General for more information. The court had not yet decided the case as of March 2002; the outcome of this appeal will determine the ultimate fate of this ambitious legislative effort to reduce drug prices for all uninsured or underinsured state residents, irrespective of age or disability status.

Healthy Maine Prescription Program (HMPP)

Overview

In December 2000, DHS—concerned about legal challenges to Maine Rx but committed to improving prescription drug access and affordability while containing state costs—applied for a Medicaid waiver to provide Medicaid discounted prices to a significant portion of the Maine Rx target population, and to obtain Medicaid manufacturer rebates to subsidize these purchases. On January 19, 2001, HCFA (now CMS) granted the requested waiver, allowing Maine to create the Healthy Maine Prescription Program (HMPP). Despite a looming challenge by PhRMA, this program was implemented by the state, and in February of 2002, HMPP was upheld in a federal district court decision that rejected PhRMA's challenge that the HMPP did not meet the criteria of a Medicaid program.[50] PhRMA had won an injunction against a similar program in Vermont last June. However, Maine's program differs from Vermont's in that Maine subsidizes its program with more than $20 million annually.[51]

Eligibility

The Healthy Maine Prescription Program is open to individuals with incomes up to 300 percent of the Federal Poverty Level. There is no asset limitation (see Table 4-2). It is estimated that the target population numbers 225,000, accounting for about 70 percent of the Maine Rx target population.[52] The eligibility criteria were established to include those not eligible for the full Medicaid benefit package but for whom Medicaid is paying Medicare cost-sharing, i.e., the QMBs (Qualified Medicare Beneficiaries), SLMBs (Specified Low-income Medicare Beneficiaries), and QDWIs (Qualified Disabled and Working Individuals). QDWIs will have the option of participating in HMPP or buying into the full Medicaid benefit package. Those in DEL are eligible to participate in HMPP as well; the latter will provide "wrap-around" discounts for

[48] *PhRMA vs. Commissioner, Maine Department of Human Services et al.,* op cit.

[49] *Pharmaceutical Research and Manufacturers of America v. Concannon*, 249 F.3d 66 (1st Circuit 2001), *cert filed*, 2001 U.S. LEXIS 9140 (U.S. 2001).

[50] *PhRMA v. Thompson*, 2002 U.S. District LEXIS 3029, (D.D.C., February 25, 2002).

[51] Huang, Josie. U.S. judge upholds drug plan for Maine. Portland Press Herald, February 26, 2002, page 1A.

[52] Michael O'D. Moore, "Waiver Issued to Reduce Drug Costs." *Bangor Daily News*, January 22, 2001.

drugs covered under DEL. However, it is expected that only enrollees in the catastrophic part of the DEL plan will take advantage of HMPP, since the basic DEL benefits are more generous than those offered by HMPP.

Benefits and Administration

HMPP is similar in design to the Maine Rx program in that individuals will apply for the program, receive a HMPP card to be presented at the pharmacy, and be eligible for a discount for covered drugs. Covered drugs will be those drugs produced by manufacturers that have entered into Medicaid rebate agreements (see Table 4-4). According to state officials, this includes most major manufacturers.

In addition to the differences in eligibility, Maine Rx and the HMPP differ in the level of the discount and the number of drugs covered. Since most manufacturers participate in the state's Medicaid program, a larger number of drugs is likely to be covered in HMPP than in Maine Rx, at least for the first two years. HMPP provides for enrollees to get discounts from two sources. First, rather than paying the pharmacy's normal retail price, the base price will be equal to the amount Medicaid pays the pharmacy for the particular drug. Second, the base price is reduced further by the average drug manufacturer rebate percentage. For example, if the average rebate is 15 percent, then the enrollee will pay the Medicaid pharmacy payment rate less 15 percent. The pharmacy sends a claim to HMPP to receive reimbursement for that 15 percent, which in turn is reimbursed to HMPP by the manufacturer in the form of the rebate.

Initially, the Medicaid pharmacy discount was expected to be larger than Maine Rx's initial discount, although over time Maine Rx is intended to get better discounts or lower prices than Medicaid.[53] In contrast to Maine Rx, participants in HMPP were also to pay a small annual enrollment fee, estimated to be $25 in the first year of operation.

Under HMPP, pharmacists submit claims to the state using the existing Medicaid infrastructure. As under the Medicaid program, Maine receives a federal match for its expenditures in HMPP. However, when the state receives rebates from manufacturers, the federal government will receive its share of the manufacturer rebates in proportion to the federal subsidy. The state's administrative costs are expected to be part of overall Medicaid costs but will be offset by the $25 enrollment fee.

Eligibility determination for HMPP is coordinated with the Bureau of Family Independence (which carries out eligibility determination for Medicaid) and the Maine Revenue Service (which carries out eligibility determination for DEL; see Table 4-6). This permits the state to identify those HMPP applicants who actually are fully Medicaid-eligible. The Bureau of Medical Services is responsible for overseeing outreach for HMPP. Outreach for the program, like that for Maine Rx, targets consumers, pharmacists, and physicians, using multiple approaches to dissemination. All pharmacies participating in the Medicaid program and DEL are automatically included in HMPP.

[53] The Maine Medicaid payment to pharmacies is the AWP -- the price that prescription drug manufacturers suggest that wholesalers charge retail pharmacies -- minus 10 percent, plus a $3.35 dispensing fee.

Program Impact

As of the time that this case study was conducted, it was not yet possible to assess the impact of HMPP or Maine Rx. The discussion that follows, therefore, focuses on the impact of the DEL expansions.

Awareness. Most respondents interviewed felt that the DEL program is currently well-publicized and that residents are highly aware of it. One state official cited the results of a 1999 survey which found that more than 75 percent of Maine residents over age 55 and nearly 70 percent of all adults were aware that there is a state program that helps low-income persons pay for their prescriptions (although there was no attempt in the survey to differentiate DEL from Medicaid). In contrast, only 65 percent of those over 55 and 53 percent of all adults were aware of Maine's property tax refund.[54]

Despite positive reviews for the program's outreach, some respondents expressed concern that some eligible individuals might be confused about their eligibility and the benefits available to them. In particular, one consumer advocate worried that individuals eligible for DEL might be unaware of their eligibility and subscribe instead to the new Maine Rx program, which would provide much lower cost savings. Many of those interviewed expressed concerns about whether enrollees and pharmacists understood the distinction between the benefits available through the Basic and Supplemental programs. Certainly, many agree that the different levels of coverage in the Basic, Supplemental and Catastrophic programs under the expanded DEL, combined with the existence of new programs, can be confusing to enrollees and prospective applicants.

