TAKE AS DIRECTED: PRESCRIPTION DRUG OPTIONS FOR HAWAII'S UNINSUREDS

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FOREWORD

This study was prepared in response to House Concurrent Resolution No. 129, H.D. 1, S.D. 1, C.D. 1 (2001). The Concurrent Resolution requested the Legislative Reference Bureau to study the feasibility of a state pharmaceutical assistance program, and include information on Hawaii's uninsured residents, access to prescription drugs, and the experience of other state pharmaceutical assistance programs. The Bureau also was requested to submit proposed legislation to establish a state pharmaceutical assistance program.

The Bureau appreciates the time and effort of all the individuals and representatives of various state departments and agencies, professional associations and organizations, as well as the private sector who met with the Bureau, in person or by telephone, to discuss prescription drug issues and concerns from a variety of viewpoints. Your cooperation made this report possible.

Special thanks are extended to Richard Cauchi, Senior Policy Specialist, Health Program, of the National Conference of State Legislatures in Denver, Colorado for generously sharing his time and knowledge, not to mention his patience and good humor in responding to prolonged questioning during several telephone conferences. We are very grateful. Mahalo nui loa.

Wendell K. Kimura
Acting Director

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Fact Sheet

STATE PHARMACEUTICAL ASSISTANCE PROGRAM

I. Highlights

In recent years, the rising cost of prescription drugs has been a key issue in most state legislatures. The cost of prescription drugs affects public programs, consumers, health care plans and insurers, and private businesses or employers. Hit hardest are individuals who lack drug benefits: the uninsured or the underinsured--most likely to be the working poor, the unemployed, the disabled, and the elderly. These individuals incur significant out of pocket expenses for their prescriptions, often paying two or three times the amount paid by a covered person buying the same prescription drug. In Hawaii, approximately 11% of the population, 123,500 individuals, have no health insurance. An additional number are underinsured and lack drug coverage benefits.

As of January 7, 2001, thirty-one states have established or authorized some type of state pharmaceutical assistance program. Most state pharmaceutical assistance programs use state revenues to provide prescription drugs at a nominal cost to a needy population, generally low-income seniors, and sometimes disabled individuals. To minimize state funding, programs created in the last two years often require somewhat higher cost sharing by participants. Discount prescription drug programs, voluntary buyers clubs, and other options such as bulk purchasing within and across states are being explored as less costly alternatives for states.

A number of states are watching two innovative programs: Maine Rx, a discount program designed to be funded by required rebates from drug manufacturers and pharmacy discounts, and Vermont's Pharmacy Discount Program, established as a section 1115 Medicaid waiver demonstration project that offers discount priced drugs to certain residents not eligible for traditional Medicaid. Both programs have been halted by pending federal litigation.

As an alternative to or in addition to state pharmaceutical assistance programs, several states are establishing programs to educate consumers and prescribers about using cost effective drugs without compromising quality of care. Some programs facilitate participation in public and private patient assistance programs. Other states have established consumer protections for discount drug cards and buyer's clubs or cooperatives. Because each state's experience is different, there is no one-size-fits-all solution. A lack of reliable data on the potential target population in Hawaii, the sometimes conflicting interests of stakeholders, problems facing established and new prescription drug programs in other states, pending litigation, and the sagging economy, both State and national, make designing a state pharmacy assistance program a formidable task for policymakers at this time.

II. Frequently Asked Questions

A. What is a state pharmaceutical assistance program?

Until very recently, the term referred to a state created program that used state revenues to provide prescription drugs at a nominal cost to a target population, primarily low-income seniors and sometimes disabled individuals. Of the 31 states that have created a state pharmaceutical assistance program, 26 use state revenues to subsidize the program.

Although all state-funded programs require cost sharing by participants, approaches vary. Established programs generally require a co-payment that may be as small as $5 for each prescription; some have two or three tier co-payment structures. State-funded programs created in the last two years have required participants to bear a higher burden of the cost, using higher co-payments or co-insurance, deductibles, and benefit caps to minimize state expenses. These programs are often referred to as "state-funded direct benefit programs."

Lately, the term "state pharmaceutical assistance program" has been used to refer to other programs: discount drug programs that use little or no state funds. Discount programs lower drug prices by establishing a ceiling price for drugs, requiring pharmacies to provide Medicaid prices for Medicare beneficiaries, using a Medicaid waiver to establish a demonstration program to provide drugs at discount prices funded by Medicaid rebates. A few states have created voluntary discount drug card programs; others are considering lowering costs by aggregating buying pools in hopes of getting lower prices through increased volume. These programs may be called "state pharmaceutical assistance programs," but they are significantly different from the traditional state-funded direct benefit model. State's costs are low; participant's costs are significantly higher. Some programs are in litigation or not yet operational. Their success or value has not yet been established.

B. What state revenues fund traditional direct benefit programs?

Approximately two-thirds of the direct benefit programs receive some or all of their funding from state general revenues; lottery and casino revenues fund Pennsylvania and New Jersey programs. Eleven states appropriated tobacco settlement funds toward state Senior Pharmaceutical Assistance programs in 1999-2000.

C. What is Maine Rx?

Signed into law in May 2001, Maine Rx is a discount drug program for any resident of Maine who lacks prescription drug coverage benefits, regardless of age

or income. Designed to be self-sufficient, Maine Rx provides access to prescription drugs at discounted prices based on mandatory manufacturer rebates and discounts from participating pharmacies. The two-stage target rebate amounts were initially equal to or better than the Medicaid rebate, and ultimately, equal to or greater than the Federal Supply Schedule price. Drugs from manufacturers who do not enter a Maine Rx rebate agreement were subject to prior authorization in Maine's Medicaid program; names of nonparticipants are public information to be released regularly.

In addition to requiring the Commissioner of Human Services to negotiate the rebates and set the pharmacy discount amounts, Maine Rx also essentially established price controls by authorizing the Commissioner to set "maximum retail prices" for prescription drugs under certain conditions. It also creates the civil offense of illegal profiteering in prescription drugs. Drug manufacturers strongly opposed Maine Rx, filing suit in federal court in August 2000, to halt its implementation.

D. What is the status of the Maine Rx litigation?

The trial court granted a temporary injunction to halt implementation; citing Constitutional violations. Maine appealed. The U.S. Court of Appeals for the First Circuit called it a close case, ruling in Maine's favor. The court found no violation of the Supremacy Clause or the Commerce Clause.

- Maine Rx did not conflict with federal law because the Medicaid law allows prior authorization restrictions, and

- Medicaid prior authorization requirements imposed on manufacturers not participating in Maine Rx would not prevent Medicaid recipients' access to medically necessary drugs.

- Maine Rx regulates only in-state activities, and the benefits appear to outweigh any incidental burden on interstate commerce.

The drug manufacturers have appealed to the U.S. Supreme Court. Undecided whether to hear the case, the Supreme Court has requested a brief on the issues from the Solicitor General to aid their decision.

Litigation is pending and Maine Rx is not operational at the time of this writing.

E. What is the Vermont Pharmacy Discount Program?

On November 3, 2000, the HCFA approved Vermont's request to amend its earlier section 1115 Medicaid waiver to expand the existing VHAP Pharmacy

Program demonstration project by establishing the Pharmacy Discount Program (PDP). PDP provides access to Medicaid drugs at discounted prices to Medicare beneficiaries with incomes 151% of the FPL or more, or any other person with incomes of 300% of FPL or less. Participants pay "Medicaid pricing.., net of the [Medicaid] rebate amount," or approximately 30% less than the cash retail price, claims Vermont.

As a Medicaid demonstration project, Vermont requires drug manufacturers to pay rebates on drugs sold to PDP participants. PDP beneficiaries qualify for prescription drug benefits only under the expanded eligibility of PDP's granted by Medicaid waviers. Since Medicaid demonstration projects established pursuant to a section 1115 waiver are required by federal law to be "budget neutral", requiring no additional state or federal funds, PDP's expanded eligibility requirements allows a greater number of residents access to prescription drugs at discount prices with no new state funds.

Drug manufacturers also opposed PDP, claiming the U.S. Department of Human Services did not have authority to grant the waiver requiring them to pay rebates, and filed suit in federal court. PDP's operation was halted by court order on June 8, 2001, pending resolution of the lawsuit.

F. What is the status of the lawsuit filed by drug manufacturers to stop the Maine Rx program and Vermont's Pharmacy Discount Program?

The trial court denied the manufacturers' request for an injunction; they appealed to the U.S. Court of Appeals for the District of Columbia. The appellate court ruled in favor of the drug companies, agreeing that DHHS had exceeded its authority by allowing Vermont to require rebates sold under the PDP. Medicaid law provides that manufacturers owe rebates on drugs "for which payment was made under the State plan." The court concluded that the rebates did not produce savings for Medicaid and the PDP payments to participating pharmacies were reimbursed by rebates, meaning Vermont made no "payment" under Medicaid law.

Recommendations

(1) Establish a state-funded direct benefit pharmaceutical assistance program to provide prescription drugs to low-income Medicare beneficiaries who do not qualify for Medicaid and have no drug coverage. These programs have an established record of success and support, and provide the most benefit to the neediest population;

(2) To minimize state subsidy, require higher cost sharing by participants and use cost control tools such as benefits caps and deductibles;

(3) Alternatively, establish a prescription drug discount card program to provide increased access to prescription drugs at discounted prices;

(4) Establish a clearinghouse/education program for consumers and providers to facilitate awareness of and participation in public and private prescription drug assistance programs; and

(5) Expand use of federally qualified health centers and safety net providers eligible to purchase prescription drugs through the federal section 340B discount drug program to increase access to prescription drugs for low-income residents.

TABLE OF CONTENTS

Page

Appendices

Chapter 1

Introduction

Nature of the Study

During the Regular Session of 2001, the Legislature adopted House Concurrent Resolution No. 129, C.D. 1 (H.C.R. No. 129, C.D. 1), entitled "Requesting the Insurance Commissioner to Convene a Mandated Benefit Advisory Taskforce and Requesting the Legislative Reference Bureau to Conduct a Study on the Feasibility of a State Pharmaceutical Assistance Program." A copy of the Concurrent Resolution is included as Appendix A.

In adopting H.C.R. No. 129, C.D. 1, the Legislature recognized that while prescription drugs are an important element in modern health care, the consistently rising costs in recent years of prescription drugs limits access for some consumers. Individuals who have no prescription drug coverage pay the highest prices. Because Medicare does not include drug benefits, low-income senior citizens and disabled individuals often face difficult choices in spending their limited financial resources.

Many states have developed state pharmaceutical assistance programs to control costs and increase access to prescription drugs. State approaches vary, but common elements exist. At least thirty-one states have established or authorized a program to provide prescription drug assistance, primarily targeting low-income seniors and/or disabled residents. Twenty-six state programs use state revenues to subsidize benefits for participants. Recently, states have considered or authorized other less costly options aimed at making affordable prescription drugs accessible to a greater number of residents. A federal prescription assistance program was announced in July 2001, when President Bush unveiled his proposed Medicare endorsed prescription drug discount card program for Medicare beneficiaries. Implementation of the federal proposal was halted in September by a federal court order. In November 2001, further litigation was stayed by the federal court, giving federal officials an opportunity to submit a redesigned program. The future of the Bush proposal is uncertain. Given the dramatic impact of the September 11, 2001, terrorist attacks on America and the pending litigation that surrounds state pharmaceutical assistance and Medicaid programs in several states, the future of prescription drug issues is uncertain at both the state and federal levels.

H.C.R. No. 129, C.D. 1, requests the Bureau to study the feasibility of a state pharmaceutical assistance program, with an emphasis on Hawaii's uninsured residents, the status of prescription drugs, and other states' experiences in developing and implementing pharmaceutical assistance programs.

Organization of the Study

This study is organized into ten chapters. Chapter 2 provides an overview of the problem: the rising cost of prescription drugs, factors contributing to the increase in prescription

drug expenditures, and the impact of the rising cost of pharmaceuticals on government, business, and consumers. Chapter 3 discusses the uninsured, both nationally and in Hawaii, including the numbers of people who are uninsured or lack prescription drug coverage, characteristics of the uninsured population, the impact of being uninsured; and information on two Hawaii programs currently working to reduce the number of uninsured residents. Chapter 4 describes how individuals obtain prescription drug benefits through public and private health insurance programs, through drug manufacturer patient assistance programs or advocacy programs that assist the uninsured in taking advantage of prescription drug assistance programs for which they qualify. Chapter 5 highlights the findings of a recent study on how federal law affects drug pricing for federal, state, and private pharmaceutical buyers and defines drug pricing terminology. Chapter 6 discusses the basic components of state pharmaceutical assistance programs: who to include; the scope of benefits; funding and cost control mechanisms; and administration, noting program similarities and differences. Chapter 7 looks at the different types of established and new state pharmaceutical assistance programs, with specific examples of each type, as well as the advantages and disadvantages to each approach. Chapter 8 provides a discussion of Maine Rx and Vermont's Pharmacy Discount Program and their respective pending federal lawsuits, including the events leading up to the development of each program, other prescription assistance programs in both states, and the issues being litigated. Chapter 9 discusses other options to lower prescription drug costs. Chapter 10 provides a brief summary of state programs or approaches aimed at increasing the availability of affordable prescription drugs, as well as the Bureau's recommendations. Proposed legislation is included as Appendices B, D, E, and F.

Chapter 2

THE PROBLEM: RISING COST OF PRESCRIPTION DRUGS

Introduction

In 2001, the rising cost of prescription drugs was one of the "hottest" health care issues in legislatures throughout the country. Prescription drugs play an important role in today's health care system. They keep us healthy and improve the quality of daily life by providing safe and quick treatment that may avoid hospitalization or more invasive procedures. They may even save lives. But for those individuals who don't have affordable access to prescription drugs, the much touted benefits of today's pharmaceuticals are of little significance.

Prescription drugs were a hot topic in legislatures because of constant media attention; constituent needs; reports emphasizing the "ominous" increase in pharmaceutical expenditures; and congressional discussions that have highlighted the issue, while providing little product results. States considered a variety of approaches to make prescription drugs more affordable for targeted populations. As of January 7, 2002, thirty-one states have some type of pharmacy assistance program established or authorized. Bills to lower drug costs through state-funded direct subsidy programs or discount programs that establish ceiling prices for drugs, mandate Medicaid prices for Medicare beneficiaries, expanded manufacturer rebate programs that include Medicaid waiver program, bulk purchasing alliances, discount cards and buyers' clubs were considered in at least forty-four states in 2001. Bills are "carried over" to the 2002 session in twenty-four states.[1]

The Rising Cost of Prescription Drugs

The Pharmaceutical Research and Manufacturers of America (PhRMA) has reported that the United States is the largest market for pharmaceuticals.[2] In 1997, the U.S. accounted for more than one-third of global pharmaceutical sales. Expenditures for prescription drugs in the U.S. are rising much faster than total health spending, accounting for nearly 8% of total health spending and 20% of the entire increase in health spending in 1998,[3] and 44% in 1999. In 2000, total retail prescription drug sales totaled $140 billion, up from $121.7 billion in 1999. This is a 16% increase in one year.[4] Estimates project expenditures of $240 billion in 2008.[5]

The growth in retail prescription drug spending is concentrated among a relatively small number of drugs and therapeutic categories of drugs. In 2000, more than half of the $20 billion increase in retail drug spending attributed to higher spending for only eight categories: drugs prescribed for high cholesterol, arthritis, chronic pain, depression, ulcers and other stomach ailments, high blood pressure, diabetes, and a predisposition to seizures. In the same year, these eight categories account for 38% of all drug sales.[6]

Of the approximately 2,000 prescription drugs on the market, twenty-three individual drugs accounted for more than half of the $20 billion increase in spending on outpatient prescription drugs: Vioxx, Lipitor, Prevacid, Celebrex, Avandia, Actos, and OxyContin. Several of these drugs are newly approved; some are new formulations or variations of existing drugs. For example, Vioxx, used for arthritis, had the highest sales growth in 2000. First sold in 1999, Vioxx increased its U.S. sales more than four-fold, from $329.5 million in 1999 to $1.5 billion in 2000. The cholesterol-lowering drug Lipitor was the second best selling drug in the U.S. in 2000. First marketed in 1997, Lipitor retail sales in 2000 increased to $3.7 billion, up 39% from the previous year.[7] A recent study that predicts a 15% to 18% increase in prescription drug expenditures through 2004 also projects that 40% of the increased spending will be for new "pipeline" drugs not yet on the market.[8]

For the fifty best selling drugs, aggregate sales increased nearly 30% in 2000. All other drugs increased sales by 11.4%. The number of prescriptions for these drugs rose 30% and 2%, respectively. The average price of a prescription for the top fifty drugs was $75.88, in contrast to the average price of $35.82 for all other drugs. In 2000, nineteen drugs had retail sales of over $1 billion, up from fifteen drugs the previous year.[9]

Comparing brand name prescription drugs to generics, PhRMA reported U.S. sales of its member pharmaceuticals[10] totaled $81 billion in 1998, while the generic industry reported sales of $8 billion in the same year.[11] The average brand name prescription in 2000 cost $65.29 per prescription, up 8% from an average price in 1999 of $60.66. In 2000, generic prescriptions averaged $19.33 per prescription, up 6% from an average price of $18.16 in 1999.[12]

Using the average estimated retail prescription cost of $45.79 (average of total brand name and generic drugs per prescription), the gross prescription drug income is distributed as follows:[13]

Manufacturer	$34.66	75.7% of cost
Wholesaler	$ 1.05	2.3% of cost
Retailer	$10.07	22% of cost

Prescription Drug Expenditures in Hawaii

Hawaii's Medicaid Fee for Service program spent more than $62 million on pharmaceuticals in 2000. The Medicaid Fee for Service program serves the "aged, blind and disabled" and has approximately 35,000 clients. There are approximately 125,000 Quest recipients enrolled in health plans that provide drug benefits.[14]

Hawaii Medical Services Association (HMSA) and Kaiser Permanente (Kaiser), the two largest health plans in the State, both report that their total cost of prescription drugs has doubled in the last five years and predict costs will double again in the next five years.[15] HMSA's prescription drug expenditures for its members was $182 million in 2000, with future drug costs estimated to increase 18% to 20% per year.[16]

Why are Drug Expenditures So High?

Increasing prescription drug expenditures, the fastest growing segment of health care spending in the country, are generally attributed to a combination of factors. There is no one single reason for increased costs. Speaking to a National Conference of State Legislators' audience, Princeton Professor Uwe Reinhardt attributed the increased costs to price increases (18%); increased use of prescription drugs (43%); and use of new, more expensive drugs (39%).

The use of prescription drugs has accelerated in recent years. In 2000, an average 10.4 prescriptions per person were dispensed, up from an average of 9.9 prescriptions per person in 1999.[17] This increased use and a shift towards the use of new, costlier drugs[18] are the primary factors contributing to increased pharmaceutical spending. A smaller factor is the one-year increase in the price of individual drugs.[19] Of some significance (and of concern to many, including the American Medical Association) is the National Institute for Health Care Management's recent statement that "the 10 drugs most heavily advertised directly to consumers in 1998 accounted for $9.3 billion or about 22% of the total increase in drug spending between 1993 and 1998.[20]

Recent research[21] points to underlying forces that account for the increased use of newer more expensive drugs:

- Better insurance coverage for drugs, including relatively low co-payments that make consumers and physicians price insensitive;
- An increase in the number of prescription medicines available, especially for chronic conditions such as diabetes, arthritis, and asthma;
- An increase in the diagnosis of chronic conditions in an aging population; and
- More aggressive marketing by the pharmaceutical industry to both doctors and consumers.

Drug manufacturers, however, suggest that rising prescription drug costs reflect the increased costs of research and development required to develop new drugs. They contend that industry spending of nearly $2 billion last year on direct-to-consumer advertising produces "greater consumer awareness of drug treatment options". Those who disagree note that the pharmaceutical industry is one of the most profitable industries, reporting a 17% increase in both revenues and assets in 2000, more than any other industry.[22]

Others suggest a lack of appropriate drug usage monitoring may lead to duplication and misuse of drugs, driving up costs. Some claim costs are rising because of increased use of prescription drugs to replace surgery and other invasive treatments and offer therapies not previously available.[23]

In Hawaii, HMSA—the largest health plan in the State—agrees that no single reason accounts for the dramatic increase in the cost of prescription drugs in recent years. HMSA reports a significant increase in longevity of its members. Since persons 65 years and over are known to consume more drugs than younger people, it is not surprising that the drugs that contribute the most to HMSA's total drug expenditures (except for antibiotics) are drugs associated with medical conditions commonly found in seniors.[24]

In testimony presented in August 2001, to the Senate Committee on Consumer Protection and Housing's Informational Briefing on Prescription Drug Costs, HMSA cited more aggressive diagnosis and treatment standards, new technologies, and faster FDA drug approval as factors that contribute to more available drugs in the market that are being used more aggressively and at a greater rate.[25] HMSA noted that direct-to-consumer advertising by drug companies encourages consumers to seek newer medications that are often more costly. As other reports have noted, HMSA also commented that "most consumers (those with drug coverage benefits) are fairly insulated from the real cost of prescription drugs" as a factor in rising prescription drug costs.