Enrollment. Based on DHS estimates, program takeup appears to have significantly improved in the wake of the DEL program expansion. While it was estimated that the program expansion doubled the number of persons eligible for DEL, the enrollment actually tripled. The Bureau of Medical Services estimates that, in 2000, about 45,000 individuals were eligible for the expanded DEL program with 41,000 enrolled, in contrast to 13,671 enrolled (and 9,200 active users) out of 21,621 eligible in 1997.[55] Before the expansion, enrollment had actually been declining in DEL, falling from 16,249 in 1996 to the 13,671 enrolled in 1997.

It should be noted that takeup rates are difficult to validate. We were unable to determine the basis for the state's estimate of program eligibles, and, in fact, estimating eligible enrollees is an extremely difficult task. Perceived changes in takeup pre- and post-program expansion could be entirely or in part the result of changes in the method of estimating eligibility or differences in the degree of error in the process.

Many of those interviewed thought that DEL's high enrollment rates were due, in part, to the process of applying through Maine Revenue Services, which is viewed as reducing program stigma and automatically puts all applicants for rental/property tax refunds into the DEL applicant pool. The 18-month enrollment period was also credited with keeping enrollments up.

---

[54] Bureau of Elder and Adult Services Web site. *Summary of selected data from 10/99 survey of Maine adult citizens*. Administered for the Maine Development Foundation by Market Decisions, Inc. http://www.state.me.us/dhs/beas/survey/99survey/statewide.htm

[55] *Final Report of the Task Force on Improving Access to Prescription Drugs for the Elderly*. State of Maine, 118th Legislature, First Regular and First Special Sessions. February 1998.

However, this streamlined, non-stigmatizing process for eligibility determination was in place long before the expansion and does not explain the change in takeup.

One interpretation of the increased takeup is that the $100,000 earmarked for expanded marketing and public education helped raise public awareness of the program. Indeed, some respondents attributed the low DEL enrollment before the expansion to lack of awareness and insufficient public education. Another possible explanation of the increased takeup rate is that the very restricted benefits offered by the program pre-expansion (with coverage of therapies for only four disease states) made it of less interest even to those who were aware of it.

Resolving whether increased enrollment is due to increased awareness, more generous benefits, or both appears to hinge on estimating pre-expansion awareness, which is difficult. Consumer advocates present anecdotal evidence of low awareness before 1998. A large number of applications were submitted to Maine Revenue Services in 1996 and 1997 (56,473 and 44,168 respectively), possibly suggesting high levels of awareness, but we cannot know how many of these applications were motivated by awareness of and interest in the rental/property tax refund and which were motivated by DEL itself. Whatever the distinct impact on enrollment of each aspect of DEL, however, the current benefit design, enrollment, and outreach processes add up to a program to which a large percentage of the target population subscribes.

Consumer Savings. It is difficult to measure the average consumer savings from the DEL program because complete data on the prices and discounts otherwise charged or provided to cash-paying consumers are not available. However, given the discounted price and the fact that the state pays 80 percent of the price, we can assume that DEL enrollees benefit from significant cost savings through the Basic program. Consumer savings from the Supplemental program are, by definition, not nearly as large, since the consumer pays the Medicaid discount minus the $2.00 contributed by the state. The magnitude of the potential savings available depends on the extent to which other discounts, such as pharmacy-provided senior citizen discounts, are available to enrollees.

Impact on Pharmacies and Manufacturers. As described earlier, DEL potentially increases pharmacy and manufacturer volume of sales at a reasonable reimbursement rate. Furthermore, observers suggested that pharmacies — as front-line providers — are unhappy having to turn away those who cannot afford drugs. However, the delays in DEL reimbursement are a concern for pharmacies and could be a particular problem for the small independent stores.

Lessons From Maine

Maine's experience with drug affordability policy reflects both the potential and the limitations of state pharmacy assistance programs. DEL is a popular and effective program, as measured by current enrollment levels, high levels of pharmacist and manufacturer participation, the recent expansions in eligibility and coverage, and the broad support for its growth. However, policy makers felt that it was politically — and arguably fiscally — necessary to trade off expansions in eligibility for those in coverage. The perceived need to contain program costs was also reflected in the increased cost-sharing instituted in the early 1990s.

While a state-subsidized program was created (and expanded) for low-income older and disabled persons, expanding fully state-funded direct benefits to a much larger uninsured and underinsured population was not considered financially viable, particularly in the context of rising Medicaid drug costs. Faced with unmet need for affordable drugs, the state moved to strategies aimed at controlling costs without direct public expenditure (Maine Rx) and to strategies that share the cost of subsidies with the federal government (Medicaid waivers).

However, arriving at a viable strategy for cost control has not been easy. While a powerful grassroots campaign in support of prescription drug affordability was successful in enacting an ambitious price-limitation statute, Maine Rx was, as expected, challenged in court by PhRMA. Constitutional constraints on regulation of manufacturers were considered in the design of the program, but it remains unclear whether it will withstand legal challenges even in its current form, and whether it will be effective if fully implemented. Maine's leadership has shown considerable commitment to its twin goals of expanding coverage while containing state costs, continuing to fight for Maine Rx despite legal challenges and designing other strategies for achieving price reductions, including the Healthy Maine Prescription Program – a program that also encountered legal challenge and may face further appellate litigation. Whatever the outcomes, Maine's story remains a noteworthy one of programmatic innovation in the service of making drugs affordable, and the tensions that accompany those innovations.

5. LESSONS LEARNED FROM THE THREE STATES

Several lessons can be drawn from the experiences of New Jersey, California, and Maine with pharmacy assistance programs that we believe will be of particular interest to other states.

Influence of State Environments on Policy Responses

When thinking about the implications of the experiences from New Jersey, California, and Maine for other states, it is important to remember the old state health policy adage: "When you've seen one state, you've seen one state." Each state approaches the issue of prescription drug affordability in the context of its own political environments, programmatic history, financial resources, and other characteristics.