At the same senate hearing, Kaiser's representative cited increased utilization and the availability of new drugs that are "as a rule, more expensive" as factors in rising outpatient drug costs.[26]

Impact of Rising Cost of Prescription Drugs

Increasing health care expenditures are driven in significant part by the rising cost of pharmaceuticals. The rising cost of prescription drugs has contributed disproportionately to an increase in health care costs and health insurance premiums,[27] affecting consumers, businesses or employers, and public programs, threatening the health of the public. Rising costs adversely affect the ability of employers and governments to provide health care coverage; uninsured and underinsured individuals face reduced access to medical services including prescription drugs.

Increased prescription drug expenditures is a rapidly growing element of Medicaid spending and state employee health plan costs.[28] In Fiscal Year (FY) 2001, nearly half the states reported that Medicaid spending was exceeding budget levels. Medicaid drug spending more than tripled between 1990 and 1999, increasing 14.8% in 1998 and 17.2% in 1999.[29] According to the Health Care Financing Administration (HCFA)[30] of the U.S. Department of Health and Human Services, prescription drug benefits were, the most used Medicaid service in FY 1998, surpassing even physician services, with Medicaid expenditures of nearly $12 billion in fee-for-service payments for prescription drugs. The elderly and disabled Medicare beneficiaries who qualify for Medicaid services account for 80% of Medicaid prescription drug spending, though they total approximately 25% of the Medicaid population.[31]

Rising prescription drug costs also contribute to increases in federal health care spending by the U.S. Department of Defense and Department of Veterans Affairs.[32]

According to an annual survey of employer health benefit plans by the Kaiser Family Foundation and the Health Research and Educational Trust, premiums for employer-sponsored

health insurance rose an average of 11% in 2001, up from an 8.3% increase the previous year. Drug costs account for one-third of the rise in cost of employer based health insurance in 1999.[33] Nearly two thirds of employers said that prescription drug spending is driving the increases. HMSA cited rising drug costs and increases in use when it increased rates for small businesses, which account for 22% of its total membership. Premiums for small businesses increased 9% on July 1, 2001.[34] Similarly, Kaiser cited rising drug costs, new technology and longer life expectation as factors causing its 3% rate increase on January 2000, following a 2% increase in 1998. In October 2001, Kaiser announced new rate increases averaging 8.7% for small businesses, January 2002.[35]

Many individuals feel the rising cost of prescription drugs indirectly, often through an increase in health insurance premiums.[36] Employers, private health insurers, and managed care plans are shifting the cost to employees and enrollees by requiring higher deductibles and co-payment for prescriptions.[37] When HMSA increased rates for small businesses, it also increased member co-payments for drug benefits to "ease the financial burden on small employers".[38] Already, rising health care costs are driving small businesses in Hawaii to find less expensive alternatives to drug coverage insurance plans. Some are signing up their employees in drug discount programs to save money. Small business owners who can't afford the monthly $30 premium for each employee's supplemental drug coverage instead pay the employee's annual membership fee for the discount program. The annual fee may be less than one monthly premium payment for drug benefits,[39] thus lowering costs for the employer while providing drugs for employees at less than full retail prices. Employer sponsored retirement health benefits are the main source of drug coverage for the elderly, and fewer employees are offering retiree health coverage in 2001.[40]

Those without drug coverage insurance are the most vulnerable to prescription drug price increases. Because they have no power to bargain for discounts, they pay the highest prices for drugs.[41] They pay more than those with drug benefits for the same drug, often paying two or three times more than those with drug benefits—even in the same pharmacy.[42] The uninsured and underinsured are cash customers who are forced to pay the full retail cost of prescription drugs, incurring significant out-of-pocket costs or going without needed medications. To protect this vulnerable population, most often the elderly and disabled, from rising out-of-pocket costs and declining health insurance prescription drug coverage, states are exploring a number of options to improve access to affordable prescription drugs.

Endnotes

1. Richard Cauchi, *2001 Prescription Drug Discount, Bulk Purchasing, and Price-Related Legislation*, Updated January 7, 2002, National Conference of State Legislatures (Denver, CO.: 2002), found at <http://www.ncsl.org/programs/health/drugdisc01.htm>.

2. Pharmaceutical Research and Manufacturers of America, 2001 Pharmaceutical Industry Profile (Washington, D.C.), found at <http://www.phrma.org/publications/publications/profile01/chapter7.phtml>.

3. Sid Socolar and Deborah Socolar, *Making Medicines Affordable: the Price Factor*, Year 2000 Draft policy from Medical Care Section of the American Public Health Association found at <http://www.medicalcaresection.org>.

4. Industry Statistics: National Association of Chain Drug Stores, found at <http://www.nacds.org>. Spending for physician and hospital services account for 32% and 21%, respectively, of the increase "even though they make up larger shares of total spending on health care." The National Institute for Health Care Management Research and Educational Foundation, *Prescription Drug Expenditures in 2000: The Upward Trend Continues* (Washington, D.C.: May 2001), at 3 (hereinafter NIHCM, *Expenditures 2000*).

5. U.S. Department of Health and Human Services, Health Care Financing Administration, *National Health Expenditure Projections 1998-2008* (1998) at Table 12.

6. NIHCM, *Expenditures in 2000* at 6.

7. *Id.*

8. C. Daniel Mullins, Ph.D.; Francis Palumbo, Ph.D., J.D.; Bruce Stuart, Ph.D., *The Impact of Pipeline Drugs on Pharmaceutical Spending*, Center on Drugs and Public Policy, University of Maryland School of Pharmacy (College Park, Md: April 2000), at 3; also found at <http://membership.hiaa.org/pdfs/drugsymposium.pdf>.

9. NIHCM, *Expenditures in 2000* at 6.

10. PhRMA's members include the leading major research intensive pharmaceutical and biotechnology companys. *See* <http://phrma.org/who/>.

11. U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Prescription Drug Coverage, Spending, Utilization, and Prices Report to the President* (Washington, D. C.: April 2000), at 149.

12. Industry Statistics: National Association of Chain Drug Stores, found at <http://www.nacds.org>.

13. *Id.*

14. E-mail from Aileen Hiramatsu, Director of Medicaid, Department of Human Services to Lynn Merrick, Legislative Reference Bureau, September 19, 2001.

15. Testimony of Stacy Evenson, Vice President of Community & Government Relations, Hawaii Medical Services Association, at the Informational Briefing on Prescription Drugs, Senate Committee on Consumer Protection and Housing, August 24, 2001. Testimony of Phyllis Dendle, Director of Government Affairs, Kaiser Permanente, at the Informational Briefing on Prescription Drugs, Senate Committee on Consumer Protection and Housing, August 24, 2001.

16. Testimony of Stacy Evenson, Vice President of Community & Government Relations, Hawaii Medical Services Association, at the Informational Briefing on Prescription Drugs, Senate Committee on Consumer Protection and Housing, August 24, 2001.

17. About 42% of the $20.8 billion increase in retail drug spending from 1999 to 2000 was attributable to an increase in the number of prescriptions dispensed. *See* NIHCM, *Expenditures in 2000* at 2.

18. About 36% of the increase was caused by a change from dispensing of lower priced drugs to higher priced medications, many of which were approved in the last five years. *Id.* at 2.

19. The increase in price of individual drugs accounts for 22% of the increased prescription drug expenditures. *Id.*

20. National Institute for Health Care Management, *Factors Affecting the Growth of Prescription Drug Expenditures*, Research and Educational Foundation (Washington, D.C.: July 1999), at 12.

21. NIHCM, *Expenditures in 2000* at 14.

22. Jeremy Kahn, "The World's Largest Corporations: Global 500 by the Numbers", *Fortune*, July 23, 2001, found at <http://www.fortune.com>.

23. John Kasprak, *Prescription Drug Costs*, Connecticut Office of Legislative Research (Hartford, CT: December 2000).

24. Testimony of Stacy Evenson, Vice President of Community & Government Relations, Hawaii Medical Services Association, at the Informational Briefing on Prescription Drugs, Senate Committee on Consumer Protection and Housing, August 24, 2001.

25. HMSA's average number of prescriptions increased 32% per member in the last six years. *Id.*

26. Testimony of Phyllis Dendle, Director of Government Affairs, Kaiser Permanente, at the Informational Briefing on Prescription Drugs, Senate Committee on Consumer Protection and Housing, August 24, 2001.

27. NIHCM, *Expenditures in 2000* at 3.

28. Joan Henneberry, *States Face Increased Expenditures for Pharmaceuticals*, Issue Brief, NGA Center for Best Practices, Health Policy Studies, February 3, 2000, found at <http://nga.org>.

29. NIHCM, *Expenditures in 2000* at 4.

30. HCFA was recently renamed the Centers for Medicare and Medicaid Services (CMS).

31. 25% of Medicaid drug spending is for aged beneficiaries; blind and disabled beneficiaries account for 55%. In 1998, prescription drug spending for blind and disabled is $1,133 per enrollee and $893 per aged enrollee. In contrast, $142 per enrollee is expended for adult enrollees and $81 per child enrollee. *Medicaid and Prescription Drugs: An Overview* Prepared for the Kaiser Commission on Medicaid and the Uninsured (October 2000), at 8; also found at <http://www.kff.org/sections.cgi?section=medicare>.

32. NIHCM, *Expenditures in 2000* at 3.

33. Health insurance premiums increased an average of 8% in 2000, with increases of 10% to 13% predicted for 2001, due largely to drug costs. NIHCM, *Expenditures in 2000* at 4.

34. *HMSA raising rates 9% for small business as of July 1*, Honolulu Star Bulletin, May 10, 2001.

35. *Kaiser rates to go up 8.7%*, Honolulu Star Bulletin, October 18, 2001.

36. Biweekly premiums for enrollees in the Federal Employees Health Benefits Programs will increase by 13.3%, or $8 each premium payment, next year. Higher costs for prescription drugs and increased use of medical services and technology were cited as primary factors causing the increase by the Office of Personnel Management. *Cost of Drugs, Use of Services, Technology Blamed for Premium Rise*, Washington Post, September 25, 2001.

37. NIHCM, *Expenditures in 2000* at 4.

38. *HMSA to increase rates for small business on July 1*, Pacific Business News, May 9, 2001.

39. For example, the GoodLife Savers Membership discount program that some small businesses in Hawaii have turned to has an annual charge of $19 for individuals and $29 for a family, with no limit on the number of family members covered. *Prescription alternatives gain momentum*, Pacific Business News, September 14, 2001.

40. Kaiser Family Foundation and Health Research and Education Trust, 2001 Annual Employer Benefits Survey found at <http://www.kff.org/docs/ehbs>.

41. NIHCM, *Expenditures in 2000* at 4.

42. In 1997, an uninsured senior spent an average of $30.76 per brand name prescription compared to $9.96 for an individual with drug benefits. *Id. at 5.*

Chapter 3

THE UNINSURED

Introduction

H.C.R. No. 129, C.D. 1, requested the Bureau to provide information on uninsured residents in Hawaii. This chapter discusses how Hawaii residents receive health insurance coverage, who are the uninsured, why they lack insurance, why counting the uninsured is difficult, the impact of not having coverage, and information on the number of residents who have no health insurance or health insurance that does not include drug benefits.

How Many People are Uninsured?

Having health insurance coverage increases the amount and kind of health care an individual may receive. It provides access to diagnostic and treatment services that may prevent or eliminate health problems. It provides financial security. People who don't have health insurance have no usual source of health care. Their health and their finances are at risk.

Counting the number of people who are uninsured is a difficult task. Different surveys produce different results, depending on the questions asked, who is counted, and when the survey is taken. Although surveys may differ in numbers, generally they agree on the basic information or trends. The U.S. Census Bureau's Current Population Survey (CPS) is the survey most often cited.[1]

Reversing a twelve-year trend, the U.S. Census Bureau reported that the share of the U.S. population without health insurance declined in 1999 for the first time since 1987 when comparable statistics were available. Despite a second decline in 2000 from 14.3% to 14.0% of the total U.S. population, more than 38 million Americans still had no health insurance coverage during the entire year. Similarly, the rate of uninsured children (persons under 18 years old) also declined in 2000, from 12.6% in 1999 to 11.6%. Approximately, 8.5 million children, however, still had no health coverage in 2000.[2]

The national decline in uninsured Americans is attributed to an increase in both public and private insurance coverage. A strong economy at that time enabled increased health insurance at work. A growth in public insurance programs helped those with low incomes.

Experts anticipate that the recent increase in Americans with insurance coverage would unlikely continue. At the time of this writing, state and national economies are uncertain and unemployment rates are rising. A decline in the number of insureds is expected to follow the increasing unemployment rates because of the loss of work related coverage. An 11% increase in employer premiums in 2001 is not likely to expand employment-based coverage. Whether public insurance programs will expand coverage to include the increasing number of unemployed or face their own budget cutbacks is uncertain.

Characteristics of the Uninsured

The higher your income, the more likely you are to have health insurance. Almost six in ten uninsured individuals live in families with incomes less than 200% of the Federal Poverty Level (FPL). The poor and near poor are more likely to be uninsured than the total population. Although Medicaid provides health care services for nearly 40% of the poor (persons with incomes below 100% of the Federal Poverty Level), the rate of uninsured among the poor is more than twice as high as the rate for the total population, 29.5% and 14%, respectively. More than nine million poor had no health insurance in 2000.[3] Nearly 27% of the near poor population (those with incomes from 100% to 125% of the Federal Poverty Level), or 3.3 million people, had no health insurance in 2000.

Some groups, including young adults, racial and ethnic minorities, and immigrants, are disproportionately likely to be uninsured for a variety of reasons. Thanks to Medicare, a federal health insurance program for individuals 65 years and older and some people with disabilities, only 0.7% of the elderly (those 65 and older) had no health insurance in 2000. Since Medicare covers virtually all seniors, most of the uninsured persons are under the age of 65. Young people ages 18 to 24 are the most likely to have no health insurance.

Although most Americans under the age of 65 obtain their health insurance through their employer, 75% of all uninsured adults are employed.[4] Certain workers are more likely to be uninsured—part-time workers, those in small firms, or certain industries such as agriculture or construction.[5] The high premium cost of health insurance makes it inaccessible to many low wage workers because they are not offered insurance by their employer and can't afford individually purchased coverage.

Full-time workers are more likely to be covered by health insurance than non-workers. The increase in the last two years in the number of people who have health insurance is largely due to an increase in the number and percentage of people who receive health insurance at work.[6] Among the poor, however, non-workers were more likely to have health insurance than employed individuals.[7] Presumably this is because the unemployed poor are receiving health care under Medicaid, while the working poor often are either not offered employer-based coverage or cannot afford to buy private insurance.

Changes in the rate of uninsureds tend to reflect changes in employment based and public programs. Logically, a strong economy increases the number of nonelderly (under age 65) individuals with health insurance.[8] States with higher than average uninsured rates tend to have higher unemployment and a larger than average low-income population.[9] Similarly, the number of children with health insurance increased as the State Children's Health Insurance Program (SCHIP) was implemented. Nearly two million children enrolled in SCHIP as of September 1999, according to the Health Care Financing Administration, and the rate of uninsured children declined from 15.4% to 13.9% in 1999.

Most often, people are uninsured because they can't afford insurance. Other reasons include: ineligibility for or don't want to take advantage of public programs like Medicaid; not offered insurance at work; or don't know where or how to get insurance coverage.[10]

Additionally, even those individuals who have health insurance may not have outpatient prescription drug coverage. Although virtually all seniors are covered by Medicare, Medicare does not include outpatient prescription drug coverage. Consequently, in addition to the 38.5 million Americans who had no health insurance in 2000, there were at least an additional ten million Medicare beneficiaries (25%) who lacked prescription drug coverage.[11] The uninsured and the Medicare population who have no drug coverage account for 52 million Americans without outpatient prescription drug benefits.[12] For those who have no drug coverage—whether they were uninsured, or underinsured—the working poor, the unemployed, the disabled, the elderly—the high cost of prescription drugs limits their access to needed medications, rendering both their health and financial stability vulnerable.

Impact of No Health Insurance

Uninsured individuals are at risk of consequences that may cause both their health and personal financial condition to suffer. They are less likely to have a usual source of health care, they get less care and later care because they often don't seek treatment until a disease or disorder has progressed. As a result, they often require acute, costly medical attention for conditions that may have been preventable by earlier treatment.[13] Because the uninsured often receive their health care in the emergency room of hospitals that receive federal funding, these hospitals spent $19 billion on uncompensated care in 1998.[14] Such a financial burden hinders their ability to care for all patients. As the Kaiser Commission on Medicaid and the Uninsured noted, "Charitable physicians and the safety net of community clinics and public hospitals do not substitute for health insurance. Lack of insurance clearly matters for the millions of uninsured Americans—affecting job decisions, financial security, access to care, and health status."

Hawaii's Insured Population

Following the national trend, the majority of the insured in Hawaii are covered by employment based insurance plans. More than 93% of persons with private health insurance coverage received it through employment based plans in 1999. State and federal government programs accounted for 33% of the total insured persons. In 2000, Medicare covered 13% of Hawaii's insured, Quest and Medicaid covered 10% and 3% respectively; and Tricare federal coverage for military dependent health care covered 7%. In 1999, 20% of insureds were covered by overlapping health plans.[15]

The two biggest private health plans in Hawaii, HMSA and Kaiser, cover the bulk of Hawaii's insured population. In 1999, HMSA covered nearly 500,000 residents and Kaiser Foundation Health Plan provided health insurance for 210,421.[16] Nearly 160,000 Hawaii residents received health care through the federal Medicare program in FY 1998.[17] Medicare provides health insurance for most individuals 65 years and older and some disabled persons.

Medicaid is a state administered means tested assistance program that provides health care to the low-income population. Hawaii's Medicaid enrollment is 160,000, with approximately 125,000 QUEST recipients enrolled in health plans and 35,000 Medicaid fee for service clients. Approximately 35,000 of Hawaii's Medicaid enrollees are 65 years and older, and are also reflected in the Medicare population.

The Uninsured in Hawaii—No Health Insurance

Approximately 10.1% of Hawaii residents, 117,000 individuals, were estimated to lack health insurance coverage in 2000.[18] In 1999, Hawaii ranked 13th in coverage, nationally. Although Hawaii employers play a larger role in providing health insurance than mainland employers and our uninsured population remains below the United States average of 14%,[19] just two years earlier Hawaii led the nation in having the lowest uninsured resident population.

Generally, Hawaii's uninsured population follows national trends. Given that Medicare covers most Americans aged 65 and over as discussed above, most of Hawaii's residents who have no health insurance coverage also are under 65: 112,360. Men are more likely to be uninsured than women in Hawaii and nationally. In Hawaii, 15% of men under 65 were uninsured, compared to 9% for females.[20] However, Hawaii women under 65 are less likely to be uninsured than the national average of 18% suggests.[21] Hawaii's children are less likely to be uninsured than children nationally. Approximately 9% (29,380) of Hawaii's children ages 18 and under were uninsured in 1997-1999, compared to a national rate of 14%.[22] Hawaii's uninsured population under the age of 65, however, is poorer than the national average, 47% of our nonelderly uninsured have incomes under 100% of the Federal Poverty Level, compared to a U.S. average of 36%.[23]

Uninsured in Hawaii—Health Survey Data 1999

Although the Department of Health's, Health Survey Data of 1999 reports a significantly lower rate of uninsured, 7%, than the U.S. Census' revised 1999 estimate of 10.3%, the Health Survey Data is useful in reporting trends in the uninsured population in Hawaii. The survey shows that the uninsured in Hawaii are more likely to live on the neighbor islands, with the Big Island having the highest uninsured rate of 9.6% in 1999. Following the national trend, the age group most likely to be uninsured in Hawaii is the 18-24 age group, which at a 13.0% rate is twice the 6.2% rate reported for the Hawaii total uninsured population. The survey reported that nearly 25% (12,513) of the uninsured in Hawaii are below poverty level. Caucasians were the most likely to be uninsured, and Japanese residents had the lowest representation in Hawaii's uninsured population.