- In New Jersey, the pharmacy assistance subsidy (direct benefit) program for low-income older adults and persons with disabilities—the Pharmacy Assistance for the Aged and Disabled, or PAAD, program—has a long history, a well-established constituency, broad popularity, and a dedicated revenue stream from casino revenue funds as its financial base. With a comprehensive benefit in place for low-income individuals, the most acute perceived problem recently has been the affordability of prescription drugs to elderly and disabled New Jersey residents with incomes somewhat above the income limits for the PAAD program. Bipartisan support emerged for building on the PAAD program by dedicating part of the new tobacco settlement revenues to create a new pharmacy assistance program—the Senior Gold program—that provides direct benefits to elderly and disabled residents with incomes up to $10,000 higher than PAAD enrollees but requires enrollees to pay a larger copayment for each prescription.
- In California, the fiscal environment imposed great pressure to minimize any new costs to state general funds. This contributed to the state's decision to establish a pharmacy assistance discount program—the California Prescription Drug Discount Program for Medicare beneficiaries—rather than a direct benefit program. It also influenced the state's decision to limit resources allocated for outreach and program enforcement mechanisms. California's response to the drug affordability issue was also shaped by one of its precipitating causes: the withdrawal of Medicare+Choice plans from a number of markets in the California, which resulted in the loss of pharmacy benefits for a socioeconomically diverse population and led to advocacy for state action to alleviate the ensuing financial pressures.
- Maine's proximity to Canada and relatively low median income has made many Maine residents (not just those with the lowest incomes) acutely aware of the problems of prescription drug affordability and cross-national disparities in pricing. The state has a tradition of providing some pharmacy benefits for elderly and disabled people with the lowest incomes through its pharmacy assistance subsidy program—Maine Low-Cost Drugs for the Elderly and Disabled (DEL). Concerns recently emerged about the growing cost of pharmacy benefits, especially in the Medicaid and state employee benefit programs. Advocates and legislators in the state wanted to achieve significant discounts for a broader population: the estimated 325,000 Maine residents without prescription coverage, regardless of income. They recognized that

much of the discount achieved by programs such as Medicaid comes from manufacturer rebates rather than price concessions by pharmacies; and they were willing to face the expected opposition by the pharmaceutical industry (which does not have a large presence in the state) to program designs requiring expanded rebates. Accordingly, Maine's leaders proceeded along multiple fronts: expanding eligibility and the number of drugs covered under the direct benefit program for low-income individuals, while pursuing approaches to making prescription drug prices more affordable for uninsured and underinsured Maine residents without relying on subsidies from the state. Legislation enacted in May 2000 established Maine Rx, a program under which the state was authorized to act as a pharmacy benefit manager to set pharmacy discounts and negotiate rebates from manufacturers for all uninsured persons in the state. When Maine Rx encountered legal challenges, the state applied for a Medicaid waiver to extend the Medicaid prescription drug discount (including both the pharmacy discount and average manufacturer rebate percentage) to state residents with incomes up to 300 percent of the federal poverty level. This led to the establishment of the Healthy Maine Prescription Program (HMPP). Both of Maine's most recently enacted pharmacy discount programs have encountered strong opposition and legal challenges from the pharmaceutical industry; the final outcome of these challenges remains to be seen.

The Importance of Political Leadership

In every one of the case study states, political leadership—commitment to the issue of improving the affordability of prescription drugs by key individuals in leadership positions who were able to build strong coalitions—was a critical element in the success of legislative initiatives (see Appendix B).

Tapping Grassroots Consumer Support

Advocates for state pharmacy assistance programs in each of the case study states were able to tap into grassroots consumer support for the programs to secure their enactment. Advocates made the point that it is unacceptable that some older persons have to choose between buying their heart medicine and paying their rent or meeting other basic needs, an argument that found broad public resonance. Political leaders who stepped forward found that there was a sufficient groundswell of support to overcome resistance, which often confronts the creation of new programs. Where existing programs were in place, they had developed a strong constituency and an impetus for expansion.

- In New Jersey, the PAAD program created in 1975 has long been a popular program, with broad bipartisan support among legislators and regulations, as well as among consumer advocates and the elderly. Because of this support, a substantial share of the state's new tobacco settlement funds was earmarked for expanded pharmacy assistance in 2001-2002, despite many other potential claims on these funds.
- In California, there was coordinated lobbying by a variety of consumer groups for the Prescription Drug Discount Program for Medicare beneficiaries. Consumer groups came in at the final hour to urge state legislators and the governor's office to support the bill establishing the program, and the bill passed with strong bipartisan support.

- In Maine, especially as the prescription drug issue emerged as a high-profile issue, it began to take on many of the aspects of a consumer crusade and to acquire broad-based grassroots support across the state. Ultimately, the Maine Rx plan was enacted with strong bipartisan and overwhelming public support, despite the controversial aspects of the plan's approach to price limitation and manufacturer rebates.

Deciding on the Target Population

A key decision in developing pharmacy assistance programs for state residents is which population or populations the program should cover. For example, should the pharmacy assistance program cover only the lowest income older and disabled persons? Should it cover older and disabled persons with moderate incomes? Should it cover only elderly people? Or should it cover a broader population, such as all state residents who lack health insurance or even all state residents? In some cases, a state may decide, as Maine has done, to adopt a multi-pronged approach that addresses the prescription drug needs of various populations.

Pharmacy assistance subsidy (direct benefit) programs are typically means-tested. Thus, decisions need to be made about what financial eligibility criteria for applicants the program can afford to sustain. Maine and New Jersey both determined the amount of money available and then "backed-in" to the financial eligibility criteria that these resources could support.

State's decisions about which populations should be covered by pharmacy assistance programs are complicated by the lack of good state-level data on eligible populations, particularly on the proportion of specified populations with adequate prescription drug coverage. Data gaps also make it difficult to evaluate takeup rates for existing benefits. Typically, federal health surveys are designed only to generate national, not state-level estimates. For state pharmacy assistance programs, as for other important state-level programs, improvement of national surveys to support state-level estimates could significantly aid in thoughtful program planning and evaluation. State-level surveys are also needed to evaluate beneficiaries' experiences with the program and the extent to which their presence improves access to care and alleviates the prevalence of high prescription cost burden.