Hawaii Residents with No Drug Coverage

While data on Hawaii's uninsured population varies from survey to survey, this study assumes an uninsured population of 117,000. These 117,000 residents who have no public or

private health care insurance logically also have no prescription drug benefits. Counting the number of residents who have health insurance but no drug coverage benefits is even more difficult than obtaining an accurate consistent count of uninsureds. Testimony submitted to the Senate Committee on Commerce, Consumer Protection, and Housing at an informational hearing held on August 24, 2001, on the high cost of prescription drugs, reported a variety of estimates of Hawaii residents without prescription drug coverage: 25% of the population; 20% of the population or 228,000 residents; 10% to 20% of the total population (which could be as low as 120,000). The ILWU says there are 50,000 residents in Hawaii who are in the gap group of Medicare and have no drug coverage.[24]

Hawaii's two largest health plans both report 10% of their members have no drug coverage. Of HMSA's approximately total members, 96% of the members who have a private medical plan through their employer have drug benefits. The 10% of HMSA's members who lack drug benefits are primarily seniors whose Medicare plans do not cover outpatient drugs.[25]

This study, estimates approximately 204,000 Hawaii residents to have no drug coverage—whether they are uninsured or underinsured. This figure includes the 117,000 uninsured residents and 87,000 residents with health coverage, but no drug benefit. The 10% of HMSA and Kaiser members who lack drug coverage, and estimates that 10% of Queens and Health Plan Hawaii also lack drug benefits.

Programs to Reduce the Uninsured Population in Hawaii

The Hawaii Uninsured Project

Given the importance of health insurance and recent increases in Hawaii's uninsured population, the HMSA Foundation recently announced "a three year commitment to support public/private organizations in Hawaii willing to work together to find solutions to the problem of the uninsured."[26] HMSA's commitment led to the foundation of the Hawaii Uninsured Project, which has convened two statewide conferences that included health care providers, government officials, nonprofit organizations, philanthropic organizations, and consumers to address the issue.

Hawaii Covering Kids

Covering Kids is a national heath access program for low-income, uninsured children. Hawaii Covering Kids is a three year project funded by the Robert Woods Johnson Foundation to create a seamless health insurance enrollment process for children and youth eligible for QUEST and Medicaid Fee for Service. Approximately 7% of Hawaii's children are uninsured; 22,050 of our children do not have health insurance. The mission of Hawaii Covering Kids is to find and enroll the 14,000 uninsured Hawaii children under the age of 19 who live at or below 200% of the Federal Poverty Level and enroll them in QUEST or Medicaid Fee for Service.

Endnotes

1. Recent changes to CPS surveys resulted in revised health insurance coverage estimates for 1999 that were included in the Census Bureau's recently released estimates. *See* Robert Mills, *Health Insurance Coverage: 2000 Current Population Reports*, U.S. Census Bureau (Washington, D.C.: September 2001) (hereafter Mills, CPR).

2. *Id.* at 3.

3. *Id.* at 6.

4. Statement of Kathryn G. Allen, Director Health Care - Medicaid and Medicare Issues, U.S. Government Accounting Office, on Health Insurance, Characteristics and Trends in the Uninsured Population, U.S. Senate Committee on Finance, March 13, 2001.

5. *Id.*

6. Mills, CPR at 3.

7. *Id.*

8. Employment-based health insurance for the nonelderly population increased from 64.4%to 66.6% between 1994 and 1999. Statement of Kathryn G. Allen, Director Health Care - Medicaid and Medicare Issues, U.S. Government Accounting Office, on Health Insurance, Characteristics and Trends in the Uninsured Population, U.S. Senate Committee on Finance, March 13, 2001.

9. *Id.*

10. Frequently Asked Questions: Access and the Uninsured, Forum for State Health Policy Leadership, National Conference of State Legislatures (Denver: March 2001), found at <www.ncsl.org.>.

11. Kaiser Family Foundation, *The Medicare Program: Medicare and Prescription Drugs* (May 2001), found at <www.kff.org/content/2001/1583-03/1583_03rx.pdf>.

12. There is no reliable data on the "underinsured", individuals who have health insurance but lack drug coverage.

13. Statement of Kathryn G. Allen, Director Health Care - Medicaid and Medicare Issues, U.S. Government Accounting Office, on Health Insurance, Characteristics and Trends in the Uninsured Population, U.S. Senate Committee on Finance, March 13, 2001.

14. Frequently Asked Questions: Access and the Uninsured, Forum for State Health Policy Leadership, National Conference of State Legislatures (Denver: March 2001), found at <www.ncsl.org.>.

15. *See* generally, *Health Trends in Hawaii* found at <http://healthtrends.org>.

16. Health Plan Hawaii provided health insurance coverage for 125,332 and Queen's Health Plan for 43,788. Department of Business, Economic Development, and Tourism, *State of Hawaii Data Book 2000* (2001) at 15.11.

17. Of Hawaii's Medicare population in 1999, 147,944 were aged (65 and over) and 13,684 were disabled. Kaiser Family Foundation, State Health Facts on Line, *Hawaii: Distribution of Medicare Beneficiaries by Eligibility Category*, 1999 found at <http://www.statehealthfacts,kff.org/>.

18. U.S. Census Bureau, Current Population Survey March Supplement, *Health Insurance Coverage: 2000, Health Insurance Coverage Status by State for All People: 2000* at Table H106, found at <http://www.census.gov/hhes/www/hlthin00.html >.

19. Estimates of Hawaii's uninsured population varies. For 1997, Health Trends Hawaii estimated 7.0% were uninsured, the U.S. Census report 7.5%, and the state Department of Health 6.4%. For 1998, the Department of Health reported 74,362 uninsureds, or 6%. For the same year, the U.S. Census reported an uninsured population of 10%, or 121,000. For purposes of this study, the figures used for the uninsured population will be 10.1%, or 117,000 residents from the U.S. Census, Current Population Survey March Supplement, *Health Insurance Coverage: 2000*.

20. In accounting for the uninsured by gender (but not age), the Hawaii Health Survey reports that 34,325 or 6.0% of the Hawaii's uninsured in 2000 were male, while 28,574 or 4.9% were female. Hawaii Department of Health, *Uninsured by County Gender, Age, Ethnicity, and Poverty, Population of Hawaii, Hawaii Health Survey 2000* found at <http://www.state.hi.us/health/stats/surveys/hhs/hhs00t21.pdf>.

21. Kaiser Family Foundation, State Health Facts Online, *Hawaii: Insurance Status*, found at <http://statehealthfacts.kff.org>.

22. *Id.*

23. Kaiser Family Foundation, State Health Facts Online, *Hawaii: Nonelderly Insured*, found at <http://statehealthfacts.kff.org>.

24. Statement of ILWU Local 142, at the Informational Briefing on Prescription Drugs, Senate Committee on Consumer Protection and House, August 24, 2001.

25. Testimony of Stacy Evenson, Vice President of Community and Government Relations, Hawaii Medical Services Association, at the Informational Briefing on Prescription Drugs, Senate Committee on Consumer Protection and House, August 24, 2001.

26. The Foundation is investing $300,00 over three years to find community solutions to reverse Hawaii's growing uninsured trend. HMSA News Release, April 6, 2000.

Chapter 4

ACCESS TO PRESCRIPTION DRUGS

Introduction

The Legislature also requested the Bureau to provide information on access to prescription drugs in Hawaii. Most nonelderly people in Hawaii get prescription drugs through drug coverage benefits in the health insurance they get through their job. Some get outpatient prescription drugs through government programs. Retirees may have drug benefits in their retirement health insurance plans. Approximately 35,000 Hawaii Medicaid enrollees are aged, blind, or disabled. For those who have no drug coverage—the working poor, the unemployed, the disabled, the elderly—there are few options available to help them get free or affordable prescription drugs.

Private Health Insurance

Although most individuals in Hawaii obtain their health insurance through their employer, drug coverage may not be included. Drug coverage is not required under Hawaii's Prepaid Health Care law. The two biggest health plans in Hawaii, HMSA and Kaiser, estimate that 90% of their beneficiaries include drug benefits in their coverage. HMSA and Kaiser both state that most of the 10% without drug coverage are seniors. Because rising drug costs are increasing employers' premiums, some Hawaii employers are enrolling their employees in private drug discount programs instead of offering supplemental drug coverage.[1] Other individuals obtain prescription drugs through drug benefits in their retirement plans or privately purchased coverage.

Public Programs—Medicaid

Medicaid, financed by both state and federal governments and administered by the states, is the major public program that provides medical services to low-income vulnerable populations who meet certain criteria and income requirements.[2] Groups traditionally covered by Medicaid include people who receive cash assistance, mothers and children, the elderly, and persons with disabilities, or blind. States may extend Medicaid eligibility to "medically needy" who may not otherwise be eligible.

Although outpatient prescription drug coverage is optional, all states offer drug benefits to their categorically needy Medicaid enrollees, and thirty-five states offer coverage to some of their medically needy enrollees. Prescription drugs exceeded physician services as the most utilized Medicaid service, based on the number of Medicaid beneficiaries who used services. With limited exceptions, Medicaid covers all drugs manufactured by a pharmaceutical company that has signed a drug rebate agreement with the Health Care Financing Administration (HCFA) of the U.S. Department of Health and Human Services as a condition to Medicaid participation.

Most states limit the number, quantity, and refills and use a "prior authorization" program to restrict the use of certain drugs.

Public Health Insurance—Medicare

In contrast to Medicaid, Medicare is a federal health insurance program for people age 65 and older; some people under 65 with disabilities, and people with end-state renal disease. Most people automatically get Medicare Part A, or hospital benefits, when they turn 65. Currently, Medicare does not include outpatient prescription drug benefits.

Supplementary medical insurance, Medicare Part B, is optional and may include prescription drug benefits. Medigap is a Medicare fee for service supplemental insurance; other Medicare beneficiaries may chose a Medicare Part C, managed care plan (Medicare+Choice), which covers hospital services and additional benefits that often include prescription drugs.

Proposed Discount Drug Card for Medicare Beneficiaries

Although Medicare prescription drug benefits has long been discussed in Congress, Medicare does not currently provide prescription drug coverage. In July 2001, President Bush announced his recent discount drug card proposed for Medicare beneficiaries. The discount drug card was expected to offer discounts of 10% to 25% on retail prescription drug prices. On September 7, 2001, however, this program was halted by a federal court judge who found that the U.S. Department of Health and Human Services did not have legal authority to create the program without congressional approval, granting a request for a preliminary injunction filed by the National Association of Chain Drugstores shortly after the program was announced. On November 7, 2001, the same federal court judge stayed the lawsuit to allow the government to submit a revised version of a proposed drug discount card polity to the Federal Register for public comment. The future of the discount card program or any type of prescription drug benefit for Medicare beneficiaries is uncertain, at best.

Public—Medicare and Medicaid

Although Medicare covers virtually all Americans age 65 and older, about 10% of Medicare beneficiaries also qualify for Medicaid. Medicaid is a critical supplement to Medicare coverage for low-income Medicare beneficiaries. Approximately 35,000 of Hawaii's 160,000 Medicaid beneficiaries are age 65 or older. Elderly and disabled Medicare beneficiaries who qualify for Medicaid services generally receive outpatient prescription drugs through Medicaid.

Public—Section 340B Discount Drug Program

Section 340B of the Public Health Service Act creates a federal discount drug program that enables federally funded safety net providers to purchase outpatient prescription drugs for

their patients at prices lower than Medicaid prices, averaging 25% to 40% discounts. Recently, the federal government announced a new initiative that will potentially expand the programs reach to a greater number of needy individuals. Section 340B demonstration projects will be allowed to participate in single purchasing and dispensing systems that serve covered entity networks; contract with multiple pharmacy services and providers; and use contracted pharmacy services to supplement in-house services. Increasing the number of pharmacies where prescriptions can be dispensed will expand and improve patient access.

Special Prescription Drug Benefits for Veterans

According to the Social Security Administration, if a Social Security beneficiary has served in the military, he or she may be eligible for medical coverage, including prescription drugs. One out of every four adult Social Security beneficiaries has served in the military and may qualify for prescription drug benefits available from the Department of Veterans Affairs (VA). A 30-day supply of prescription medications costs only $2 through the VA, and disabled or low-income veterans can receive medications for free.[3]

The Fiscal Year National Defense Authorization Act, Public Law 106-398, established the TRICARE Senior Pharmacy Program (TSRx) for all Medicare eligible retirees of uniformed services, their family members and survivors. TSRx includes access to prescription drugs at military treatment facilities, retail pharmacies (including Department of Defense network pharmacies) and through TSRx mail order program. All Medicare beneficiaries who are age 65 by April 1, 2001, automatically qualify, whether or not they have purchased Medicare Part B. Beneficiaries who reach age 65 on April 1, 2001 or later must be enrolled in Medicare Part B to qualify for this benefit. The program will limit out-of-pocket costs and increase access for an estimated 1.4 million eligible beneficiaries.[4]

Private Drug Company "Patient Assistance Programs" for the Uninsured

Many drug manufacturers voluntarily offer medications free or at a discount cost to people who qualify for their "patient assistance programs". Each drug company has its own criteria and list of drugs available for free to qualifying applicants. Generally, these programs help low-income persons with no drug coverage. Insured individuals who have exhausted their drug coverage and Medicare beneficiaries without supplemental drug coverage could be eligible for many of these programs.[5]

Drug company patient assistance programs usually require health care providers' involvement in the application and receipt of free medications. One study reports that half of the programs contacted required a health care provider to apply on behalf of a patient and most send the medications to the health care provider for distribution to the patient. Patients rarely pay a co-payment, dispensing fee, or shipping charges on drugs available through patient assistance programs.[6]

Since the uninsured often lack access to health care providers, requiring that a health care provider submit the application on behalf of the uninsured presents a stumbling block to receiving prescription drugs and the most effective use of this program. Although information on these programs are available on the internet, which includes a listing of programs in a directory compiled by the Pharmaceutical Research and Manufacturers of America (PhRMA), some health care providers have noted that drug companies do not advertise their patient assistance programs and reported that providers must ask drug company representatives for information.[7] These programs are said to be underutilized because they are not publicized widely enough and because they often require both the patient and doctor to file extensive paperwork. Despite these limitations, a PhRMA survey found that members' programs provided $500 million worth of prescription drugs to 1.5 million individuals in 1998.[8] By comparison, U.S. prescription drug sales reached $125 billion in 1999, according to IMS Health.

Advocates for the Uninsured

The Medicine Program is a national organization of volunteers who help make prescription drugs available to those who can't afford them. For a $5 fee per prescription drug request, the Medicine Program simplifies the application process of drug companies' patient assistance programs and makes getting the required medications easier. To receive Medicine Program assistance, applicants must have no insurance coverage for outpatient prescription drugs, must not qualify for government programs that provide prescription medication, like Medicaid, and must meet income requirements. Applicants who qualify at the highest income limits generally are AIDS, transplant or cancer patients who need high-priced medications. The Medicine Bank sends the applicant an application to give to their physician to complete and send to the pharmaceutical company.

Recently, several states have created a clearinghouse or patient assistance programs to educate consumers about the requirements and benefits of public and private prescription drug assistance programs and facilitate participation for prescribers and consumers. Similar to the Medicine Program, the MEDBANK of Maryland is funded by a grant from the Maryland Health Care Foundation to provide access to free medications for low-income, underinsured, chronically ill patients. All referrals must be made by a physician or other health care professional. MEDBANK volunteers work exhaustively to find the right program to cover every patient. Health care professionals refer, the rest is up to MEDBANK of Maryland.

Some advocacy groups provide online information to patients. For example, NeedyMeds, www.needymeds.org, makes information about pharmaceutical manufacturers programs freely and easily accessible to patients, but does not assist in the application process.

Some organizations help health care providers, not patients. Volunteers in Health Care is a national nonprofit organization established in 1997 by the Robert Wood Johnson Foundation, as a resource to assist health care providers organize or expand health services for the uninsured in their community. Volunteers in Health Care's online RxAssist makes available to health care providers a compilation of information on more than one hundred drug manufacturers' patient assistance programs.

Access to Prescription Drugs for Hawaii Residents with No Drug Coverage

Public Health Insurance

- Quest
- QuestNET
- Medicaid Fee For Service
- 340B health care facilities
- VA benefits

Nonprofit Programs

- Drug manufacturers' Patient Assistance Programs.
- Advocacy groups help consumers/providers get drugs from manufacturers' programs.
- Medicine Program for consumers.
- Needymeds.org – online information for consumers.
- Robert Wood Johnson Foundation Rx Assist – online information for health care providers.
- Medicine Bank – gives donated medication to Hawaii community health centers.

Endnotes

1. This program, however, is somewhat limited in the pharmacies available in the network. *Prescription alternatives gain momentum*, Pacific Business News, vol. 39, no. 27, September 14, 2001.

2. Federal financial assistance is provided to states through federal matching payments based on the state's per capita income. Federal funds provided 53% of Hawaii's Medicaid funding in 2000.

3. To take advantage of this benefit, a veteran must have been honorably discharged from the military, must enroll with the VA, and must be seen by a VA doctor. The VA may charge for a doctor visit, but insurance may cover this charge (disabled or low-income veterans can visit doctors for free). The condition does not have to be a service-related injury. *See* <http://www.ssa.gov/enews/enews010101.htm#veterans>.

4. U.S. Department of Defense—*Fast Facts*, December 2000, found at <http://www.tricare.osd.mil/ndaa/fast_facts.htm>.

5. *See generally* U.S. General Accounting Office, *Prescription Drugs—Drug Company Programs Help Some People Who Lack Coverage*, GAO-01-137 (Washington, D.C.: November 2000).

6. *Id.*

7. *Id.* at 10.

8. *Id.* at 4.

Chapter 5

FEDERAL LAW AND PRESCRIPTION DRUG PRICING: WHAT STATES NEED TO KNOW

Introduction

Rising prescription drug costs affect all prescription drug buyers, from the individual consumer to large public and private purchasers. Prescription drug pricing is a complex combination of competing interests, involving drug manufacturers, wholesalers, retail pharmacies, insurers, pharmacy benefit managers, group purchasing organizations, and individual consumers. There is no one price for a specific drug product. Instead, prescription drug prices reflect a variety of distribution channels; distribution channels affect the ultimate price paid by consumers.

Some large public and private prescription drug purchasers negotiate prices directly with pharmaceutical manufacturers. Other buyers, such as insurance plans, self-insured employers, and hospitals, use representatives like pharmacy benefit managers or group purchasing organizations to negotiate prescription drug prices with manufacturers, wholesalers, and/or retail pharmacies for them, their enrollees or employees. Retail pharmacies generally purchase their pharmaceuticals from wholesalers. Most individual consumers buy their outpatient prescription drugs at a retail pharmacy and most outpatient prescription drugs are paid for by private insurance plans, pharmacy benefit managers, employers, or government programs. People who have no drug coverage are cash customers who pay for their drugs out of their own pocket.

Prescription drug buyers in the private market, whether uninsured cash customers, private pharmacy benefit managers, or large institutional purchasers, generally pay higher prices then government program buyers. Because federal programs get deeper discounts on prescription drugs than any other buyer, federal program price regulations impact, to a degree, the prices paid by all other buyers. In designing a state prescription drug assistance program, state policymakers should understand how federal drug discount programs work and their effect on pharmaceutical market prices. The Commerce Clause and the Supremacy Clause of the U.S. Constitution also must be taken into account. Constitutional issues raised in Maine and Vermont's federal court lawsuits are discussed in chapter 8.

This chapter will briefly discuss the pharmaceutical marketplace, focusing on how federal discount programs affect the pricing of prescription drugs for federal buyers and nonfederal buyers. For a more thorough analysis, interested persons will find much useful information in *Pharmaceutical Discounts Under Federal Law: State Program Opportunities,* William H. von Oehsen, III, Public Health Institute – Pharmaceuticals & Indigent Care Program, May 2001. This chapter provides a general summary of that study.

Prescription Drug Pricing Terminology

Terminology defined below illustrates the complexity of prescription drug pricing. Information on drug prices is often not available to most public or private buyers because the information is considered proprietary. An understanding of prescription drug pricing is essential for policymakers who seek to make prescription drugs affordable for some or all residents of their state.

Average Wholesale Price (AWP): The average list price that a manufacturer suggests that wholesalers charge pharmacies. AWP is typically less than the retail price because the retail price includes a pharmacy's own price markup. The AWP is often referred to as a "sticker price" because it is not the actual price that large prescription drug buyers usually pay.[1] Because AWP is not the actual transaction price, AWP serves as a reference in pricing, negotiation, and reimbursement.[2]

AWP information is publicly available.

Average Manufacturer Price (AMP): The average price paid to a manufacturer by pharmaceutical wholesalers for prescription drugs the wholesalers distribute to retail pharmacies. Federal Supply Schedule prices and prices for direct sales to HMOs and hospitals are excluded. AMP is a benchmark created by the Omnibus Budget Reconciliation Act of 1990 to aid in determining Medicaid rebates.

AMP information is not publicly available. The Congressional Budget Office (CBO) estimated AMP to be approximately 20% less than AWP for certain prescription drugs used by Medicaid beneficiaries.

Nonfederal Average Manufacturer Price (NFAMP): The average price paid to a manufacturer by wholesalers for prescription drugs distributed to nonfederal purchasers.

NFAMP information is not publicly available.

Federal Supply Schedule (FSS): The price available to a federal purchaser for prescription drugs listed on the FSS. FSS prices are intended to equal or better prices that drug manufacturers charge their "most-favored" nonfederal customers under comparable terms and conditions. Because terms and conditions may vary by drug, the most-favored customer price is not always the lowest price in the market.

FSS prices are publicly available.

Federal Ceiling Price (FCP): The maximum price that drug manufacturers can charge the Veterans Administration, Department of Defense, Public Health Services, and the Coast Guard for their brand-name drugs listed on the FSS, even if the FSS price is higher. FCP must be at least 24% lower than NFAMP.

FCP information is not publicly available.

Medicaid rebate net price: The effective price for outpatient prescription drugs after manufacturer rebates are paid to state Medicaid programs. The basic rebate on brand-name drugs is the greater of 15.1% of the AMP and the "best price" the manufacturer charges any other purchaser. Rebates for generic drugs are 11% of AMP. An additional rebate is required for brand-name drugs whose AMP increases exceed inflation in the consumer price index. FSS prices and prices charged to state pharmaceutical assistance programs are excluded from calculation of "best price" for Medicaid rebates.[3]

Information on Medicaid rebate amounts is publicly available; AMP and "best price" information is not.

Veterans Administration national contract price: The price the VA has obtained through competitive bids from manufacturers for certain prescription drugs as a condition for including those drugs in the VA formulary.

VA contract prices are publicly available.

Private Sector Prescription Drug Buyers

Private sector buyer models include cash customers, pharmacy benefit managers, and institutional purchasers. Pharmacy benefit managers negotiate rebates on drug prices from manufacturers and discounts from retail pharmacies on behalf of enrollees of an insurance plan or employees of a large self-insured business. Large, private institutional purchasers like hospitals or HMOs may operate their own pharmacies, saving on overhead and profit margins reflected in retail pharmacy prices. Institutional purchasers generally buy directly from manufacturers, eliminating drug wholesaler markup.[4] Cash customers are consumers who pay for their drugs out of their own pocket because they have no drug benefits. These individuals buy from retail pharmacies and pay the highest prices for prescription drugs. Because individuals with no drug coverage have no power to negotiate discounts or rebates on the prescription drugs they buy, they pay more for their prescriptions than any other buyer.

Federal Discount Drug Programs as Pharmaceutical Buyer

Federal agencies generally pay the lowest prices of all prescription drug buyers. The federal government buys drugs under a number of programs; the federal market for prescription drugs includes the Federal Employee Health Benefit program, Medicaid, the Department of Veterans Affairs (VA), the Department of Defense, the Public Health Service, and the Coast Guard.[5] Some federal programs, such as the Federal Supply Schedule and the VA Formulary, determine prices through voluntary negotiations between the federal government and each participating manufacturer. Other programs, like section 340B of the Public Health Services Act, use statutory discounts. The Medicaid drug rebate program explicitly ties statutorily required manufacturer discounts or rebates for drugs covered by Medicaid to the manufacturer's

best private-sector prices. A drug manufacturer's "best price" information is not publicly available.

Although these federal programs use different mechanisms to purchase prescription drugs, their common goal is to obtain drug prices at least as low as prices offered to the most favored private-sector purchasers. Federal drug prices are influenced by federal law creating the Medicaid rebate program; relief granted certain federally funded programs by section 340B of the Public Health Services Act; prescription drugs included in the Federal Supply Schedule as a condition of Medicaid reimbursement; the Federal Ceiling Price which limits drug prices that can be charged to four federal agencies. Although not mandated by federal law, the VA's national contracts with drug manufacturer's often result in the lowest price for certain brand-name drugs.[6] Because federal drug pricing arrangements affect pricing for non-federal prescription drug buyers, state policymakers should consider how federal programs might impact a state prescription drug program's ability to provide prescription drugs at an affordable price to its target population.

Descriptions of federal programs follow immediately below; their potential impact on state prescription drug prices is discussed on pages 30 through 31.

Medicaid Rebates

The Omnibus Budget Reconciliation Act of 1990 (OBRA), established the Medicaid rebate program. Administered by the U.S. Department of Health and Human Services' Centers for Medicare and Medicaid Services (CMS[7]), the Medicaid rebate program requires drug manufacturers pay state Medicaid programs quarterly rebates for each covered outpatient prescription drug.[8] To participate in Medicaid, manufacturers must pay rebates equal to the lower of (a) 15.1% of the average manufacturer price (AMP), paid by wholesalers for brand name drugs or (b) the manufacturer's "best price" to any other customer. The 15.1% discount off AMP is the minimum Medicaid price. Prices for federal drug programs and prices for state pharmaceutical assistance programs are expressly exempted from Medicaid "best price" calculations, giving the exempted programs the significant ability to buy drugs at prices lower than Medicaid prices. For generic and over-the-counter drugs, manufacturers pay an 11% rebate.[9]

The average Medicaid rebate net price for brand name drugs is 39% of the average wholesale price (AWP) or 24% off the AMP.[10] Because state Medicaid programs are entitled to a manufacturer's best price or better, the Medicaid net price generally is as good or better than the "best price" paid by private sector buyers. Only government programs expressly exempted from Medicaid's best price formula are able to buy drugs at prices lower than Medicaid prices.

Public Health Service 340B Drug Pricing Program

The Public Health Service 340B Drug Pricing Program[11] (340B), limits the cost of outpatient prescription drugs for clinics, health departments, hospitals, and other organizations

that receive funds from the Public Health Service. After the Medicaid rebate program was established in 1990, drug manufacturers offered fewer discounts to buyers since the new Medicaid "best price" formula would require them to give the same discount in the form of rebates to all state Medicaid programs. Since 1992, however, section 340B has required drug manufacturers to provide discounts on outpatient drug purchases to federally funded safety net providers and programs that care for our most vulnerable patient population. The 340B discount is a condition for Medicaid coverage of the manufacturer's outpatient prescription drugs.[12]

Public Health Service safety net providers are critical in providing access to health care to low-income populations, many of whom lack drug coverage. Section 340B enables these public hospitals, community, migrant and homeless health centers, HIV/Aids clinics, and other health care providers to buy outpatient prescription drugs at significant savings, even lower than Medicaid prices.

Under the 340B drug discount program, safety net providers have saved hundreds of millions of dollars on outpatient drug costs, savings that allow them to serve a greater number of low-income patients. Public hospitals that qualify for 340B drug pricing serve a population that is more than 80% uninsured, Medicare, or Medicaid patients. As public teaching hospitals, they depend on government funding to operate. Many would likely close or severely limit their hospital pharmacies without access to 340B drug prices. Similarly, community and migrant health centers estimate outpatient drug cost savings of 20% to 60% since the 340B program began. Savings on prescription drug costs have enabled these health centers to improve patient services, expand services for special populations, and offer larger discounts to a greater number of patients. Like 340B public hospitals, community and migrant health centers claim that savings under the 340B drug pricing program allow them to maintain or even expand pharmacy services for their patients.

In general terms, section 340B requires pharmaceutical manufacturers to provide safety net providers that receive federal funds outpatient prescription drugs at or below a price equal to AMP minus the Medicaid rebate percentage.[13] Qualified safety net providers are entitled to discount prices that are approximately 51% less than AWP, 39% lower than AMP, and 19% lower than Medicaid net prices,[14] or as stated in a Department of Health and Human Services press release, 340B drug discounts average 25% to 40% on most drugs.[15]

Federal Supply Schedule

The Federal Supply Schedule (FSS) is a list of pharmaceutical products and prices applicable to federal departments and agencies that buy prescription drugs. The VA administers the FSS and also accounts for the most FSS pharmaceutical purchases.[16] FSS contract prices for federal buyers are negotiated with drug manufacturers by the VA; they reflect a substantial discount off market prices. FSS prices must be equal or better than the price a drug manufacturer offers its "most favored" nonfederal customer under comparable terms and conditions.[17] FSS prices for federal buyers are lower than prices available to any nonfederal buyer.

Federal law gives federal buyers advantages that enable them to buy prescription drugs at prices lower than other public or private sector buyers. Federal law requires drug manufacturers to list their brand name drugs on the FSS for federal buyers as a condition to reimbursement for their drugs covered by Medicaid.[18] Since Medicaid accounts for a significant portion of U.S. drug sales, manufacturers willingly list their products on the FSS to enable their participation in the Medicaid program.

Federal law further gives federal buyers another advantage by requiring pharmaceutical manufacturers to disclose pricing information to the VA that is not available to other buyers.[19] The VA uses this information in FSS negotiations with manufacturers to ensure the best price for federal buyers.[20] On average, FSS prices are slightly above 340B prices for federally funded safety net providers, or about 48% below AWP[21]. Stated another way, FSS prices available to federal drug programs are 35% and 15% lower than AMP prices and the Medicaid net price, respectively.[22]

Federal Ceiling Price

Federal law provides the four largest federal prescription drug buyers, the Veterans Administration, Department of Defense, Public Health Service, and the Coast Guard, an additional advantage that even other federal buyers don't have—a ceiling price. This ceiling price enables the "Big 4" agencies to purchase drugs at prices lower than any state or most federal buyers. To qualify for Medicaid reimbursements, manufacturers must not only list their brand name drugs on the FSS, but they also are required to sell FSS listed drugs to the "Big 4" agencies for at least 24% less than the <u>average</u> price paid to manufacturers by nonfederal buyers, or NFAMP.[23] Although <u>all</u> federal agencies, including the Big 4, receive substantial discounts (generally not matched for state programs or private buyers) on prescription drugs bought at FSS prices, only the VA, Department of Defense, Public Health Service, and the Coast Guard are protected from drug price increases by a ceiling price known as the Federal Ceiling Price (FCP).

Although the FCP discount is calculated similar to the Medicaid rebates, there is no "best price" requirement that parallels Medicaid's best price determination.[24] FCP prices are tied to the <u>average</u> price of sales to nonfederal buyers, not the "best price". This is important because, unlike Medicaid best price, the FCP allows nonfederal buyers to negotiate drug purchases at prices lower than FCP without requiring that the lower price be extended to the Big 4.

FCP prices were estimated to be 8% less than FSS prices, as of February 2000.[25] FCP is estimated to be 52% less than AWP, 40% less than AMP, 21% lower than Medicaid net prices, and "slightly lower" than 340B prices.[26]

Veterans Administration National Contract Prices

Although not a discount mandated by federal law, the Big 4 federal agencies are authorized to negotiate with pharmaceutical manufacturers for prescription drug purchase prices below the FCP. The VA has exercised this authority with more success than any other federal

agencies.[27] The VA's success in securing significant voluntary discounts from drug manufacturers, without benefit of federal mandate, should prompt state lawmakers to examine the VA's approach to drug purchasing.

Using a drug formulary and its considerable buying power to move market share under a national contract, the VA seeks competitive bids from manufacturers for discounts on products that are "therapeutically equivalent within specific drug classes".[28] The selected manufacturer enters a national contract with the VA to sell the drug at prices that may be less than FCP or FSS prices in exchange for the manufacturer's product being included on the VA formulary for use throughout the entire VA health system. Competition for these national contracts has been reported to be "intense".[29]

Impact of Federal Drug Pricing

Requirements on State Programs

In seeking to provide prescription drugs to residents at affordable prices, state lawmakers should have a basic understanding of drug pricing terminology. Understanding the difference between AWP and AMP, for example, is essential to defining the state's role in increasing access to affordable prescription drugs. In addition, it is also necessary to remember the federal laws regulating the drug purchases of federal buyers discussed above and how those laws may impact a state program.

Medicaid "Best Price"

The Medicaid rebate program's "best price" requirement has, perhaps, the most significant potential impact for states. If a drug manufacturer sells a covered drug to any non-Medicaid buyer at a discount greater than 15.1% off AMP, that buyer's price becomes the manufacturer's "best price" and the manufacturer must give a matching discount to all state Medicaid programs. Other than prices for specifically exempted government programs, Medicaid net prices generally reflect the manufacturer's best price available for any buyer.[30] If a state program does not qualify for a best price exemption, manufacturers have no incentive to offer prices lower than the rebates paid to Medicaid programs. Without a Medicaid best price exemption, a state prescription drug program is unlikely to negotiate a discount lower than the Medicaid price.

Generally speaking, states have the potential to lower drug costs below Medicaid prices. Federal law clearly grants a "best price" exemption for "any prices used under a State pharmaceutical assistance program".[31] As of January 7, 2002, thirty-one states have established or authorized a program to make prescription drugs more widely available, most often to low-income elderly residents. The overwhelming majority of these programs, 26 of 31, are direct benefit programs that use state funds to subsidize pharmaceutical costs for the target population. The Medicaid best price exemption has been successfully used by these traditional state-funded programs, regardless of the target population or drugs covered by the program, to get rebates that

lower drug costs below Medicaid prices. Less clear, however, is what other types of state created programs or approaches to lower drug costs would be entitled a best price exemption as a "state pharmaceutical assistance program".

William H. von Oehsen, in his thorough study, *Pharmaceutical Discounts Under Federal Law: State Program Opportunities*, notes the uncertainty of whether the best price exemption applies to other than the traditional state-funded subsidy programs.[32] Federal law provides little assistance. In setting out the formula for determining Medicaid rebates, the applicable law merely states that "any prices used under a State pharmaceutical assistance program" are excluded from the definition of "best price".[33] The law does not define "State pharmaceutical assistance program". State programs to lower drug costs that are only partially state-funded may fall outside the exemption. Programs funded through manufacturer rebates or pharmacy discounts may not be exempted. Having bulk purchasing arrangements and pharmacy benefit managers as program administrators and negotiators raises similar questions. Without a "best price" exemption, states are essentially limited to Medicaid prices as the lowest price available. To get the lowest prices, the best price exemption is critical.

340B Drug Pricing

State programs must establish procedures to avoid duplicate discounts for a single prescription. State pharmaceutical assistance programs that negotiate manufacturer rebates for covered drugs could face this conflict if a program enrollee purchases their prescription from a 340B safety net provider pharmacy. The manufacturer's initial discount is given at the time of the drug sale to the 340B provider. The state program's request to the same manufacturer for the program's rebate negotiated for drugs offered to its enrollees is the second discount for the same prescription. Procedures must be established to separate the claims.

Because 340B covered entities may be disqualified from the program if they get their outpatient drugs through group purchasing, including 340B safety net providers in-state bulk purchasing arrangements may be counterproductive. For 340B providers, the advantages of participating in a 340B drug program probably outweigh the benefits of bulk purchasing arrangements.

Federal Ceiling Price

Because state-funded pharmaceutical assistance programs are excluded from Medicaid's best price formula, manufacturers are willing to negotiate with these programs for rebates that may exceed Medicaid rebates. Nonexempt programs could only hope to match, not better, Medicaid prices. The Federal Ceiling Price creates a similar, but less serious, obstacle for states. FCP is based on the <u>average</u> manufacturer price to nonfederal buyers, which may include certain state programs.

Federal Ceiling Price creates no problems for state-funded direct subsidy programs price negotiations because rebates paid directly by manufacturers are not included in NFAMP

calculations. Bulk purchasing arrangements or rebates, or discounts from wholesalers, however, may have trouble getting substantial discounts, particularly in large programs that would more seriously lower the NFAMP average.[34]

Veterans Administration Success

Using National Contracts

Because the VA has successfully negotiated voluntary discounts on drug prices that are lower than prices available to any other buyer, William H. von Oehsen suggests that states take note of how the VA gets these prices. He claims three factors contribute to the VA's success: VA's national contract prices are excluded from Medicaid best price calculations; brand name drug sales to the VA are subject to a ceiling price, FCP; and the VA is authorized to negotiate prices lower than the FCP. The VA's large volume gives it clout in price negotiations based on its potential ability to move market share of certain drugs if a drug is included in the VA's national formulary. While volume or size of the potential market is significant, a state's ability to move market share is more likely to influence price negotiations.

Summary

Although federal law gives federal agencies a significant advantage over non-federal pharmaceutical buyers, federal law also provides a valuable opportunity for state prescription drug programs. A "State pharmaceutical assistance program" is expressly exempted from the Medicaid "best price" requirement that allows drug manufacturers to offer those program rebates or discounts lower than Medicaid prices without being required to give the new "best price" to Medicaid programs. The best price exemption has long been held to apply to state-funded direct benefit prescription drug programs, but whether newer types of state prescription drug programs that have little or no state funding such as retail discount programs, rebate programs, or discount card programs, can claim the exemption is uncertain.

The VA's successful national contract drug prices are influenced by factors Hawaii lacks: VA's patient volume, use of a formulary, integrated health care system with its own health care providers and pharmacy. The distribution chain is much smaller when the VA is the buyer, eliminating a number of costly layers. Also, VA's drug formulary increases the ability to influence VA physicians' prescribing habits. Influencing prescribing habits translates to VA's ability to move market share. Manufacturers are more willing to lower prices in return for an increase in volume.

Understanding drug pricing terminology is challenging. Further reflection on how a pharmaceutical buyer's place in the distribution chain affects the purchase price and how a potential purchase price relates to the relevant federal law adds to the challenge.

Endnotes

1. The average age acquisition price paid by retail pharmacies in eleven states was actually 18.3% below AWP, according to a recent study. Discounts for large purchasers like HMOs can be even greater. William H. von Oehsen, III, *Pharmaceutical Discounts Under Federal Law: State Program Opportunities* (Washington, D.C.: May 2001), at 9 (hereafter von Oehsen).

2. Profile of the Prescription Drug Wholesaling Industry Final Report, Task Order No. 13, Prepared for the Office of Policy, Planning, and Legislation, Food and Drug Administration of the Department of Health and Human Services by the Eastern Research Group, Inc., February 12, 2001.

3. *See* 42 U.S.C. sec. 1396r-8(c)(1)(C).

4. von Oehsen, at 6.

5. Robin Strongin, *Issue Brief/No. 755, Pharmaceutical Marketplace Dynamics*, National Health Policy Forum (Washington, D.C.: May 31, 2000), at 11.

6. von Oehsen, at 16.

7. Formerly the Health Care Finance Administration.

8. *See* 42 U.S.C. section 1396r-8(a)(1).

9. An additional rebate is paid to the states if a brand name drug's AMP increases faster than the rate of inflation. Private buyers, such as HMOs and PBMs, and state pharmaceutical assistance programs also use manufacturer rebates in drug pricing, but do not receive additional rebates based on inflation rates. *See* von Oehsen, at 11.

10. von Oehsen, at 12.

11. Section 340B of Public Law 102-585, the Veterans Health Care Act of 1992.

12. *Id.*

13. Covered entities are free to negotiate even deeper discounts than the required discount amount. *See generally* U.S. General Accounting Office, *Prescription Drugs - Expanding Access to Federal prices Could Cause Other Price Changes*, Report to Congressional Requesters (Washington, D.C.: August 2000) (hereafter GAO, *Prescription Drugs*).

14. von Oehsen, at 14.

15. U.S. Department of Health and Human Services, *New HHS Initiative Will Expand Access to Prescription Drugs for Safety-Net Patients*, HHS News, June 18, 2001 (Washington, D.C.: 2001), found at <http://www.hhs.gov/hews>.

16. In Fiscal Year 1999 VA purchased $1.2 in pharmaceuticals, approximately 83% of all sales at FSS prices. GAO, *Prescription Drugs* at 16.

17. GAO, *Prescription Drugs* at 16.

18. *See* 38 U.S.C. sec. 8126, Veterans Health Care Act of 1992, Public Law 102-585, sec. 603.

19. GSA Acquisition Regulation section 515.804-6(b).

20. von Oehsen, at 15.

21. *Id.* at 16.

22. *Id.* at 15.

23. 38 U.S.C. sec. 8126, Public Law 102-585, sec. 603.