Determining the Scope of the Benefit

The scope of the benefit to be offered by a state pharmacy assistance program is another key decision for states. Is the program to be limited to specific types of health conditions and/or prescription drugs? Like several other states, Maine initially limited the cost of its DEL program by covering only drugs used for certain conditions. As of 1996, the state covered drugs for only four chronic conditions. These disease-specific restrictions were debated vigorously in the expansion discussions and were often seen by consumers as arbitrary. In response to these concerns, Maine increased the number of covered conditions from four to 14, added coverage for all generic drugs, and provided a more limited supplemental benefit for other drugs. This example suggests that given the magnitude of the underlying unmet needs, programs that are limited to specific drugs or conditions as a means of controlling program costs are likely to be subject to pressures for expansion over time. Other important decisions related to the scope of

the benefit in a pharmacy assistance program include the structure of copayments, benefit ceilings, and deductibles.

Finally, states need to consider whether—and if so, to what degree—the program will address the needs of persons with catastrophic prescription expenses. The three case study states varied in their approaches in dealing with this issue.

- New Jersey's Senior Gold program includes a provision that once participants' annual out-of-pocket expenses reach a certain level ($2,000 for singles, $3,000 for couples), they pay only $15 per prescription. The state waives the enrollees' coinsurance requirement in such instances.
- California's Prescription Drug Discount Program for Medicare beneficiaries has no special component for individuals with catastrophic prescription drug expenses.
- Maine's DEL Supplemental Program includes a provision that once an enrollee has spent $1,000 out-of-pocket in a year at the discounted price, the state will pay 80 percent of the costs of all additional prescriptions.

Whatever design is chosen for a state pharmacy assistance program, program advocates are naturally motivated to stress the benefits of the program and minimize likely program costs. If expectations exceed what can realistically be provided by a given program design, however, the potential for disappointment exists. In California, for example, some participants were unhappy because the discount offered did not always exceed other discounts available in the market. This experience suggests that it may be prudent to avoid raising unrealistic expectations for new program initiatives.

Importance of Identifying a Stable and Permanent Funding Source

A critical challenge for states that create direct benefit pharmacy assistance subsidy programs is to find a stable and permanent funding source. Direct benefit programs are expensive if they cover more than a narrowly defined population and offer beneficiaries any significant level of economic protection against the costs of prescription drugs. Furthermore, per capita pharmacy expenditures have been increasing far faster than incomes—and indeed, faster than other health care expenditures—so program costs can outstrip targeted revenues even if enrollment does not rise.

- In New Jersey, maintaining PAAD as a relatively generous program was facilitated by the dedication of casino revenue funds to the program (casino revenue funds have increasingly been augmented by state general funds as the PAAD program's costs have increased). When tobacco settlement funds became available as a new source of funds that could be dedicated in part to pharmacy benefits, New Jersey enacted the Senior Gold expansion.
- In contrast, Maine's DEL program relied entirely on general funds until 1998. Without a dedicated funding source, the program was limited in scope, providing relief only to those within 125 percent of the federal poverty level for only a limited number of chronic conditions. When tobacco settlement funds became available as a

new source of funds that could be dedicated in part to pharmacy benefits, Maine moved to significantly expand this direct benefit program

There is some concern that state funds from the settlement with tobacco manufacturers are not a permanent source of funding for pharmacy assistance programs, because the proceeds from the settlement are available for only 20 years. If tobacco settlement funds are eventually replaced by equivalent permanent tobacco tax revenues, there may not be a problem; if not, states whose program rely on such funds may eventually have to cover their pharmacy assistance program commitments with an alternative permanent funding source.

Controlling Program Costs

Managing the costs of direct benefit pharmacy assistance programs is critical for states, as growth in per person pharmacy expenditures is likely to lead to escalating program costs. This same expenditure growth increases the burden on consumers, leading to pressures to expand income eligibility and scope of benefits. In the case of direct benefit programs established for very low-income people, for example, a common pattern has been the creation of a strong constituency for the program and a growing perception that there is a need to expand eligibility to individuals with modest to moderate incomes who find the cost of prescription drugs increasingly burdensome.

Income limitations in many programs have been set at levels that excluded many individuals with chronic conditions that have trouble paying for the cost of their prescription drugs. In Maine's DEL program, the income eligibility had been, for a lengthy period, at a level that corresponds to 120 to 130 percent of the federal poverty line. By 2000, however, the income eligibility limit had increased to about 185 percent of the federal poverty level, notwithstanding financial constraints related, in part, to the absence of a dedicated funding source for the program (a proposal to use a tobacco tax to extend coverage had been vetoed by Maine's governor in 1997).

There are several approaches that states can use to control program costs other than changing eligibility criteria and the scope of benefits. These include modifying the level of consumer cost-sharing, leveraging market share to negotiate or mandate pharmacy discounts and manufacturer rebates, and tightly administering a program. Participant cost-sharing provisions have been a principal method by which states have sought to contain the costs of direct-benefit pharmacy assistance programs:

- In the early 1990s, New Jersey raised the consumer copayment in the PAAD program in response to increased program costs.
- In the late 1980s, Maine increased consumer cost-sharing in the DEL program to make up for a shortfall in state revenues. Maine has also sought to contain costs and encourage use of less-costly drugs by creating differential cost-sharing for different types of drugs. Thus, the state sets relatively low copayments for all generic drugs through the DEL Basic Program, but requires much higher consumer cost-sharing for brand-name drugs (other than those used for a specified list of conditions) made available through the DEL Supplemental Program.

To limit their own costs while assisting a broader target population, states such as Maine and New Jersey are following the example of Medicaid and leveraging their market share to obtain rebates from drug manufacturers for their direct benefit programs (although New Jersey excluded the CPI penalty and thus gets a lower rebate for its PAAD program than for Medicaid). Maine and New Jersey also use Medicaid formulas as the basis for determining their direct benefit program's payment rates to pharmacies. Participation by pharmacies in the direct benefit programs has been high. In Maine, for example, participation has been universal. State pharmacy assistance programs are paying pharmacies amounts that are attractive to the pharmacies, and preferable, in some cases, to payments from private pharmacy benefit managers.