24. von Oehsen, at 16.

25. *Id.* at 16.

26. *Id.*

27. *Id.*

28. *Id.*

29. *Id.*

30. Discount prices for outpatient prescription drugs required by federal law as discussed above are expressly excluded from Medicaid best price calculations. Consequently, even though the discounted drug prices negotiated for federal programs under FSS, FCP, or 340B requirements are lower than Medicaid net prices, the discounts granted federal buyers are not extended to state Medicaid programs.

31. 42 U.S.C.A. section 1396r-8(c)(1)(C).

32. William H. von Oehsen states that he asked HCFA to clarify best price exemption issues by letter dated January 19, 2000, but received no response before his May 2001, report. *See* von Oehsen, at 22-23.

33. 42 U.S.C. section 1396r-8(c)(1)(C).

34. von Oehsen, at 25.

Chapter 6

ELEMENTS OF STATE PHARMACEUTICAL ASSISTANCE PROGRAMS

Introduction

Until recently, the term "state pharmaceutical assistance program" described a state-funded program providing prescription drug coverage or assistance to a defined population, usually low-income seniors who do not qualify for Medicaid and sometimes to certain disabled individuals. These programs are the oldest pharmaceutical assistance model and by far the most common. Of the thirty-one states that have some type of authorized or established pharmaceutical assistance program, twenty-six provide a direct subsidy using state funds.

Traditional state pharmaceutical assistance programs use state revenues to subsidize drug costs; participants' out-of-pocket expense for each covered prescription in a direct benefit program is usually a nominal amount. These state-funded programs may be described as "direct benefit" programs to distinguish them from more recent approaches that typically allow program participants to buy drugs at a discounted price and require little state funding. State subsidized private insurance or tax credit programs are direct benefit models that are used infrequently.

Five states have recently created programs that offer a discount only, no state subsidy is provided.[1] These newer discount-type programs have less stringent eligibility qualifications and a lower cost to states, but provide a less valuable benefit for enrollees. Discount prices may be achieved with discount cards, price controls, bulk purchasing, buyer's clubs, or even Medicaid waivers. Although several states have authorized some type of prescription drug discount program, very few were in operation at the time this study was written. Programs in Maine and Vermont, have been halted by litigation. Washington's Awards program was terminated by court order. The issues that are being litigated in Maine and Vermont are discussed in chapter 8.

Even though there is no single model program, all states must deal with "similar issues of design, administration, and funding" in designing a prescription drug assistance program.[2] Because of the significant use of state revenues, these issues are most critical in direct benefit programs. Generally, states must consider:

(1) Potential beneficiaries--who to include;

(2) The scope of the benefits;

(3) Program funding and cost control; and

(4) Administration.

This study uses the terms "state pharmaceutical assistance programs" and "state prescription drug assistance" interchangeably to refer to <u>any</u> type of program created by a state

with the intent of providing increased access to prescription drugs at an affordable price to any target population.

Eligibility

State prescription drug assistance programs generally determine eligibility by age, income, and residency. Eligibility criteria ultimately dictate the size of the program. In establishing eligibility requirements, a state may target only its most vulnerable or its neediest population. On the other hand, some state programs provide comprehensive coverage. Program objectives may face issues of depth versus breadth of coverage, and aid in determining the eligibility requirements.

Because traditional state-funded direct benefit pharmaceutical assistance programs almost exclusively target low-income elderly individuals who do not qualify for Medicaid, eligibility in these direct benefit programs is most commonly determined by age and income. Where disabled individuals are covered, the age requirement is lowered, or not applied. State residency also is a common program requirement; although the length of required residency varies. Other criteria may determine eligibility. For example, Maryland limited eligibility by declaring federal, state, and local correctional facility inmates to be ineligible for the Maryland Pharmacy Assistance Program.[3] Some programs require that enrollees have no benefit program that includes drug coverage.

Income requirements for single, couple, or family enrollees in direct benefit programs using state funds are either set amounts or specific percentage of the Federal Poverty Level (FPL). Maximum income allowed for individuals ranges from around $10,000[4] up to $25,770 for Maryland's Short Term Prescription Drug Subsidy Plan and $35,000 for New York's Elderly Pharmaceutical Insurance Coverage. Income threshold may be adjusted annually to account for cost of living adjustments to Social Security income. Some states provide an income limit exception for individuals with "catastrophic" prescription drug expenses, usually a set percentage of income. For example, Maine and Delaware make exceptions for residents with drug expenses above 40% of their income. A few state programs also have asset limits.

Most state subsidy programs provide coverage for beneficiaries age 65 and older. State programs that include the disabled most commonly base eligibility on receipt of disability benefits through Social Security or Medicare. Age requirements for disabled beneficiaries, if any, may be as low as age 16.

More recent approaches used by states to lower drug costs, other than the traditional state pharmaceutical assistance program funded by state revenues, may target a broader population and often have no age or income requirements for eligibility. These programs include discount programs, aggregate purchasing, purchasing cooperatives, and even Medicaid waivers that authorize prescription drug coverage for beneficiaries not normally eligible under Medicaid income limits.[5] Medicaid waiver programs may allow incomes up to 300% of FPL.

Scope of Benefits—Drugs Covered

In creating a pharmaceutical assistance program, a state must determine the type of drugs and conditions to be covered. The traditional state subsidized direct benefit programs most commonly cover all prescription drugs subject to a manufacturer's rebate agreement with the program and insulin (and insulin syringes) or all drugs covered by state Medicaid programs. Some cover prescribed non-prescription drugs.

Drug coverage restrictions include restrictions on injectibles (other than insulin), antihistamines and cough preparations, cosmetic, and diet and fertility/contraceptive drugs. Certain states limit drugs covered to specific diseases or conditions. As of July 2001, the Illinois Pharmaceutical Assistance Program covers prescription medication used for heart disease, diabetes (including insulin, syringes, and needles), arthritis, Alzheimer's disease, Parkinson's disease, glaucoma, lung disease, smoking related diseases, and osteoporosis. The program originally limited coverage to drugs to treat heart disease, diabetes, and arthritis. Maine previously limited coverage to drugs from participating manufacturer's used for chronic diabetes, asthma, chronic lung disease, cardiac conditions, and arthritis. Kansas covers up to $1,200 for maintenance drugs for specific diseases. The newly operational North Carolina Prescription Drug Assistance Plan covered only certain drugs used to treat cardiovascular disease and diabetes.

The newer discount programs generally cover all prescription drugs. A few of the most recent programs, like the Arizona Prescription Medication Coverage Pilot Program, have not determined all details of the program.

Program Funding

Traditional direct benefit pharmaceutical assistance programs are funded by state revenues. As much as two-thirds of the programs receive some or all of their funding from state general revenues. A number of programs receive earmarked funding from tobacco taxes or the state's tobacco settlement funds. Lottery and casino revenues are used in Pennsylvania and New Jersey.[6] Most direct benefit programs receive manufacturers' rebates that are modeled on the Medicaid rebate program established in OBRA 1990. In the past, manufacturers have entered into rebate agreements in exchange for their products being covered by a state's pharmaceutical assistance program and not subject to prior authorization. Some say manufacturers are less likely to enter into rebate agreements in the future.

The more recent prescription drug programs that are <u>not</u> the traditional state-funded direct benefit model are, obviously, less costly to states. Generally, beneficiaries buy their prescriptions drugs at a retail pharmacy at a price discounted to less than the full retail price, while states may pay pharmacy dispensing or processing fees or other administrative costs. The California Drug Discount Program for Medicare Beneficiaries requires pharmacists to allow Medicare recipients to buy drugs for the same price paid by Medi-Cal, California's Medicaid program. Pharmacies must participate in the discount program as a condition for Medi-Cal

participation. The New Hampshire Senior Prescription Drug Discount Program is funded by rebates and incentives from pharmaceutical manufacturers.[7]

Because federal law requires Medicaid waiver demonstration projects to be budget neutral, programs established to provide prescription drug benefits pursuant to Medicaid waivers should not require additional state funding. Vermont was granted a section 1115 of the Social Security Act waiver[8] (section 1115 Medicaid waiver), by the Health Care Financing Administration of the U.S. Department of Health and Human Services[9] to expand its pharmacy program to include Medicare beneficiaries with income above 150% of the FPL who have no prescription drug benefits and other adults with incomes 300% of FPL or less who lack drug coverage.[10]

The Healthy Maine Prescriptions Program is a similar Medicaid waiver project. It provides prescription drugs to Maine residents with incomes up to 300% of the FPL. As Medicaid waiver programs, Maine and Vermont claim manufacturer rebates are required for prescription drugs sold to participants in the waiver programs that would not ordinarily qualify for Medicaid pharmacy benefits. Because drug manufacturers have filed lawsuits in federal court against both programs, the future of Medicaid wavers as a tool to expand prescription drug benefits is uncertain pending the resolution of both cases.

Cost Controls

Controlling program costs is a key task, especially for state-funded direct benefit programs. Newer programs provide prescription drugs at a reduced or discounted price for eligible enrollees, but do not provide a state subsidy for enrollees to buy prescription drugs.[11] Although approaches differ, all programs manage costs by requiring cost-sharing by program enrollees, most often in the form of co-payments or co-insurance payments. Cost controls, including their calculation and application, vary widely among the programs.

Beneficiary cost sharing is most frequently in the form of co-payments where the program participant pays a set amount for each prescription. But there are variations in co-payment amounts or calculations. The required co-payment in state established subsidized direct benefit program is usually a modest sum, ranging from $3 to $12. Some programs may require a higher co-payment for name brand prescriptions. South Carolina's SilverRxcard[12] requires a $10 co-payment for generic drugs and a $21 co-payment for name brand. Co-insurance requires a participant to pay a set percentage of the cost for each prescription. Co-insurance requirements are used more frequently in newer state-funded programs that require participants to bear a larger portion of the cost, although they vary in their application. For example, the Kansas Senior Pharmacy Assistance program requires a co-payment of not more than 30% of the cost of each prescription, while the Delaware Prescription Drug Assistance Program[13] requires a program participant to pay of $5 or 25% of the cost of each prescription, whichever is greater. A discount program, the New Hampshire Prescription Drug Discount Pilot Program[14] provides "percent discounts depending on brand of medication", up to 40% on generic drugs and 15% on brand name drugs.[15]

A few states use deductibles or an annual cap on benefits to keep costs down.[16] These cost controls are used more often in recently created state-funded programs. Annual enrollment fees, even modest ones, are thought to discourage enrollment and are used infrequently.[17] Other cost management approaches used relate to the scope of benefits: lower co-payments for generic drugs; limits on the number of prescriptions each month; restrictions on the drugs or conditions covered; generic substitutions; prior authorization; limits on the drug dispensed (i.e. a 30-day supply); use of mail order services. Use of a drug formulary, whether closed, incentive, or open, can affect program costs. State-funded direct benefit pharmaceutical assistance programs "generally do not use formularies to limit coverage to specific products within a given therapeutic class".[18] Manufacturer rebates are a significant part of many programs, particularly state-funded direct benefit programs; retail pharmacy discounts are also used.

Administration

State pharmaceutical assistance programs must balance promoting program participation with often limited resources available to the program. Given the above discussion, it should not be surprising that program administration also varies among the states. Several states have added to or borrowed from their state Medicaid program to administer their prescription drug assistance programs, and may even administer all or some of the program through the state agency that administers Medicaid. States using this administrative approach say they eliminated duplicative efforts and avoided developing an entirely new system of eligibility determination and claims processing.[19] These programs may use the same eligibility determination system or claims adjudication system, or both, as Medicaid. Some states administer their drug programs through another assistance program, such as rent or property tax relief.[20]

It is interesting to note that the three largest programs in terms of both program participants and budgets, New Jersey, New York, and Pennsylvania, all specifically declined to link their drug programs to their Medicaid systems, and sacrifice "economies of scale" given the similarities in a number of program functions.[21]

In summary, state pharmaceutical assistance program creators must give serious consideration to the intended target population and the scope of benefits to be offered. Who will be eligible? What drugs will be covered? Are there any restrictions on drugs covered? Are all conditions covered? Funding and resources available to the program impact the programs reach and scope of coverage. Efficient and effective administration is critical. For state-funded direct benefit programs in particular, control measures are key.

Generally speaking, traditional state-funded direct benefit programs define eligibility most often by age, income, and residency. Programs target primarily low-income seniors; some include the disabled. Most direct benefit programs cover prescription drugs covered by Medicaid. Some offer only certain drugs, cover only certain conditions, or provide only drugs made by manufacturers who enter rebate agreements with the program. Direct benefit programs require cost-sharing, most commonly in the form of a nominal co-payment or co-insurance payment for each covered prescription. Deductibles and benefit caps are used more frequently in newer programs. Funding is most often state general revenue, although a number of states use

tobacco settlement funds, casino or lottery revenues, or other designated sources. Voluntary or required rebates from pharmaceutical manufacturers lower program costs in direct benefit programs and some discount programs. Some programs mandate or negotiate discounts from pharmacists as well.

Discount programs have broader eligibility requirements. Some programs include any resident; others target only Medicare beneficiaries. Generally, discount programs have no income requirements.

Having discussed components of state pharmaceutical assistance programs in this chapter, the different program models will be discussed in chapter 7. Program advantages and disadvantages, similarities and differences, and the experience of several states will be analyzed.

Endnotes

1. California, New Hampshire, Iowa, and West Virginia have newly created prescription drug discount programs that are not subsidized by the state. Washington began a discount program in 2001, but it ended operation in June. *See* Richard Cauchi, *State Pharmaceutical Assistance Programs*, Updated January 7, 2002, National Conference of State Legislatures (Denver, Co.: 2002), found at <http://www.ncsl.org/programs/health/drugaid.htm> (hereafter NCSL, *State Pharmaceutical Assistance Programs).*

2. Robin Strongin, *Issue Brief/No. 755, Pharmaceutical Marketplace Dynamics,* National Health Policy Forum (Washington, D.C.: May 31, 2000), at 11.

3. Medicaid recipients and non-residents also were deemed ineligible.

4. *See* NCSL, *State Pharmaceutical Assistance Programs* at State Subsidy Programs, Chart 1.

5. NCSL, *Id.* at Chart 2.

6. *See* National Governors Association, *State Pharmaceutical Assistance Programs Chart*, December 18, 2001, found at <http://www.nga.org> (hereafter NGA Chart).

7. National Pharmaceutical Council, *Pharmaceutical Benefits under State Medical Assistance Programs* found at <http://www.npcnow.org/productlist/mppd.asp>.

8. Section 1115 of the Social Security Act gives the Secretary of Health and Human Services broad authority to waive provisions in Title XIX, the Medicaid statute. These "waivers" permit a state to further the purposes of Title XIX "to make more adequate provisions for aged persons, blind persons, dependent and crippled children, maternal and child welfare, (and) public health..." Generally a waiver is approved for a five-year period, subject to annual renewal. A central element of many of the waivers described here is the expansion of Medicaid eligibility to low-income persons not covered under federal rules of Title XIX. The new populations covered, however, vary from waiver to waiver, as does the scope of coverage, and the nature of the provider organizations.

9. Health Care Financing Administration is the federal agency that runs the Medicare and joint federal-state Medicaid programs. In the summer of 2001, the agency changed its name to the Centers for Medicare & Medicaid Services "as part of the first wave of efforts to reform and strengthen the services and information available to nearly 70 million Medicare and Medicaid beneficiaries and the health care providers who serve

them." According to the Secretary of Health and Human Services Tommy G. Thompson, the agency's new name "reflects the increased emphasis at the Centers for Medicare & Medicaid Services on responsiveness to beneficiaries and providers, and on improving the quality of care that beneficiaries receive in all parts of Medicare and Medicaid." U.S. Department of Health and Human Services, News Release, June 16, 2001. Found at <http://www.hhs.gov/news/press/2001pres/20010614.html>.

10. The program was operational as of January 1, 2001, but halted by a June 8, 2001, federal court ruling.

11. NCSL, *State Pharmaceutical Assistance Programs*, at Chart 2.

12. The SILVERxCARD program will allow seniors to receive discounts on prescription medications up to the annual deductible of $500, after which SILVERxCARD will cover all prescription costs above the participant's co-payment amount. Found at <http://www.silverxcard.com/program.html>.

13. The Delaware Prescription Assistance Program (DPAP) began January 14, 2000, as a result of the passage of Senate Bill No. 6 during the 1999 legislative session. This program is funded through tobacco settlement funds, and provides up to $2,500 per individual in each State fiscal year for eligible clients. The State fiscal year runs July 1st through June 30th. The goal of the program is to provide prescription assistance to elderly and/or disabled individuals currently without prescription coverage who have incomes below 200% of the poverty level or have prescription costs exceeding 40% of their income. This program covers medically necessary prescription drugs. The program does not pay for any of the drugs or diabetic supplies for Medicare recipients. Medicare currently covers these supplies for both insulin and non-insulin dependent patients. Found at <http://www.state.de.us/dhss/dss/prescription.html >.

14. The New Hampshire Senior Prescription Drug Discount Program is free and open to any New Hampshire resident 65 or older, regardless of income or homeownership status. Members will be eligible for discounts on generic and brand name medications at participating pharmacies. Discounts will vary based on the pharmacy and the medication, but could reach up to 40% for generic medications and up to 15% for brand name medications. With the card, seniors will pay the lower of the pharmacy's usual price; the pharmacy's sale price; or the pilot programs discounted price. National Prescription Administrators, a private pharmacy benefits manager representing 7 million customers nationwide, will administer the program. Found at <http://www.state.nh.us/governor/health/helpseniors.html >.

15. *See* NGA, at Chart 1.

16. For example, the Minnesota Prescription Drug Program pays for most prescription drugs after enrollees pay the first $35 monthly deductible (per person). Found at <http://www.dhs.state.mn.us/hlthcare/asstprog/prescription_drugs.htm>.
Kansas Senior Pharmacy Assistance Program provides a maximum drug benefit of $1,200 annually for eligible individuals. *See* NCSL, *State Pharmaceutical Assistance Programs*, at Chart 1.

17. The Michigan Elder Prescription Insurance Coverage (EPIC) Program has a $25 annual fee.

18. U.S. General Accounting Office, *State Pharmacy Programs: Assistance Designed to target Coverage and Stretch Budgets* (Washington, D.C.: September, 2000), at 11 (hereafter GAO, *State Pharmacy Programs*).

19. GAO, *State Pharmacy Programs*, at 19.

20. GAO, *Id.*

21. Issue Brief No. 762, *State-Based Pharmaceutical Assistance Programs: Temporary Fix or Lessons for Medicare?* National Health Policy Forum (Washington, D.C.: April 25, 2001).

Chapter 7

STATE PHARMACEUTICAL ASSISTANCE PROGRAMS: THE OLD AND THE NEW

Introduction

Existing or authorized state pharmaceutical assistance programs are usually described as either "state funded direct benefit" pharmaceutical assistance programs or state created "discount" drug programs that require little or no state financing. State programs include:

(1) State-funded direct benefit programs.

- ♦ Traditional pharmaceutical assistance programs.
- ♦ Subsidized prescription drug insurance coverage.
- ♦ State income tax credit.

(2) Programs that provide access to prescription drugs at discounted prices.

- ♦ Ceiling prices on prescription drugs.
- ♦ Medicaid prices for Medicare beneficiaries.
- ♦ Medicaid section 1115 waiver.
- ♦ Bulk purchasing.
  - ❖ Within a state and across states.
- ♦ Buyer's clubs.
- ♦ Prescription drug discount cards.

Given the differences in the economic condition, political landscape, and population demographics in each state, one state's approach to the high cost of prescription drugs is not easily transferred to another.[1] There is no one-size-fits-all program.

State-Funded Direct Benefit Programs

State-funded direct benefit programs use state funds to subsidize prescription drug costs for program participants who meet eligibility requirements, most frequently determined by age,

income, and residency.[2] They primarily target low-income seniors who do not qualify for Medicaid and have no prescription drug coverage; some include disabled individuals.[3] Historically, participants paid only a nominal amount for their prescription drugs. Recently created state-funded programs, however, may require participants to pay a higher portion of the cost for each prescription. Co-payment or co-insurance payments in these programs may be as much as 50% of the prescription drug cost, in contrast to "nominal" co-payments of $5 in earlier programs. Newer programs also are more likely to impose deductibles or benefit caps; enrollment fees are still rare. Instead of the normal point of purchase subsidy, Indiana's HoosierRx reimburses participants for their drug expenditures, requiring participants to bear the burden up front and reap the state subsidy much later.[4]

While general fund revenues finance the majority of state-funded direct benefit programs, some have a dedicated funding source such as lottery or casino revenues. Since 1999, at least eleven states have established or expanded pharmaceutical assistance programs using tobacco settlement funds. States use manufacturer rebates to keep costs low, often conditioning program coverage on rebate agreements.