Rebates for Broader Target Populations

An important question for states in designing pharmacy assistance programs is whether to try to extend the price advantages that Medicaid gets from manufacturer rebates to broader populations. Historically, states have been able to secure manufacturer rebates on drugs they pay for on behalf of low-income clients, both in Medicaid and state pharmacy assistance subsidy programs, in which the state typically pays the bulk of drug costs (with some beneficiary cost-sharing). Many states lack the budgetary resources to subsidize prescription drugs for all the low and moderate-income individuals who have difficulty affording prescriptions, however—and recently, states have been exploring new ways to extend the savings associated with drug manufacturer rebates to state residents who are paying for most or all of their drug costs. It is likely that the next several years will see a number of skirmishes between states and drug manufacturers. The boundaries of the rebate system will be tested and states can be expected to explore strategies such as joint actions and federal legislative proposals that strengthen their negotiating positions vis-à-vis drug manufacturers.

Importance of Strong Program Administration

Many sources we interviewed in New Jersey, California, and Maine stressed the importance of strong program administration for state pharmacy assistance programs. They highlighted, in particular, the importance of (1) a skilled program administrator; (2) advisory structures that solicit participation in program development from key stakeholders; (3) developing application and eligibility procedures to minimize stigma; (4) linking state pharmacy assistance program eligibility determination processes with those for other programs; (5) conducting program outreach; (6) effective data and claims processing systems; (7) appropriate use of drug utilization review procedures; (8) timely payment to pharmacies; and (9) developing good systems for recovering funds from Medicare and other third-party payers.

Good Administrator and Advisory Bodies. New Jersey's PAAD program was cited as being especially well administered. The PAAD program's current administrator, they noted, has been in the position for nearly 20 years and has developed a strong, collaborative relationship with all stakeholders. Furthermore, an advisory board made up of consumers, medical providers, and pharmacy and manufacturer representatives advises the PAAD program on programmatic changes. PAAD program managers have repeatedly demonstrated a capacity to develop innovative solutions to programmatic issues that have arisen over the years.

Application and Eligibility Procedures. Keeping application procedures for state pharmacy assistance programs as simple and non-stigmatizing as possible is important. Experience with a variety of programs—the State Child Health Insurance Program, the Qualified Medicare Beneficiaries (QMB), and Specified Low-Income Medicare Beneficiaries (SLMB) programs, and similar means-tested efforts for the near-poor—suggests that uptake of benefits by individuals who are eligible and in need will be impeded if application procedures are cumbersome or perceived as stigmatizing. Each of the states we studied has taken important steps in this direction. In New Jersey and Maine, applications are submitted by mail rather than in person. In California's Prescription Drug Discount Program, anyone who is enrolled in Medicare is eligible for the discount—and there is no separate application process for the discount program. For direct benefit programs, linking eligibility determination with eligibility for other programs is an important tool for simplifying program administration and reducing burden.

Lengthening eligibility periods also simplifies administration and maximizes uptake. In Maine, for example, reapplication is required only every 18 months. In New Jersey, applicants with the lowest incomes need only reapply once every two years, because it is less likely that they will become ineligible. Enrollees with higher incomes are required to reapply annually.

Outreach. Informants indicated that outreach is important, especially for new state pharmacy assistance programs. State residents who may be most in need, such as socially isolated older persons, individuals with limited literacy, and individuals with cognitive impairments of aging, may be unaware of the program. Thus, state pharmacy assistance programs need to use a variety of methods to ensure that the population knows about the program. At least initially, funding needs to be available to support outreach efforts. In California, this was an area that appears to have suffered from emphasis on avoiding any new state costs; legislators and others in the state are now discussing ways to provide funds for outreach.

Effective Data and Claims Processing Systems. To assess the impact of program implementation and inform policy over time, there is a considerable need for better data on program operations, on the experiences of program participants with the programs, and on the extent to which the programs are successful in improving access to pharmaceuticals and reducing costs to consumers. For the discount approach taken by California, it is difficult to determine how many people are using the discount program or how much they are saving, since only price inquiries, not transactions, are processed by the state. This also means missed opportunities to improve the appropriateness of prescription use patterns, such as flagging potential interactions among drugs dispensed by multiple pharmacies.

It is similarly difficult to determine the extent to which California pharmacies are offering the Medicaid discounts and price quotes to Medicare participants. As with outreach and evaluation of program impact, few resources have been made available for enforcement. In both of the direct benefit states (New Jersey and Maine), it is difficult to assess the extent of benefit takeup among those eligible, because of the absence of good, current information on the joint distribution of age/disability status, income, and adequate pharmacy coverage from other sources. For the same reasons, it is also difficult to determine whether some subgroups of eligible citizens are disproportionately unlikely to participate, or to identify barriers to implementation.

State experience with administration of the Medicaid pharmacy benefit has served as the model for many aspects of the management of direct benefit state pharmacy assistance program programs. All three study states developed on-line, point-of-sale systems for authorizing Medicaid prescriptions and processing claims. Both Maine and New Jersey use these systems to pay state pharmacy assistance program claims as well, while California modified its system to provide price quotes to pharmacists. These programs also share price schedules and dispensing fees with Medicaid, and receive similar rebates. Medicaid experience also offers a useful model for drug utilization review procedures, supported by the point of sale systems. Both New Jersey and Maine are implementing these systems with their state pharmacy assistance programs to monitor such issues as drug-drug interactions; therapeutic duplication; high dose; low dose; early refill; and generic equivalents. Thus, states contemplating new programs can benefit from building on existing Medicaid program management systems.

Concluding Observations

The experiences of New Jersey, California, and Maine—each of which has taken its own approach to the issue of prescription drug affordability, reflecting different political, economic, historical, and health policy environments—are well worth consideration by other states contemplating new or expanded approaches to prescription drug assistance. States will face great uncertainty in the next several years. Federal actions, such as new Medicare benefits or possible subsidies for state pharmaceutical assistance programs, may reshape the environment. Judicial decisions (including those related to Maine's initiatives) may redefine the boundaries of viable state action. Market developments such as Medicare HMO withdrawals and benefit changes may affect the nature of the underlying problem of non-coverage. Finally, changes in the economy or in states' revenue pictures may affect their ability to undertake new initiatives. As events unfold over the next several years, it will be important to continue to exchange information among states in this policy area, with its substantial human and economic implications.

APPENDIX A: KEY INFORMANTS INTERVIEWED IN THE THREE STATES

Key informants interviewed for these case studies are identified below.