Because some new programs supplement existing programs and represent an expansion in individuals eligible or benefits provided, differences in scope of benefits or cost sharing are easily reconciled. Programs funded by tobacco settlement revenues may require higher cost sharing because the source of funding is finite. Some new programs represent a state's initial effort to lower prescription drug costs and may reflect a cautious startup. North Carolina's new program covers only certain drugs that treat cardiovascular disease and diabetes, while long established programs may cover all prescription drugs available under Medicaid.[5]

New programs may be wise to start small. The uncertain future of manufacturer rebates is reflected in litigation over rebates required in Medicaid waiver programs or discount programs. Manufacturers have also initiated litigation to halt implementation of drug formularies or "preferred lists" by state Medicaid programs.[6]

Programs that subsidize prescription drug insurance benefits or income tax credits for drug expenditures are discussed separately in this chapter.

The Old: State Funds Provide Drugs at Nominal Cost

New Jersey Pharmaceutical Assistance to the Aged & Disabled

Created in 1975, New Jersey's Pharmaceutical Assistance to the Aged & Disabled (PAAD) program is one of the oldest and largest state-funded pharmaceutical assistance programs. Unlike most state-funded programs, however, PAAD uses casino revenues to subsidize drug costs. Participants include approximately 188,000 seniors and disabled residents[7] who meet income requirements and have drug costs not fully covered by any plan or insurance.[8]

Participants present a program identification card when buying a covered drug, paying the pharmacy $5 co-payment for each covered prescription.[9] Certain generic drugs must be

dispensed instead of a prescribed brand name drug, unless the prescribing physician writes "Brand Medically Necessary" on the prescription.[10] Manufacturer rebates are required[11] and used to offset the cost of benefits provided; only those drugs subject to a rebate agreement are covered.[12] PAAD pays pharmacies the "reasonable cost"[13] of drugs dispensed that exceeds the participant's co-payment. A Drug Utilization Review (DUR) component monitors drug usage. Most participants need to submit a renewal application every two years, although some renew annually.[14]

The New: Supplements an Existing Direct Benefit Program

New Jersey Senior Gold Prescription Discount Program

On May 15, 2001, New Jersey established the "Senior Gold Prescription Discount Program" (Senior Gold), for senior and disabled residents who qualify for no other state-paid drug benefits and who meet Senior Gold's slightly higher income requirements. Senior Gold has higher cost sharing requirements than PAAD: co-payments are $15 plus 50% of the remaining "reasonable cost"[15] of the prescription.[16] After unreimbursed out-of-pocket expenses exceed $2,000 for individuals, or $3,000 for married couples, participants pay only the $15 co-payment. Generic drugs are required, unless a prescriber specifies "no substitutes", and participants pay the difference between the cost of the drug and the commissioner's maximum, plus the co-payment.

Unlike PAAD, Senior Gold's required manufacturer rebates is based only on the State's per-prescription cost. The State reimburses participating pharmacies in an amount equal to the difference between the co-payment and the "reasonable cost" of the prescription drug.

Acknowledging the difficulty in quantifying the number of eligible persons, New Jersey estimated 180,000 seniors and 10,000 disabled would qualify for Senior Gold. Based on 25% to 40% participation of estimated eligibles, state costs are expected to be between $70 million and $86 million in the first full year, including $4.1 million in administrative costs. Like many new programs, Senior Gold is financed by tobacco settlement funds. Senior Gold is a payor of last resort.

The New: A State's First and Only (State-Funded) Program

Missouri Senior Rx

Expected to be operational on July 1, 2002, Missouri's new Senior Rx program is similar to the New Jersey program, but requires participants to meet an initial deductible of $250 or $500, depending on income, after which the state will pay 60% of prescription medication costs. Unlike New Jersey's Senior Gold, the Missouri program does not add to a pre-existing "traditional" program and does not decrease participant cost after an out-of-pocket expense has reached a specified level. Prescription drugs not covered by a Senior Rx rebate agreement will not be reimbursable, but nonparticipation will not affect the manufacturer's Medicaid status.

Medicaid recipients are not eligible and the program is a payor of last resort. Pharmacies are reimbursed a dispensing fee of $4.05, plus the Average Wholesale Price (AWP) minus 20% for brand name drugs or the AWP minus 10.43% for generics.

The New: State Funds Reimburse Out-of-Pocket Drug Costs

Kansas Senior Pharmacy Assistance Program

The Kansas Senior Pharmacy Assistance Program provides state-funded reimbursement to seniors currently receiving Qualified Medicare Beneficiary Program or Low Income Medicare Beneficiary Program benefits who meet income requirements and do not have or qualify for any drug benefit. The annual reimbursement limit is $1,200. Legend drugs and diabetic supplies not covered by Medicare and prescription drugs that treat chronic illness are covered (no over-the-counter, lifestyle, or acute illness drug coverage). The Senior Pharmacy Assistance program is a one-year program, effective July 1, 2001.

Advantages of State-Funded Direct Benefit Programs

- Qualifies for Medicaid "best price" exemption for "state pharmaceutical assistance programs" to get pricing below the "commercial rates"[17] or Medicaid rates without having to give the same discount to all Medicaid programs under the rebate program.
- Provides meaningful coverage to neediest population.
- Long history and wide use can provide useful knowledge to other states creating new programs.
- Retail pharmacy participation ensures widespread access to participants.
- Can impose formulary or preferred drug list.

Disadvantages of State-Funded Direct Benefit Programs

- Requires significant investment of state revenues.
- Continued availability of meaningful rebates is questioned by some.

Insurance Programs

Generally, insurance program participants may have to make premium payments, co-payments to pharmacy when a prescription is dispensed, and meet a deductible before state

subsidized benefits begin. Benefits and cost sharing are often scaled to participant income. Two states, Nevada and Massachusetts, introduced subsidized prescription drug insurance coverage programs for certain low-income residents in 2001, both using tobacco settlement funds.[18] Massachussetts' Prescription Advantages covers seniors and disabled; Nevada Senior Rx covers only seniors. Although both programs are their state's only prescription drug assistance program, Prescription Advantage replaced an earlier state-funded program.

Massachusetts' Prescription Advantage

Prescription Advantage is described as a "state-backed prescription drug insurance plan" for seniors and disabled residents not eligible for Medicaid. On October 1, 2001, Prescription Advantage replaced the Senior Pharmacy Program, a state-funded program that previously provided drugs covered by Medicaid to seniors and certain disabled up to 188% of FPL.

Prescription Advantage has a sliding scale state subsidy up to 500% of FPL, but no income limits. Participants' monthly premiums, co-payments, and deductible are income based. The program incorporates the catastrophic cost element of the Senior Pharmacy Prescription Advantage. After a participant pays $2,000 or 10% of gross annual household income (whichever is less), the participant is responsible only for premium payments for the rest of the year. Prescription Advantage uses a formulary and a three-tier co-payment for generic drugs, select brand name drugs, and additional brand name drugs.[19] Prescription Advantage pays after any other drug benefits are paid.

Nevada Senior Rx

Senior Rx is the only state created prescription drug assistance program in Nevada. It is a state-funded privately managed insurance benefit for residents age 62 and over with incomes less than $21,500 and who are not eligible for Medicaid drug benefits. Early reviews were mixed, at best.[20] Initial enrollment was so low during the first few months of 2001 that lawmakers substantially revised the program in June 2001. Enrollee costs were reduced and the program was simplified.[21] Senior Rx now provides up to $5,000 in annual benefits and tobacco settlement funds subsidize the $1,180 annual premium and $100 deductible costs. The program covers all drugs on a "preferred prescription" list and participants make a co-payment of $10 for generics or $25 for brand name drugs per prescription.[22]

Advantages

- Can use formulary to move market share and increase possibility of obtaining manufacturer discounts.
- Public insurance programs may qualify for Medicaid "best price" exemption.
- Private insurance gives state fixed costs.

Disadvantages

- Retiree programs might end their programs to "buy in" or terminate coverage altogether to save money.
- Complex insurance program would be relatively expensive to administer and difficult for consumers to understand.
- Income related cost structure may create adverse selection, those most likely to enroll will be most expensive; asks higher incomes to knowingly pay more for benefit.
- Public insurance premiums may increase because costs likely to rise.
- Terminating enrollees for not paying premiums would be difficult.
- Using private PBM may eliminate Medicaid "best price" exemption.

Tax Credits

In 2001, only Missouri and Michigan offered state income tax credits for prescription drug expenditures. Both states tax credit programs will terminate by the end of 2001, and be replaced by newly created state-funded direct benefit programs that target seniors.[23] Elimination of this approach indicates its relatively small benefit to a few individuals is outweighed by its drawbacks.

Advantages

- Financial relief for some.

Disadvantages

- Costs the state money not recovered through income tax.
- Minimal savings.
- Delayed benefit doesn't increase affordable access for neediest population—too little, too late.

State Created Discount Drug Programs

In 2001, legislation was enacted in Arkansas, California, Florida, Maine, Maryland, New Hampshire, Oklahoma, Oregon, South Dakota, Texas, Virginia, and West Virginia to lower the cost of prescription drugs for sizable target populations by discount programs, bulk purchasing, expanded manufacturer rebates, price negotiations or price controls.[24] Discount programs reduce the retail cash price for individuals with no drug benefits, but require little state funding. Most state discount programs are new programs without documented evidence of success or failure. Many are not yet operational.

Ceiling Price for Prescription Drugs—Price Control

Maine Rx

In May 2000, Maine Rx was signed into law as the first state discount program to authorize the establishment of "maximum retail price" for prescription drugs. Implementation of the program was halted by federal litigation initiated by the pharmaceutical industry. Because of the nationwide attention the program has received, Maine Rx is discussed in greater detail in chapter 8.

Medicaid Prices for Medicare Beneficiaries

California Discount Prescription Medication Program

In 1999, California enacted a law to allow Medicare beneficiaries to buy prescription drugs at a price "not to exceed the Medi-Cal reimbursement rate for prescription medicines" plus a $.15 fee for transmission charge. The program is funded by pharmacy discounts that are required as a condition of Medicaid participation. It is believed that the retail pharmacists accepted this legislation as a least drastic alternative. An estimated 1.3 million Medicare beneficiaries are eligible.

The stiff burden on retail pharmacies and growing dissatisfaction resulted in S.B. No. 639, approved by the Governor on October 10, 2001, establishing the Golden Bear State Pharmacy Assistance Program to provide low cost drugs for any Medicare beneficiaries. Participation in Golden Bear is voluntary for Medicare beneficiaries, pharmacies, and drug manufacturers. Participants are required to register, on a one-time basis at participating pharmacies. At registration, participants pay an administrative fee to the pharmacy that the pharmacy retains. Pharmacy prices may not exceed a specified amount, with rebates funding Department of Health reimbursements to participating pharmacies. The program will be implemented only if the Department of Health negotiates a sufficient number of rebate agreements and receives any required federal approvals.

Florida Medicare Prescription Discount Program

Similar to California's Discount Prescription Medication Program, Florida's Medicare Prescription Discount Program, effective July 1, 2000, allows any Medicare beneficiary to purchase any prescription drugs at Medicaid participating pharmacies at discounted prices. Pharmacies are required to provide the discounted price[25] as a condition of participating in Medicaid. Unlike California, the U.S. Department of Health and Human Services expressly approved a Florida Medicaid plan amendment to allow the state to implement new provider qualifications "requiring Medicaid participating pharmacies to give price discounts to Medicare beneficiaries similar to those required by Medicaid program."[26]

Advantages

- Little state costs.
- Lower drug prices would save taxpayers money because increased drug use would reduce use of expensive treatments, many that might be paid by Medicaid or Medicare.
- Pharmacy only discount avoids constitutional challenges under commerce clause used when states limit drug manufacturer prices.
- State could administer pharmacy only discount program easily.

Disadvantages

- Discounts of limited value to those with great need and moderate income.
- Pharmacy only discount doesn't take advantage of "best price" exemption.
- Pharmacy only discount places burden on pharmacist whose profit margin is smaller since pharmacy dollars are split 70/30 between the manufacturer and the pharmacy.

Medicaid Waivers—Prescription Drug Discounts for Eligibles

Vermont's Pharmacy Discount Program was established as a Medicaid waiver demonstration program after Vermont's November 2000, request to amend its earlier section 1115, Medicaid waiver was approved by the Health Care Financing Administration of the U.S. Department of Health and Human Services. A federal court ruling on June 8, 2001, has halted this program's operation. Maine's section 1115 waiver program, Healthy Maine Prescription Program, faces a similar court action but remains operational at the time of this writing. Because federal law requires Medicaid waiver demonstration projects to be budget neutral, programs

established to provide prescription drug benefits pursuant to Medicaid waivers should not require additional state funding.

As Medicaid waiver programs, Maine and Vermont claim manufacturer rebates are required for prescription drugs sold to participants in the waiver programs that would not ordinarily qualify for Medicaid pharmacy benefits. Because drug manufacturers have filed lawsuits in federal court against both programs, the future of Medicaid wavers as a tool to expand prescription drug benefits is uncertain pending the resolution of both cases. Despite the healthy industry opposition, a number of states are poised to request Medicaid waivers if Maine and Vermont prevail in the courts.

Maryland Pharmacy Discount Program

Maryland created the Maryland Pharmacy Discount Program as part of Medicaid through section 1115 waiver. If the federal waiver is approved, any Medicare beneficiary without drug coverage will be eligible to enroll and will receive a discount on purchases tied to the Medicaid price less rebates. Persons with incomes at or below 175% of the poverty line ($15,033 single; $20,318 couple) will receive a subsidy of 35% of the costs. If the waiver is not approved, the Pharmacy Discount Program will be run as part of the existing state Pharmacy Assistance Program. In that case, eligibility will be limited to persons with annual incomes at or below 250% of poverty ($21,475 for single; $29,025 for couple). The discount will be tied to the Pharmacy Assistance Program prices less rebates. Persons with incomes at or below 175% will receive a subsidy of 25% of the costs.

Arkansas Prescription Drug Access Program

In 2001, Arkansas created the Prescription Drug Access Program, a Medicaid waiver prescription drug benefit that allows only two prescriptions per month for seniors with no drug coverage and incomes at QMB level, has an enrollment fee of $25 and requires co-payments of $10 for generics and $25 for brand name drugs.[27] The program is not operational because waiver approval has not yet been received.

Advantages

- ♦ May qualify for Medicaid "best price exemption" as Medicaid demonstration project.
- ♦ No additional state or federal funds required.
  - ❖ Federal law requires Medicaid waivers to be budget neutral.

Disadvantages

- Future uncertain because of litigation in Maine and Vermont.
- Unsettled issues of federal preemption because discount prices may violate Medicaid nominal co-pay requirement.
- Opposed by manufacturers.
- Requires waiver from CMS.
- Medicaid waivers unlikely to be granted, until Vermont and Maine litigation is resolved.
- If perceived as Medicaid entitlement, perceived stigma may limit participation.

Bulk Purchasing

A number of states are considering bulk purchasing to lower drug costs by combining the pharmaceutical purchases for groups defined, hoping the increased volume will increase their leverage in price negotiations with drug manufacturers. There are two approaches to combined pools as a tool to lower costs: bulk purchasing within a state and bulk purchasing across a coalition of states.

Bulk Purchasing Within a State

According to a recent report from the National Governors Association on pharmaceutical purchasing pools, Georgia has pooled funds of state employees, higher education health insurance premiums, and the Georgia Medicaid and PeachCare for Kids program, and uses a bulk purchasing program. A private pharmacy benefit manager, Express Scripts Inc., will work with Georgia's Department of Community Health to administer the drug benefits for the pool population.[28] In October 2000, services for Medicaid and PeachCare for Kids participants began.

In 2001, Texas created the Interagency Council on Pharmaceuticals Bulk Purchasing to consider bulk purchasing of prescription drugs by state agencies, including Department of Health and Mental Health, state employees, retirees, teachers, prison systems, and any other agency that purchases pharmaceuticals using existing distribution networks.[29]

Bulk Purchasing Across the States

Since 1999, a number of states have formed coalitions to explore lower prescription drug costs for a variety of populations that include the Northeast Legislative Association on Prescription Drug Pricing, the Northern New England Tri-State Coalition, and the Pharmacy

Working Group. The Minnesota Multistate Contracting Alliance for Pharmacy, however, has been around since 1985.

Minnesota Multistate Contracting Alliance for Pharmacy

Administered by the Minnesota Department of Administration, Materials Management Division, the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP) now has nearly 3,000 participating facilities in 38 states, including Hawaii.[30] Participating states are eligible to get pharmaceuticals and related items and supplies at reduced contract prices; contracts are administered by MMCAP staff. In promoting the benefits of membership, MMCAP's website states "Members are expected to buy pharmaceuticals from the MMCAP contract, not from any other nongovernmental contract with which they may be associated."[31]

Pharmacy Working Group

An alliance of personnel agencies seeking to pool drug purchases for their Medicaid and state employees seven states, the Pharmacy Working Group is an interstate bulk purchasing initiative: Louisiana, Mississippi, Missouri, New Mexico, South Carolina, West Virginia, and Maryland. The total annual pharmacy claims in the seven states is nearly $853 million. West Virginia spearheads the project, and recently sent out a request for proposals for a pharmacy benefit manager (PBM) for a multistate pool.[32] Seven companies submitted bids. The PBM would process claims, collect and report data, and establish and maintain drug formularies.[33] The group plans to pay its PBM on a fixed fee basis instead of a percentage of their drug expenditures. They also want to "put the rebates back to the states" instead of the current practice that allows PBMs to keep most of the rebate funds. The group plans to pick a manager by March and start the program in July in West Virginia. The other states would have the option to join at any time.

Northeast Legislative Association on Prescription Drug Pricing

The six New England states, plus New York and Pennsylvania, have formed a similar bulk purchasing alliance called the Northeast Legislative Association on Prescription Drug Pricing (NELA). Although it was reported in October 2001, that the coalition was having difficulty funding its budget,[34] NELA is now trying to implement a bulk purchasing plan in increments, a few drugs at a time, while trying to form a regional buying pool.[35] Because the most dramatic expense increases are concentrated among a small number of categories of drugs and among a relatively small number of drugs, those categories will be targeted first, according to Cheryl Rivers, Executive Director of NELA, former Vermont state senator. The incremental start will give the coalition experience in negotiating discounts by setting up a list of preferred drugs, e.g. drugs for heart conditions or allergies.[36]

Advantages

- Increased volume may improve chances to negotiate higher savings.
- Bulk purchasing restricted to state pharmacy assistance programs, excluding state employees and others, may qualify for Medicaid "best price" exemption.
  - Can include Medicaid participants and 340B programs because they have "best price" exemption (and anyone else who has 'best price' exemption).

Disadvantages

- New approach without established success.
- May not be considered a "state pharmaceutical assistance program" for Medicaid best price exemption, if program has state employees or others included.
- Anyone outside Medicaid 'best ' exemptions may harm opportunity to get good discount from manufacturer.
- Administrative issues may frustrate across-states efforts.

Buyer's Clubs and Prescription Discount Card Programs

Voluntary buyer's clubs and discount drug cards are essentially the same model: a pharmacy benefit manager or "third party" negotiates prices for each prescription drug; there is no defined discount amount that applies uniformly to all manufacturers or pharmacies. In this model, state investment may be minimal. Administrative program costs may be subsidized by a modest enrollment fee paid by participants. Unlike most proposed state bulk purchasing arrangements, consumer participation in buyer's clubs and discount drug card programs is voluntary. Eligibility and benefits vary and most programs lack statutory authority.

Washington Awards—Retail Pharmacy Discount for Ages 55 and Older

On August 29, 2000, Governor Gary Locke of the State of Washington issued Executive Order 00-04 to establish a Washington State Alliance to Reduce Drug Spending, commonly known as AWARDS, to provide discount drug prices for residents 55 and older who lacked drug coverage. Participation was limited by income requirements. Governor Locke directed the Secretary of Washington's Department of Health and the Administrator of the Health Care Authority to implement the program no later than January 2001. Retail pharmacy discounts were to be negotiated by the Health Care Authority and the program was intended to be self-supporting, or "without cost to the state".[37] The program was enjoined by the courts, and later terminated.

Public Prescription Drug Discount Card Plans

In 2000, several states—New Hampshire, Washington, West Virginia, and Iowa—announced agency-sponsored discount card programs.

Iowa Priority Prescription Savings Program

Federally Funded Rebate Program for Medicare Benefits

Iowa's Priority Prescription Savings Program (Iowa Priority) is the first program of its kind in the nation. It is a nonprofit organization created through an alliance of consumers, physicians, pharmacists and pharmaceutical companies, and funded by a $1 million federal grant from HCFA. Iowa Priority is open to any Medicare beneficiary for a $20 annual membership fee that covers the program's administrative cost. Members will present a card at any Iowa pharmacy to receive a discounted price on any prescription, "actual discounts will vary by prescription."[38] Early enthusiasm promised discounts of up to 70%; more recent estimates predicted a minimum of 10% discounts.[39] Iowa Priority uses a pharmacy benefit manager to negotiate discounts from manufacturers, process claims, and provide other services. The program received approximately 500 to 750 phone calls a day from residents wanting information or to enroll during its first four days of operation.[40] Initial interest was so positive that the organizations' phone system was expanded. Information is also available online or through the Iowa Department of Elder Affairs Area Agencies on Aging throughout the state. Discounts are expected to be available January 2, 2002.

West Virginia Golden Mountaineer Card—Pharmacy Discount for Ages 60 and Older

The new Golden Mountaineer Card was mailed to all West Virginia resident's ages 60 and older in September 2001. Using the card, participants pay the lower of the pharmacy's usual and customary price or average wholesale price minus 13% for brand name drugs and maximum allowable cost minus 60% for generics. AdvancePCS, which administers the card, reimburses pharmacies for the discount and refunds them a dispensing fee. At least one pharmacist has claimed pharmacy losses of 37% of gross profits on each Golden Mountaineer prescription, attributable at least in part to PBM-related fees, while seniors' savings are only 10.4%.[41]

Advantages

- Easy access to retail pharmacies.
- Simple enrollment procedures.
- Negotiated discounts will reduce out-of-pocket expenditures.

- Administration by nonprofit keeps program costs low.

Disadvantages

- Private PBM adds increased expense and administrative burden to pharmacies in Golden Mountaineer.
- Offers minimal discounts, similar prices available through internet pharmacy.
- Some discount plans were implicated in fraudulent schemes, promising more than delivered.

To repeat the obvious, the establishment of a state pharmaceutical assistance program presents no shortage of issues for policymakers to consider.

Endnotes

1. *See* Appendix C for a list of key points to be considered in designing a state pharmaceutical program.

2. State-funded direct benefit programs that include disabled individuals may establish separate requirement for disabled participants.

3. Program enrollments range from under 1,000 to nearly 235,000. As of 2000, two programs, Pennsylvania's Pharmaceutical Assistance Contract for the Elderly and New Jersey's Pharmaceutical Assistance for the Aged and Disabled accounted for 49% of the enrollment; the addition of New York and Massachusetts programs accounted for 72%. Testimony of Stephen Crystal, Research Professor and Chair, Division on Aging, Associate Director for Research, Center for State Health Policy, Institute for Health, Health Care Policy, and Aging Research, Rutgers University; on Medicare Reform, U.S. Senate Finance Committee, April 24, 2001 (hereinafter "Crystal").

4. Currently, the Indiana HoosierRx provides quarterly refunds to qualified low-income seniors who have no drug coverage. The program is scheduled to begin providing direct benefits at the point of purchase in 2002.

5. Newer state funded programs also target primarily low to moderate-income seniors without public or private drug benefits. Established and newer programs often require generic drugs, with exceptions that allow prescribers to specify no substitutions or that allow brand name drugs at higher cost to participant. Some programs include nonprescription medication or medical supplies. *See generally* Richard Cauchi, *State Pharmaceutical Assistance Programs*, Updated January 7, 2002, National Conference of State Legislatures (Denver, CO.: 2002), found at <http://www.ncsl.org/programs/health/drugaid.htm> (hereafter NCSL, *State Pharmaceutical Assistance Programs*) and National Governors Association, *State Pharmaceutical Assistance Programs Chart*, December 18, 2001, found at <http://www.nga.org> (hereafter NGA Chart).

6. *See* Chapter 8 herein for discussion of federal court litigation arising from rebates required by Maine Rx, a discount program and Vermont's Pharmacy Discount Program, a section 1115 waiver demonstration program. On November 30, 2001, the Pharmaceutical Research and Manufacturers of America filed a lawsuit to stop Michigan from implementing a preferred list of drugs for its Medicaid program. The plan initially applies to Medicaid beneficiaries who do not have managed care prescription drug benefits.

Manufacturers contend the plan will require them to offer "steep rebates" to get on the approved list. Six of the largest companies told the state that they will not participate: Eli Lilly, Johnson & Johnson, Merck, Pfizer, Pharmicia, and Wyeth-Ayerst Laboratories. *Pharmaceutical Trade Group Sues Michigan on Drug-Price Plan,* Bloomberg News, December 3, 2001.

7. Participants include 163,958 seniors and 23,400 disabled residents as of September 2000. *See* NCSL, *State Pharmaceutical Assistance Programs,* Chart 1.

8. Eligible residents whose prescription drugs costs are partly covered may receive reduced assistance. Signing the PAAD application authorizes New Jersey to collect payments made on behalf of participants from any other program that may cover prescription drugs. *See* 30 New Jersey Statutes, section 4D-20 *et seq.* (hereafter NJS).

9. Participating pharmacies must display prominently the usual price charged to others on receipts issued with prescriptions bought by PAAD participants as a condition of receiving reimbursement from the program. *See* NJS, section 4D-22.1.

10. A participant may pay the difference between a listed generic drug and the prescribed brand drug, in addition to the co-payment, if the participant prefers to receive the prescribed brand name drug. *See* 30 NJS, section 4D-22.

11. Obviously taking federal law into consideration, the N.J. Commissioner of Human Services is expressly required to ensure PAAD rebates "do not have the effect of establishing a new federal 'best price…'". *See* 30 NJS, section 35.2.

12. Insulin, insulin needles, certain diabetic testing materials, syringes and needles for injectable medicines used for the treatment of multiple sclerosis are also covered under PAAD. Drugs covered by rebate agreements may not be subject to prior authorization or other restrictions on access. *See* 30 NJS, sections 4D-22 and 4D-22.2.

13. Reasonable cost is defined to mean the maximum allowable cost of prescription drugs and a dispensing fee, as determined by the commissioner, except for diabetes testing material, insulin and related equipment. *See* 30 NJS, section 4D-22.

14. Renewal forms are mailed to participants approximately four months before expiration of the PAAD card; completed forms are mailed to Department of Health and Senior Services, Division of Consumer Support, State of New Jersey:

    Mailing Address: PAAD Program
    CN 715
    Trenton, NJ 08625

    PAAD has a toll free number 1-800-792-9745 for participants questions.

15. Reasonable cost is defined to mean the cost of a prescription drug as established for the PAAD program. *See* 30 NJS, section 4D-22.

16. In addition to the higher cost sharing trend of new programs, Senior Gold participants have higher allowable income limits than PAAD participants which may account in part for higher cost sharing in Senior Gold. *See* 30 NJS, section 4D-45.

17. Manufacturers will not give prices lower than Medicaid prices "unless there is a real market incentive to do it". Comments by William von Oehsen, NCSL Health Policy Conference, *State Pharmacy Assistance Programs in 2001*: Crafting New Approaches and Building on Old Ones (Seattle, Washington: November 16, 2001).

18. A third program, Maryland's Short-Term Prescription Drug Subsidy Plan, expanded its enrollment cap to 30,000 recently to include all Medicare-eligible residents over 65 and individuals who have annual household incomes at or below 300% of FPL and monthly premiums were reduced from $40 to $10. Annual benefit is limited to $1,000. *See* NCSL, *State Pharmacy Assistance Program*.

19. According to Prescription Advantage's homepage on the Internet, "Nearly all pharmacies across Massachusetts and the nation accept the Prescription Advantage card." Prescriptions may also be filled through a "cost-saving mail order service", or refilled over the Internet or over the phone. Found at <http://www.800ageinfo.com/info/prescriptiondocument.asp>.

20. When Nevada's Department of Human Resources sent out requests for proposals to insurers, the program intentionally set few restrictions in hopes of attracting a number of responses. Instead, the only response received was from an insurer unlicensed in Nevada. Testimony of Barbara Buckley, Nevada AssemWoman, on Medicare Reform, U.S. House Subcommittee on Health, February 15, 2001.

21. David Gross, *State Pharmacy Assistance Programs 2001: An Array of Approaches*, Issue Brief Number 50, AARP Public Policy Institute (Washington, D.C.: July 2001), at 4.

22. Legislators earmarked 15% of the tobacco settlement to fund the Senior Rx program, amounting to about $5.7 million this year, or enough to serve nearly 5,000 people on a first-come, first-enrolled basis. As of October 5, 2001, Senior Rx had reached its required size of 3,500, with 3,582 seniors enrolled. *See* Nevada Office of the Governor, *Senior Rx Reaches 3,582 Enrollees*, News Release (October 5, 2001), and found at <http://www.nevadaseniorrx.com>.

23. On October 1, the new Michigan EPIC program began operation replacing earlier state pharmacy benefits. On October 5, Missouri enacted a new Senior Rx program. These two changes eliminate the last two states providing a senior pharmaceutical state income tax credit.

24. *See generally* Richard Cauchi, 2001 Prescription Drug Discount, Bulk Purchasing, and Price-Related Legislation, Updated January 16, 2002, National Conference of State Legislatures (Denver, CO.: 2002), found at <http://www.ncsl.org/programs/health/drugaid.htm>.

25. Florida's Senior Prescription Affordability Act of 2000 provides that Pharmacies must charge any Medicare beneficiaries the Medicaid rate for ingredients and fees, plus 4% of the Medicaid ingredient payment, or the Average Wholesale Price (AWP) minus 9% + $4.50 dispensing fee.

26. *U.S. Backs Florida Plan to Cut Drug Costs*, The New York Times, September 19, 2001.

27. Arkansas Senate Bill 932, Regular Session 2001.

28. Samantha Ventimiglia, *Pharmaceutical Purchasing Pools*, Issue Brief, National Governors Association Center for Best Practices, Health Policy Studies Division (October 24, 2001), at 4. *See* <http://nga.org/cda/files/102401pharmpools.pdf>.

29. The Council also is required to investigate options of expanding Medicaid purchasing, and using federally qualified health facilities. Legislation establishing the council also includes provisions for manufacturer and wholesaler price reporting and enforcement powers for the Attorney General.

30. MMCAP has an annual sales volume of $600 million, and contracts with over 130 drug manufacturers. Until 1997, the Hawaii Health System Corporation (HHSC), purchased pharmaceuticals through MMCAP for public hospitals it administers. Currently, HHCS purchases its prescription drugs through a GPO that serves

1,200 hospital systems nationwide. *See* <http://www.mmd.admin.state.mn.us/mmcap.htm> and telephone interview with Hawaii Health Systems Corporation, by Lynn Merrick, January 3, 2002.

31. *See* <http://www.mmd.admin.state.mn.us/mmcap.htm>.

32. Although Maryland participated in the initiative, it was the only state of the seven members not included in the bulk purchasing group.

33. *Seven companies bid on multistate drug purchasing pool project*, The Associate Press State and Local Wire, December 17, 2001.

34. Vermont appropriated $45,000 toward the Northeast Legislative Association on Prescription Drug Prices. Maine has included $18,000 for each of the next two years in its budget, but the money still has not arrived. The other states - Massachusetts, Connecticut, Rhode Island, New York and Pennsylvania—have not made a commitment and New Hampshire has said it's unlikely to chip in this year toward the $100,000 budget. *Regional drug coalition may try incremental approach*, AP State and Local Wire, December 13, 2001.

35. *Id.*

36. A meeting scheduled for January 2002, will discuss whether taking the incremental approach is a good idea and whether it can be done without duplicate authorizing legislation in all states.

37. *See* Exec Order 00-04, *Establishing a Washington State Alliance to Reduce Prescription Drugs Spending "AWARDS" Program*, signed by Governor Gary Locke on August 29, 2000.

38. *See* <http://www.iowapriority.org>.

39. *Drug co-op sign-up set for seniors*, DesMoines Register, November 8, 2001.

40. *Interest in Iowa Priority Prescription Savings Program Surpasses First Week Expectations*, News Release, Iowa Priority, November 19, 2001, found at <http://www.iowapriority.org>.

41. *W.Va. Rx Card Costs Pharmacy 37% Of Profits, Pharmacist Tells House Cmte.*, Health News Daily, October 26, 2001.

With the Golden Mountaineer Card, which began in September, seniors pay the lower of the pharmacy's usual and customary price or average wholesale price minus 13% for brand name drugs and maximum allowable cost minus 60% for generics. AdvancePCS, which administers the card, reimburses pharmacies for the discount and refunds them a dispensing fee.

Chapter 8

MAINE AND VERMONT: TWO PROGRAMS WITH ISSUES

This chapter discusses the much-watched Maine Rx program, as well as the Vermont Pharmacy Discount Program, including events that preceded the establishment of both programs. The programs are significant not only because drug manufacturers fervently oppose both programs and have initiated litigation in federal court to halt their implementation or operation, but also because:

- Maine Rx authorizes the State to establish "maximum retail prices" for drugs; requires manufacturer rebates for drugs sold out-of-state; and creates the new civil offense of profiteering in prescription drugs; and

- Vermont's Pharmacy Discount Program, an expansion of Vermont Health Access Plan Pharmacy Medicaid waiver project, requires manufacturer rebates to lower drug costs for residents who don't qualify for Medicaid prescription benefits, and is very similar to the Healthy Maine Prescriptions program, also a Medicaid demonstration project subject to pending federal litigation, created to provide affordable drugs for much of Maine Rx's target population.

Maine Prescription Drug Programs

Maine has a notable tradition of state involvement in prescription drug issues. In 1975, Maine established one of the first two state-funded direct benefit pharmaceutical assistance programs for low-income older residents, the Elderly Low Cost Drug Program. In recent years, the Maine Legislature and the governor have "wrestled with issues concerning taxes on tobacco products, improving the health of Maine citizens and whether and how those issues should be connected."[1] The Legislature has convened several groups and requested studies and recommendations to improve access to affordable prescription drugs for Maine residents.[2]

In the spring of 2000, Maine passed a law that established Maine Rx, a program to provide discount prescription drug prices for all "uninsured and under-insured" state residents, with no age or income restrictions.[3] Maine Rx has attracted national attention, with nearly 30 states introducing similar legislation in 2001. In October 2000, however, implementation of Maine Rx was halted when a federal court issued an injunction against implementing most of the law. State legislatures are closely monitoring the status of this pioneering program.

The legal challenges preventing the implementation of Maine Rx motivated Maine's Department of Human Services (DHS) to request various Medicaid waivers to establish a prescription drug program that would aid "a significant portion of the Rx target population".[4] The Health Care Financing Administration (HCFA) of the United States Department of Health

and Human Services granted the waiver on January 19, 2001, and the Healthy Maine Prescriptions program (Prescriptions program) was established on June 1, 2001. The Elderly Low Cost Drug program (Elderly Program) was incorporated as a component of the Prescriptions program.

The Healthy Maine Prescriptions Program

The Healthy Maine Prescriptions program, a Medicaid waiver demonstration project, has added significance because it was established to temporarily take the place of Maine Rx, the discount drug program many states are watching. Like Maine Rx, the Prescriptions Program targets Maine residents who lack drug coverage, and allows participants to buy certain prescription drugs and over the counter medications or supplies at discounted prices.[5] The Elderly Program, a state financed direct benefit program established in 1978, was incorporated as a component of the Prescriptions Program and is discussed separately below.

Eligibility[6]

Participants must be Maine residents and, unlike Maine Rx, must meet certain income requirements. Although household income must be less than 300% of the FPL, there are no asset requirements. Residents covered under the pre-existing Elderly Program automatically qualify for the Prescription Program. Individuals enrolled in both programs receive the more generous discount where benefits overlap.[7] Individuals who receive Medicaid prescription drug benefits are not eligible.[8]

Benefits

The Healthy Maine Prescriptions Drug Card covers most, if not all, prescription drugs available under Medicaid prescription benefits.[9] Savings of "up to 25% on prescriptions" are touted on Healthy Maine Prescriptions' website. Some over the counter medications, such as insulin and syringes, are also covered if prescribed by a physician. Certain prescriptions require prior approval from DHS before they may be dispensed.[10]

Procedure

Participants are issued a Healthy Maine Prescriptions card, which they present at participating pharmacies to buy discounted prescription drugs. For each covered prescription, participants pay the Medicaid rate minus the established program subsidy—essentially, the Medicaid rebate amount (e.g., if the program subsidy or rebate is 15%, a participant pays 85% of the Medicaid rate for each prescription). Maine reimburses the pharmacy the subsidy amount for prescriptions dispensed to participants and bills drug manufacturers to collect rebates quarterly.

Funding

As a Medicaid demonstration project, the Prescriptions Program is required by law to be "budget neutral". Medicaid manufacturer rebates paid to the State and DHS established pharmacy discounts finance the program.[11] Originally, a required enrollment fee was expected to offset administration costs, but no enrollment fee is currently required.[12]

Elderly Low Cost Drug Program

Maine's Elderly Low Cost Drug Program was one of the first two state pharmaceutical assistance programs in the nation, implemented in 1978 as a traditional direct benefit type program and financed by state funds. Like other direct benefit programs, rebates from drug manufacturers helped to lower program costs.[13] Initially, the program covered prescription drugs for only two conditions. During the late 1990s, the program expanded—the number of drugs covered increased and the target population grew.[14] Catastrophic coverage was added.

As a component of the Prescriptions program, the Elderly Program now provides low cost prescription and nonprescription drugs, medication and medical supplies to disadvantaged, elderly, and disabled individuals.[15]

Eligibility

Participants must be a Maine resident and at least 62 years old, or 19 years old and disabled by Social Security standards. Household income must be less than 185% of the FPL.[16] Income limits are 25% higher for individuals who spend at least 40% of their household income on prescription drugs. An individual that receives state supplemental income benefits or Medicaid pharmaceutical benefits does <u>not</u> qualify for the Elderly Program.

Benefits[17]

Brand name drugs to treat certain illnesses and generic drugs for <u>any</u> condition are covered. Because of significant state funding, prescription drug costs for Elderly Program participants are much lower than the discount prices available under the Prescriptions program. Under the basic program, Maine pays 80% of the cost of generic drugs[18] and 80% of the cost of brand name drugs to treat chronic conditions of diabetes, heart disease, high blood pressure, chronic lung disease, arthritis, high cholesterol, incontinence, thyroid disease, osteoporosis, Parkinson's disease, glaucoma, multiple sclerosis, and ALS.

Supplemental coverage includes all prescription drugs and medications provided under Medicaidif not already provided in the basic component, with certain exceptions. DHS pays $2 for each supplemental coverage prescription, and the consumer pays the remainder (the Medicaid price minus the manufacturer's discount).

After a participant has spent $1,000 on prescription drugs in a year, the State pays 80% of the cost of all subsequent prescriptions.

Procedure

As a component of the Prescriptions program, the procedure is much the same (but drug prices are lower for drugs available under the Elderly Program's Basic Coverage): participants present a Healthy Maine Prescriptions program card (formerly an Elderly Low Cost Drug Program card) when filling a prescription,[19] the participating pharmacy collects the appropriate co-payment, then bills the state for the difference between the agreed-upon selling price for the drug (plus a dispensing fee) and the co-payment collected. Maine reimburses the pharmacy quarterly, and collects rebates from the drug manufacturer for prescriptions dispensed to Elderly Program participants.

The Elderly Program uses the same Drug Utilization Review as Medicaid. The system tracks patients drug usage and "steers" them to use generics. The Elderly Program is the payor of last resort, paying for the drug only if there is no other insurance coverage. DHS is required to produce and provide educational materials to be mailed to eligible residents or included with drug purchases.