Key Informants in New Jersey

Senator Robert Singer

Edward Gore,
Staff to Senator DiFrancesco

Kathleen Mason
Director, New Jersey Pharmacy Assistance for the Aged and Disabled (PAAD) program

Frank Mikorski
Vice-Chairman, AARP State Legislative Committee, PAAD Advisory Council

Joseph Riordan
Senior advocate, PAAD Advisory Council member

Jerry Flanagan
Legislative Coordinator, New Jersey Public Interest Group Citizen Lobby

Frank Pelly
Director of Government Affairs, New Jersey Pharmacists Association and PAAD Advisory Council member

Melanie Willoughby
Executive Director, New Jersey Council of Chain Drug Stores

James Carey
Director of State Government, Novartis Pharmaceutical Corporation and PAAD Advisory Council member

Marjorie Powell
Assistant General Counsel, Pharmaceutical Research and Manufacturers of America (PhRMA)

Susan DeSipio
Director, State Health Policy, PhRMA

Key Informants in California

Senator Jackie Speier
California State Senate

Michael Ashcraft
Member of Senator Speier's staff

Leonard Terra
Supervising Pharmaceutical Consultant, Department of Health Services

Janice Hall
Associate Analyst, Department of Health Services

J. Kevin Gorospe
Senior Pharmaceutical Consultant, Department of Health Services

Clare Smith
Executive Director, California Health Advocates

Patrick Luby
Legislative Representative, AARP

Joan Lee
California Gray Panthers

Betty Perry
Public Policy Director, Older Women's League of California

Bill Powers
Congress of California Seniors

Carlo Michelotti
Chief Executive Officer, California Pharmacists Association

Virginia Herold
Assistant Executive Officer, California Board of Pharmacies

Marjorie Powell
Assistant General Counsel, PhRMA

Susan DeSipio
Director, State Health Policy, PhRMA

Key Informants in Maine

Senator Chellie Pingree
Maine State Senate

Representative Joseph Bruno
Maine House of Representatives

Allison Lazos
Legislative Aide, Senate Majority Office

Kevin Concannon
Commissioner, Department of Human Services

Jude Walsh
Director of Quality Improvement, Bureau of Medical Services

John Grotton
Vice President, Good Health Systems

Marcia Pykare
Data Processing Manager, Goold Health Systems

Beth Katz
Department of Human Services

Christine Gianopoulos
Executive Director, Bureau of Elder and Adult Services

John Marvin
Director of Region 1, National Council of Senior Citizens

Mary Henderson
Executive Director, Maine Equal Justice Project

Jean Dellert
Legislative Volunteer, AARP

Christine Burke
Legislative Representative, Maine Community Drug Store Coalition

Jim McGregor
Governmental and Public Affairs Director, Maine Merchants Association

Marjorie Powell
Assistant General Counsel, PhRMA

Susan DeSipio
Director, State Health Policy, PhRMA

APPENDIX B: THE POLITICAL HISTORY OF THREE STATES' PHARMACY ASSISTANCE INITIATIVES

This appendix describes the political history of pharmacy assistance initiatives in the three case study states—New Jersey, California, and Maine.

New Jersey's Pharmacy Assistance Initiatives

New Jersey's pharmacy assistance initiatives include the Pharmaceutical Assistance for the Aged and Disabled (PAAD) Program, a pharmacy assistance subsidy program for elderly and disabled Medicare beneficiaries with low incomes, as well as the recent Senior Gold program expansion, which offers a more limited benefit to elderly and disabled individuals with slightly higher incomes.

Pharmaceutical Assistance for the Aged and Disabled (PAAD) Program

New Jersey's PAAD program was created in 1975 to help near-poor older persons whose incomes were just above Medicaid eligibility and who could not afford the cost of needed prescriptions. According to all who were interviewed, the PAAD program has received consistent, broad bipartisan support among legislators and regulators since its enactment and is strongly supported by both consumer advocates and older persons in the state.

From the outset, the PAAD program has also been supported by representatives of the pharmaceutical industry and pharmacists. This support was fairly important in a state that is home to several pharmaceutical manufacturers. When the program was first introduced, the state had turned to the pharmacist associations to help design the program, and these associations were instrumental in its passage. Respondents from the pharmacist associations said that they supported the program because it provided a definitive source of funding for a population thought likely to be delaying or avoiding purchasing needed prescriptions. Of all the organizations interviewed, none was opposed to the PAAD program, although some were opposed to certain revisions to program design that have occurred over the years.

Senior Gold Program

The legislation to establish the Senior Gold program was initiated by the New Jersey State Senate President in response to concerns raised by constituents that many low- and moderate-income older persons who were only slightly above PAAD income limits were still unable to afford prescription drug coverage. The primary impetus for the introduction of Senior Gold, according to sources we interviewed, was the availability of a new revenue stream through the tobacco settlement. The governor's office had originally earmarked tobacco settlement funds to maintain the existing PAAD program, but consumer advocates vigorously lobbied to have these funds set aside for new benefits, rather than substituted for existing state commitments. Other reasons for the introduction of this program, according to some respondents, included the high-profile press coverage of the rising cost of prescription drugs nationally and lack of Medicare coverage.

The debate about Senior Gold is ongoing. While all of those interviewed support the goal of extending coverage to older persons just above the PAAD limits, there were differing opinions about how best to accomplish this goal. Pharmacists and some legislators supported an expansion of the existing PAAD program rather than the development of an entirely new benefit program that they suggested may be more difficult to administer and less generous than the PAAD program in what it covers. Pharmaceutical manufacturers also have concerns about Senior Gold, although they have not been particularly vocal in their opposition. Manufacturer representatives interviewed who support state coverage for the lowest income older persons contended that any expansion to individuals with higher income levels should be through a private sector option or through a national Medicare benefit. These respondents also expressed concerns that the state was acting hastily given their perception that a Medicare prescription drug benefit could soon be passed. These respondents noted that if the Medicare prescription drug benefit requires a maintenance of effort on the part of the states with pharmacy assistance programs, the state could be locked into the higher expenditures of the expanded program.

In contrast, other legislative respondents were less sure of the immediate passage of a Medicare benefit and believed it was important to act sooner rather than later to provide some relief to low and moderate income older and disabled residents. They believed that the federal government would not penalize states with existing state pharmacy assistance programs by imposing a maintenance of effort requirement on the federal benefit. They also argued that even if Medicare prescription drug benefit required a maintenance of effort by the states, the state could provide a benefit by "wrapping around" a Medicare benefit. With more state funds dedicated, New Jersey would be able to provide a more generous benefit to a larger group of older persons, or possibly extend the benefit to other low-income groups.

Most consumer advocates interviewed supported the bill. While recognizing that Senior Gold provides a more limited benefit than the PAAD program, they felt the program would provide some relief to a broader group of older persons that are also burdened by the high cost of prescription drugs. Consumers also strongly supported the catastrophic coverage feature in Senior Gold.

California's Pharmacy Assistance Initiative: The Prescription Drug Discount Program for Medicare Beneficiaries

A bill to establish California's Prescription Drug Discount Program for Medicare beneficiaries (SB 393) was initially proposed by the chair of the California Senate Insurance Committee, and her lead staff person. This senator has considerable experience in the California Legislature, having previously served in the Assembly. She proposed the bill as one in a series of initiatives to address prescription coverage and pharmaceutical cost issues. Neither she nor her staff saw the discount program as the "answer" to the high cost of prescription drugs in California; rather they described it as a stop-gap measure to alleviate the financial burden of Medicare beneficiaries with no drug coverage who pay cash for their prescription drugs.

According to legislative staff, the bill's sponsor considered four possible policy approaches address high drug costs: (1) limiting markups by wholesalers; (2) creating a state-funded direct benefit program for low-income older persons; (3) seeking price reductions at the manufacturer level through fees; or (4) controlling prices at the pharmacy level. It was felt that there were few

potential significant savings at the level of wholesalers, because there are only three major wholesalers in the state (these are primarily pass-through agencies that take minimal commissions and "do not price gouge" according to legislative staff). According to her staff, the bill's sponsor did not consider a direct benefit program because of the cost of such a program and because it therefore could only serve a limited number of people. Legislative staff and consumer advocates interviewed also suggested that older persons in California were resistant to a means-tested program that could be perceived as a 'hand-out' by the state as a welfare-type benefit. According to legislative staff, controlling prices at the pharmacy level seemed the "best" first approach. Later in the session, the senator sponsored a price-control bill to cap drug prices in the state at Canadian rates. That bill was defeated in committee, according to legislative staff, due largely to strong opposition and heavy lobbying by pharmaceutical manufacturers.

Other California legislators also introduced bills in this session related to pharmaceutical costs and coverage. One assembly member, for example, proposed a direct benefit program for low-income older persons that would be subsidized by a tax on the pharmaceutical industry. According to consumer groups that had supported the bill, the direct benefit program died in committee because the pharmaceutical industry opposed it, claiming that they already paid a state supplemental rebate to the California Medicaid program (Medi-Cal) above and beyond the federal requirement, and that they should not pay for this program as well.

Interviews with most of the key stakeholders suggest that the passage of this particular prescription drug discount bill (SB 393) over other initiatives can be attributed to four factors: simplicity of design, no specific appropriation of state funds for the discount, minimal opposition, and strong legislative support from a legislator with a long history of consumer advocacy and considerable influence. In contrast to other more controversial bills, SB 393 was something of a "sleeper" bill that received significant press attention only after California's governor had signed it; this lack of public attention assisted in its relatively easy passage.

According to a member of the California governor's office and one consumer advocate interviewed, strong bipartisan support was due in part to the fact that rural Republican-held counties were hardest hit by the Medicare+Choice pull-outs. Advocates of the bill argued that it would be cost-free to the state, which appealed to fiscal conservatives. Providing Medicare constituents with what legislative staff estimated as 20 to 40 percent price savings at no cost to the state was a "no-brainer," according to the SB 393's sponsor. While consumer advocacy groups supported the bill and lobbied legislators and the governor at the sponsor's urging, they also strongly supported the direct benefit program sponsored in the Assembly.

The California Department of Health Services (DHS), the agency responsible for running the Medi-Cal program, had minimal involvement in the bill's development. DHS did not openly oppose the bill. However, according to legislative staff and one contact within DHS, they were concerned that the program could discourage pharmacy participation in the Medi-Cal program and, thus, possibly limit access to drugs for Medi-Cal beneficiaries. The Department feared that some pharmacies might decide to drop their Medi-Cal participation rather than suffer the losses that could occur from extending the discount to a much larger group of participants.

Prescription drug manufacturers took no position on SB 393, because the costs were to be borne by pharmacies and there was no discussion of seeking manufacturer rebates. Instead,

manufacturers focused their attention on fighting the Assembly bill and another bill by SB 393's sponsor to peg drug prices to Canadian prices.

The strongest opposition to SB 393 came from pharmacies and pharmacy associations, because the program requires that pharmacies reduce their profit margins for cash-paying customers. However, the senator and her staff were able to defuse some of this opposition. In individual meetings with the California Pharmacists Association, they argued that the discount would bring more older persons into pharmacies and away from mail order, thereby increasing the volume of sales—both drugs and other items—which would offset some of the losses incurred by the discount. The senator's staff also argued that the price based on the Medi-Cal discount is still a fairly generous rate, and that while pharmacies might see their profit margin reduced relative to retail sales, they would not be losing money as they did with some of the private insurance companies' negotiated discounts.

The pharmacy environment in California may have contributed to the somewhat restrained opposition to the prescription drug discount bill. According to several accounts, pharmacies in the state, particularly the independent pharmacies, have been resisting trends toward the use of mail-order prescriptions, Internet drug purchasing, large discount houses like Costco and Wal-Mart, and the expansion of large chains. In addition, as in most states, the pharmacy lobby in California was split among several different associations representing chains and independents. Given the widespread support for the prescription drug discount bill, it was difficult to consolidate effective opposition against a likely popular program for older residents.

In response to the pharmacy lobby's concerns, the California legislature passed a separate bill to phase out a 50 cent per prescription pharmacy tax that had been deducted from Medi-Cal dispensing fee payments since 1995 to make up for a budget shortfall. They also allowed the pharmacies to charge the customer a 15-cent data processing fee that pharmacies would need to pay to get the Medi-Cal price quote from the state. At the urging of at least one association, the legislature also included a provision that DHS conduct a rate study that assesses the appropriateness of Medi-Cal rates to pharmacies. The associations are hopeful that such a study will reveal the inadequacy of the Medi-Cal rate in covering their costs and may result in higher Medi-Cal reimbursement in the future. The week that the governor signed the bill, the California Pharmacy Association issued a media release supporting the bill.

Maine's Pharmacy Assistance Initiatives

Maine's has several pharmacy assistance programs: the Maine Low-Cost Drugs for the Elderly and Disabled (DEL) program and the Maine Rx and the Healthy Maine Prescription Program (HMPP).

Expansions of the Maine Low-Cost Drugs for the Elderly and Disabled (DEL) Program

Maine's Low-Cost Drugs for the Elderly and Disabled (DEL) was one of the first state pharmacy assistance subsidy programs in the country. For many years its enactment in 1975, pressures to further improve state residents' access to affordable prescription drugs in Maine were largely offset by fiscal concerns. By the end of the 1990s, however, the economic upturn and the earmarking of the tobacco settlement for health-related programs gave state officials somewhat more flexibility in their efforts to improve state residents' access to affordable prescription drugs.

In 1997, a governor's task force was charged with studying ways to improve drug affordability for seniors. Maine's Task Force on Improving Access to Prescription Drugs for the Elderly was chaired by the Maine Senate Majority Leader, who would later sponsor the Maine Rx program. Several state legislators and consumer advocates served on the task force, and it was staffed by Maine's Department of Human Services. Several of the task forces' recommendations were subsequently implemented. These included (1) increasing DEL outreach and education; (2) seeking a Medicaid waiver to bring the DEL population into Medicaid drug-coverage, and (3) after significant debate over the tradeoff between expanding eligibility and expanding coverage, making DEL a more comprehensive benefit while moderately expanding eligibility.

According to interviews, there was broad bipartisan legislative support, the backing of the governor, and stakeholder support for expanding Maine's DEL program. To some extent, this support was facilitated by the earmarked tobacco revenues. Pharmacy groups were supportive, despite DEL's limits on the retail prices of prescription drugs, because pharmacists were likely to benefit from the increased volume of sales. Similarly, prescription drug manufacturers perceived potential benefits from consumers' increased purchasing power. In fact, during debates over the Maine Rx plan, the manufacturers proposed an even greater expansion of the DEL program as an alternative to the Maine Rx program.

Maine Rx

The Maine Rx legislation, in contrast to the DEL expansions, was strongly opposed by manufacturers and, in the final hours when the bill had changed, by pharmacy groups. A broad grassroots coalition—including seniors, labor, women's groups and religious organizations—supported its passage. This coalition, spearheaded by the Maine Council of Senior Citizens, also included other advocacy groups for the older persons, the state employees' union, the AFL-CIO, women's groups, and religious organizations. These supporters sought the legislative leadership of the Senate Majority Leader, who only a few years earlier had unsuccessfully fought manufacturers in an attempt to increase DEL rebates, and had witnessed a request by the state for voluntary increases by manufacturers go virtually unanswered.

Together, these advocates backed a bill that pegged manufacturer drug prices to the Canadian market. While this bill passed both houses in response to overwhelming public sentiment, the Governor, who supported the concept of providing more affordable access to prescription drugs, was concerned about a constitutional challenge to the bill. After consulting with the Attorney General and the Commissioner of Human Services, the governor convened an ad hoc committee to rewrite the bill with the aim of withstanding legal challenge. In eight days, together with constitutional experts, they designed S.P. 1026, "An Act to Establish Fairer Pricing for Prescription Drugs," which would create what is now known as Maine Rx. It was introduced on the next-to-last day of the legislative session, and passed the following day, with the groundswell of public opinion forcing the hand of some reluctant legislators.

The revised bill was felt by its designers and supporters to be an improvement over the original in a number of ways. First, its stated aim was to use a 'market-based' strategy of negotiating rebates with the drug manufacturers rather than price-setting, making it a more acceptable approach ideologically. Second, it avoided the constitutional issues raised by pegging prices to a non-U.S. standard. Third, by having the state negotiate rebates with manufacturers and impose

price controls at the retail level, it aimed to avoid the interstate commerce issues raised by directly regulating the wholesale transaction, generally an out-of-state event. While the new bill did ultimately compare prices to the Federal Supply Schedule, proponents viewed this as intrastate commerce, since that schedule is used by the Veterans Administration hospitals within the state. However, as described earlier, the Pharmaceutical Research Manufacturers of America (PhRMA) has filed suit against the state, claiming that the program constitutes state regulation of interstate commerce and violates the supremacy clause of the U.S. Constitution.

Opponents of Maine Rx criticized both the rapidity with which it was introduced and passed was well as its content. Critics—especially pharmaceutical manufacturers, pharmacy groups, and the business community—argued that the bill does not substitute negotiation for price-setting, because: (1) the state uses coercive powers to influence manufacturer participation; (2) if 'negotiations' fail, the bill ultimately invokes retail-level price-setting as a last resort in 2003; and (3) the legislation sets retail prices for participating pharmacies in the interim. Pharmacy groups noted that while they did not oppose the original bill because it was focused on manufacturers' prices, the new bill shifted the onus of the price discount onto the pharmacies, a change which they would have fought if given the opportunity. In addition to their concerns over the future of price-setting, pharmacy groups also expressed concern about the ambiguities in the amount they will be reimbursed and the possibility of reimbursement delays. Business interests in general feared that the bill's price-setting provisions establish a dangerous precedent for the regulation of other businesses.

In explaining the passage of Maine Rx legislation, some observers see an important contextual factor to be the relative political weakness of the pharmaceutical industry in Maine. These observers cite two reasons for this weakness. First, there is little pharmaceutical manufacturing in the state. Second, campaign finance reform laws limit the amount that large industries such as drug manufacturers can contribute to political campaigns. The passage of the Maine Rx bill is also attributed to leadership in the grassroots, political, and bureaucratic sectors, and to the power of the grassroots campaign, which—among other strategies—took advantage of the state's proximity to Canada to dramatize price differences. Respondents noted that many legislators who opposed the bill in private session, were, because of public sentiment, afraid to vote against it. Finally, in part because of the compelling campaign waged on its behalf, the bill was revised and passed with a rapidity that disarmed opponents.