Funding

Originally financed completely through state funds, only the basic coverage of the Elderly Program now receives state funds. Supplemental coverage is intended to be self-sufficient, funded through manufacturer rebates and co-payments. Beginning January 1, 2001, all manufacturers and labelers that participate in Medicaid are required to participate in the Elderly Program, drug rebate program.[20]

Prescription Program and the Elderly Low Cost Drug Program—Overlap

The Department of Human Services administers the Healthy Maine Prescriptions program, including its Elderly Low Cost Drug program component. Individuals who enroll in both programs are entitled to the more generous discount if the programs' benefits overlap. Individuals who are eligible for both programs receive a single certificate of eligibility. Or, as stated in a DHS press release announcing the June 1, 2001, start date for the Healthy Maine Prescriptions program, the Prescriptions Program "supplements", the Elderly Low Cost Drug program, gives seniors discounts on drugs covered by the Prescriptions Program but not by the Elderly Program.[21] If a rebate paid for any prescription under the Prescriptions Program, a rebate is not due under the elderly low cost drug program.[22]

Litigation

Although the Pharmaceutical Research and Manufacturers of America (PhRMA) filed an action in federal court in July 2001, to enjoin the Healthy Maine Prescription Program, the pending litigation has not halted its operation.[23]

Maine Rx—States are Watching

Background

Because Maine Rx requires little or no state funding, has no age or income restrictions, and, perhaps most importantly, because it authorizes price controls to keep prescription drug prices reasonable, the program has received a lot of national attention. As discussed above, affordable prescription drugs for all residents have been an issue in Maine for some time. Although Maine's economy during the late 1980s made spending state general funds difficult, Maine's improved fiscal condition and tobacco settlement funds allowed expansion of the Elderly Program in the late 1990's; the Elderly Program's long established record of success led to strong support for expansion.

Reviewing recommendations from a number of task forces or commissions convened to study prescription drug affordability, Maine's Legislature recognized that "affordability is critical in providing access to prescription drugs". An early version of Maine Rx was enacted in 1999: a statewide discount prescription drug program for residents who lacked drug coverage called the Maine Resident Low Cost Prescription Drug Program.[24] Never implemented, the program was repealed when the law establishing Maine Rx was signed into law by Maine Governor Angus King, in May 2000.

In contrast to the broad support for Elderly Program expansions, drug manufacturers and eventually pharmacy groups strongly opposed the legislation to establish Maine Rx. Seniors and senior advocates, unions, women's groups, and religious organizations provided grassroots support for Maine Rx, joining with a key leader in the Senate, Majority Leader Chellie Pingree who was instrumental in the bill's passage. When an earlier version of Maine Rx tied manufacturer drug prices to Canadian prices, Governor King convened a committee to redraft the bill to stand up to constitutional challenges. Eight days later, the rewritten bill was introduced on the next-to-the last day of the legislation and passed the next day.

The resulting bill created Maine Rx to "reduce prescription drug prices for residents of the State."[25] It allows any Maine resident who lacks drug coverage benefit to buy prescription drugs at discounted prices from participating retail pharmacies. Maine Rx is designed to use manufacturer rebates and pharmacy discounts to reduce the cost of prescription drugs, at no cost to the State. Maine serves as pharmacy benefit manager in establishing or negotiating rebates from drug manufacturers and pharmacy discounts.[26]

Eligibility

Any Maine resident who lacks drug benefit coverage is eligible.[27]

Benefits

Once implemented, Maine Rx cardholders will be able to buy prescription drugs from participating pharmacies at discounted prices. Drugs made by manufacturers who enter a Maine Rx rebate agreement with DHS will be covered by the program.[28]

Two stages of discount prices were anticipated. The "initial discount price" available at the program's initial start-up is defined to mean a price less than or equal to the average wholesale price (the price the manufacturer suggests the wholesaler charges the pharmacy for the drug), minus 6%, plus the Medicaid dispensing fee. A "secondary discounted price", originally scheduled to take effect by October 1, 2001, is a price equal to or less than the "initial discounted price" minus the rebate amount.[29]

Procedure

Ultimately, any qualified Maine resident who has received a program enrollment card is then eligible to purchase prescription drugs at a discounted price from any participating retail pharmacy upon presenting the card. The discounted price is based on the drug manufacturer rebate amounts and pharmacy discounts negotiated or established by DHS. A discussion of the roles and responsibilities of the parties other than the consumer follows:

1. Department of Human Services:

The Maine Department of Human Services administers Maine Rx,[30] but is authorized to contract with a third party to administer any or all parts of the program, including outreach, eligibility, claims, administration, and rebate recovery and redistribution. The DHS Commissioner negotiates the drug manufacturer rebates, taking into consideration Medicaid rebates, the average wholesale price of prescription drugs[31] and any other information on prescription drug prices and price discounts, while the "department" (DHS) establishes the "discounted prices" for participating retail pharmacies.[32] Initial and subsequent rebates at least equal to the Medicaid rebate and the Federal Supply Schedule price, respectively, are Maine Rx's targets.[33] DHS is required to undertake outreach efforts to build public awareness and maximize enrollments.

In optimistic anticipation of congressional action to establish prescription drug benefits for Medicare beneficiaries, DHS is authorized to adjust the requirements and terms of the program to accommodate any new federally funded prescription drug programs.

2. Drug Manufacturers and Labelers:

Drug manufacturers and labelers that participate in the elderly low cost drug program or "any other publicly supported pharmaceutical assistance program", presumably Medicaid, are required to enter into a rebate agreement with DHS for Maine Rx and make rebate payments to the State according to a schedule established by DHS. The names of nonparticipating drug manufacturers and labelers shall be released to health care providers and the public by DHS. As a further consequence, prior authorization requirements are imposed in the Medicaid program for prescription drugs provided by those nonparticpating manufacturers and labelers.

3. Retail Pharmacies:

Participating retail pharmacies are required to sell prescription drugs covered by a Maine Rx rebate agreement to participants at DHS—set discounted prices. Initially, prescription drugs were to be sold to participants at the "initial discount price" beginning January 1, 2001, and at the "secondary discounted price" no later than October 1, 2001. Participating pharmacies are required to disclose the amount of savings provided by Maine Rx to program participants.

Pharmacies submit claims for drugs sold to Maine Rx participants to DHS, who in turn, reimburses each participating pharmacy on a weekly or biweekly basis for discounted prices and for professional fees set by the Commissioner, initially "set at $3 per prescription."

The Prescription Drug Price Reduction Act's "Maximum Retail Price"

The "price control" portion of Public Law 786 is known as the "Prescription Drug Price Reduction Act" (the Act) and is intended to "make more prescription drugs more affordable for qualified Maine residents". The Act provides that, under certain conditions, the DHS Commissioner "shall establish maximum retail prices for any or all prescription drugs sold in the State".[34] The Act establishes a Prescription Drug Advisory Commission (Commission) to review access to and the prices of prescriptions drugs and to advise the Commissioner on drug pricing, including the need for maximum retail prices. DHS provides staffing for the Commission and must adopt rules about setting and reviewing maximum retail prices.

The Commissioner, by January 5, 2003, is required to determine whether the Maine Rx prescription drug costs are "reasonably comparable to the lowest cost paid for the same drugs delivered or dispensed" in Maine. If the average cost for one or more prescription drugs is not reasonably comparable to the average lowest cost for the same drug, the Commissioner is required to "establish maximum retail prices for any or all prescriptions drugs" sold in Maine, effective July 1, 2003. The Commissioner is authorized to take actions determined necessary if limited access to drugs "could threaten or endanger the public health or welfare".[35]

Profiteering in Prescription Drugs

Subchapter III of Public Law 786 establishes the civil offense of illegal profiteering, defines the elements, authorizes a State civil action against a violator, establishes a penalty, and requires the Maine Attorney General to investigate suspected violations at the Attorney General's own initiation or in response to petition by the Commissioner or fifty residents.

Maine Rx: The Litigation

Trial Court

In August 2000, PhRMA brought an action in the U.S. District Court in the District of Maine against Maine's Attorney General and the DHS Commissioner, contending that Maine Rx violated the U.S. Commerce Clause and was preempted by federal law (the Medicaid statute) under the Supremacy Clause.[36] PhRMA requested a preliminary injunction to block enforcement of Maine Rx's mandatory rebate agreement provision and the Medicaid prior authorization required for dispensing prescription drugs for nonparticipating manufacturers and labelers.

PhRMA contended Maine Rx violated the dormant Commerce Clause because it:

- Regulates drug manufacturer's out-of-state transactions through the profiteering provision and required rebate agreements;
- Ties Maine Rx rebates to rebates for drugs sold in other jurisdictions; and
- Prohibits manufacturers from rearranging their distribution channels.

PhRMA also contended Maine Rx's prior authorization provision curtails Medicaid patients' access to manufacturer's drugs to punish nonparticipating manufacturers in violation of the Supremacy Clause.

In response, Maine argued that Maine Rx will not affect out-of-state drug prices and the use of the Medicaid rebate amount invokes a "national" standard and is not the "economic parochialism" prohibited by the dormant Commerce Clause. Additionally, the State argued any effect on interstate commerce is outweighed by its interest in making drugs affordable for those residents least able to pay for them,[37] (note—Maine Rx has no income limit) and the state's attempt to leverage its market power as a drug buyer to lower prices for its citizens is an allowable market participant exception of the Commerce Clause. Finally, Maine contended that federal law, 42 U.S.C. section 1396r-8, expressly granted states the broad authority to adopt programs that impose prior authorization requirements in dispensing drugs in Medicaid programs.[38]

On October 26, 2000, the District Court issued a preliminary injunction that enjoined Maine from enforcing the Maine Rx rebate requirement by imposing Medicaid prior authorization for nonparticipating manufacturers and from enforcing the illegal profiteering

provision to out-of-state transactions, even if the prescription drugs "eventually end up and are ultimately purchased in Maine".

Appellate Court

Maine appealed. The U.S. Court of Appeals issued its order on May 16, 2001, reversing the District Court and vacated the temporary injunction. In noting that "this is a close case", the appellate court concluded that:

- There is no conflict between Maine Rx Medicaid law that results in federal preemption because the Medicaid prior authorization procedures required for drugs made by manufacturers not participating in Maine Rx are consistent with those permitted by Medicaid and the prior requirement administrative burden will not harm Medicaid recipients;

Maine Rx does not violate the dormant Commerce Clause:

- It regulates only in-state activities; and

- Local benefits appear to outweigh any incidental burden on interstate commerce.

On May 30, 2001, PhRMA requested reconsideration by the appellate court. The court denied PhRMA's request for reconsideration on June 14, 2001.

U.S. Supreme Court

On July 31, 2001, PhRMA appealed to the U.S. Supreme Court. On October 9, 2001, the U.S. Supreme Court issued a "one sentence order" requesting an opinion on the Maine Rx law from the U.S. Solicitor General.

Discussion of Maine Rx and Court Opinion

It is uncertain when the litigation over Maine Rx will be resolved.

Although Maine Rx directs the DHS commissioner to use best efforts to achieve rebates at least equal to Medicaid rebates and the best price for prescription drugs sold to federal agencies, those goals would seem to be unreachable (see discussion on federal law in chapter 5). Achieving a rebate better than Medicaid rebates is possible under certain "best price" exemptions in federal law. Traditional state-funded pharmaceutical assistance programs are specifically exempt and may negotiate rebates better than Medicaid prices. Since Maine Rx is <u>not</u> a traditional state-funded program that has proudly announced no state funds are required, it is questionable whether it would qualify under the "state pharmaceutical assistance program"

exemption to receive rebates better than Medicaid without requiring the drug manufacturer to extend the same price to all Medicaid programs.[39]

Similarly, federal supply schedule prices must be equal to or better than prices offered to a manufacturer's "most favored" nonfederal customer. Since FSS prices are approximately 15% lower than the Medicaid net prices, a rebate that equals FSS prices would be lower than Medicaid prices and only possible if Maine Rx qualifies for a "state pharmaceutical assistance program" best price exemption.

Vermont Prescription Drug Programs: VScript and VHAP Pharmacy

Vermont has two pharmacy benefit programs currently operating: VScript and VHAP Pharmacy. VScript began as a traditional state-funded direct benefit program for low-income seniors and disabled residents; it covers only maintenance drugs. VHAP Pharmacy is a section 1115 Medicaid waiver demonstration project that provides pharmacy assistance for certain low-income seniors and disabled residents who do not qualify for Medicaid; as a Medicaid demonstration program, VHAP covers all prescription drugs covered by Medicaid.

VScript & VScript Expanded

VScript, was established as a traditional state-funded direct benefit "pharmaceutical assistance program for elderly and disabled Vermonters" in 1989.[40] VScript allows elderly or disabled individuals on Medicare who have no drug benefits with incomes from 151% to 175% of the FPL, to receive Medicaid covered maintenance drugs only, with a $1 co-payment for each prescription less than $30, or $2 for each prescription of $30 or more. Drug manufacturers are statutorily mandated to pay rebates "in an amount at least as favorable as the rebate paid to…the Medicaid program".[41] In March 1999, VScript became part of Vermont's section 1115(a) waiver demonstration project.

In January 2000, VScript was expanded to include Medicare eligible Vermonters with incomes of 175% to 225% of the FPL. VScript Expanded, as the newer program is called, is state-funded and covers the same prescription drugs as the original VScript, but VScript Expanded participants have higher cost sharing requirements—50% of the cost of each prescription.

Vermont Health Access Plan Pharmacy (VHAP Pharmacy)

A second program, VHAP Pharmacy, began on January 1, 1996, as part of the Vermont Health Access Plan (VHAP) initiative. The Vermont Health Access Plan was established in 1995 as a section 1115(a) Medicaid waiver demonstration project to provide health care services to uninsured low-income residents not eligible for Medicaid and to provide a "prescription drug benefit to the State's lower income elderly or disabled Vermonters on Medicare".

The VHAP initiative was designed to improve access and quality of care by using managed care to deliver services to VHAP participants and to traditional Medicaid recipients. Revenues saved by implementing use of managed care for Medicaid programs allowed Vermont to expand eligibility. VHAP Pharmacy is one such expansion.

VHAP Pharmacy allows non-Medicaid elderly or disabled individuals who lack drug coverage and who have incomes up to 150% of the FPL to buy drugs covered by Medicaid (VScript covers only maintenance drugs) for a $1 co-payment for prescriptions less than $30, or $2 for prescriptions $30 or more. VScript has approximately 5,100 participants and VHAP Pharmacy has more than 8,600.

VHAP Pharmacy Discount Program—Halted by Court Order

Vermont's Pharmacy Discount Program is relevant because its ultimate resolution will determine whether a state may establish a Medicaid waiver demonstration project to provide discounted drugs to low-income residents who lack drug coverage, but do not qualify for traditional Medicaid. Also, it's future is important because of its similarity to the Healthy Maine Prescriptions Program, the discount drug program for certain Maine residents who lack drug benefits that was established after litigation halted the implementation of Maine Rx. Both programs are discount drug programs established after receiving approval from HCFA to create or expand programs providing affordable access to prescription drugs for low-income residents who do not receive Medicaid drug benefits. After PhRMA's victory in halting the operation of Vermont's Pharmacy Discount Program, they filed a similar action to stop the Healthy Maine Prescription Program. In addition, a number of states have pending discount drug programs very similar to PDP, hoping that PDP will be upheld and they will be allowed to establish their programs as a Medicaid waiver demonstration project and receive rebates to fund discounts on prescription drugs.

Even after the establishment of the VScript (including its expansion) and VHAP Pharmacy programs, rising drug costs continued to be an issue in Vermont. In March 2000, Vermont submitted an amendment to its section 1115 demonstration waiver to expand the VHAP Pharmacy Program. On November 3, 2000, HCFA approved Vermont's request to amend its demonstration project to "institute the VHAP Pharmacy Discount Program", noting approval would "permit Vermont to expand its pharmacy program (VHAP Pharmacy Program) to cover two new groups and will extend access to discounted prices for prescription drugs to them."[42] The Pharmacy Discount Program (PDP) was that expansion of the VHAP Pharmacy Program.

Under the PDP, nearly 70,000 Vermont residents, mostly seniors, qualified for partial Medicaid benefits—prescription drug only—under its expanded eligibility requirements. The PDP participants would not normally have qualified for Medicaid services.

The Pharmacy Discount Program was implemented January 1, 2001, but its operation was halted by a U.S. Court of Appeals for the District of Columbia Circuit decision issued June 8, 2001, that declared the HFCA waiver invalid.[43]

Eligibility

Beneficiaries are Medicare eligible persons with an income of 151% of the FPL or greater, or any non-Medicare eligible person whose income is 300% of the FPL or less. PDP's target population was estimated to be 37,500 Medicare beneficiaries and 31,350 residents with incomes under 300% FPL. The Pharmacy Discount Program served approximately 5,400 Vermonters at the time that its operation was halted.

Benefits

PDP provides access to drugs covered by Medicaid at discounted prices, participants pay "Medicaid pricing for all Medicaid covered drugs, net of the rebate amount required under the Omnibus Reconciliation Act of 1990."[44] Vermont claimed "this translates into a cost to the individual that is approximately 30% lower than what the person normally pays for the prescription."[45]

Procedure

PDP operates similar to the Healthy Maine Prescription Program. For each prescription filled, a pharmacy files a claim with the program's processing agent and receives the difference between the participant's payment and the Medicaid payment rate. The administrative agency collects the rebate from pharmaceutical manufacturers.

Funding

As an expansion of an existing Medicaid waiver demonstration project, the establishment of PDP is required by federal law to be cost neutral. Drug manufacturers are required to pay rebates to Vermont for drugs purchased by PDP participants.

Litigation

Trial Court

The Pharmaceutical Research and Manufacturers of America (PhRMA), representing drug manufacturers who have Medicaid rebate agreements with the U.S. Department of Health and Human Services, filed a lawsuit against the Secretary of the U.S. Department of Health and Human Services seeking a preliminary injunction to stop operation of the Pharmacy Discount Program.[46] PhRMA contended that HCFA's approval of Vermont's request to amend its Medicaid waiver to change the eligibility requirements for Medicaid pharmaceutical services violates federal Medicaid law. Refusal to pay rebates to the PDP program, manufacturers argued, could result in their disqualification from participation in the entire Medicaid program.[47]

PhRMA alleged that since neither the federal nor Vermont government made payments under the PDP, the PDP violated Medicaid law that provides drug manufacturers to "owe rebates only for drugs 'for which payment was made under the State plan'." PhRMA also claimed the program requires participants to pay approximately 82% of the price of their prescriptions, in violation of Medicaid's requirements that states charge Medicaid beneficiaries no more than a "nominal" amount.[48]

On January 17, 2001, sixteen days after Vermont began implementing PDP, the District Court concluded that PhRMA was unlikely to win on the merits and denied PhRMA's request for a preliminary injunction.[49] PhRMA appealed from the District Court's denial of its request for a preliminary injunction.

Appellate Court

On appeal, the Secretary of Health and Human Services (HHS) asserted that "payment" means payment, and contended that Vermont made "payment" even though the state received reimbursement from drug manufacturers. The Secretary also contended that the manufacturers did not have standing to represent the interests of PDP participants.

On June 8, 2001, the U.S. Court of Appeals for the District of Columbia Circuit ruled for PhRMA, reversing the district court and remanding the case for further proceedings. Ignoring questions of policy or effectiveness of the PDP, the court addressed only the issue of whether the Department of Health and Human Services exceeded its statutory authority by authorizing Vermont to require drug manufacturers to make rebates for drugs sold under the PDP.[50]

The court noted that legislative history indicates the rebate requirement was imposed to reduce the cost of Medicaid and to prevent drug manufacturers from overcharging the government and taxpayers for Medicaid drugs. Because Vermont's PDP payments are "fully reimbursed by manufacturer rebates, and because the rebates produce no savings for the Medicaid program", the court concluded that Vermont's payments to pharmacies were not "payments" within the meaning of Medicaid law.[51]

Discussion of Vermont's Pharmacy Discount Program and Court Opinion

Similar to Healthy Maine's Prescription Program, Vermont's Pharmacy Discount Program was created as a Medicaid demonstration project to provide lower prescription drug costs for state residents who have low to moderate income and no drug benefits. Under both programs, drug manufacturers are required to make Medicaid rebate payments for prescription drugs sold to program participants who would not ordinarily qualify for Medicaid services. The programs present a powerful tool that establish mandatory Medicaid rebates to lower drug prices in programs that neither are traditional Medicaid pharmacy programs nor traditional state-funded pharmaceutical assistance programs.[52]

The court did not consider PhRMA's alternative argument, that PDP violates Medicaid law that provides that a state may charge Medicaid beneficiaries only a "nominal" amount for their prescriptions.[53] The Secretary of Human Services may authorize a state's "experimental 'pilot' or 'demonstration'" project that is "likely to assist in promoting the objectives of [Medicaid.]"[54] In noting that the Social Security Act (Act) authorizes the Secretary of HHS to waive certain Medicaid requirements for a "demonstration" project, the court opined that "the Act does not authorize him to waive any requirements of section 1396r-8's rebate provision or the requirement that Medicaid beneficiaries contribute no more than a 'nominal' amount to the cost of medical benefits they receive."[55] Although it is certain that demonstration projects may expand Medicaid eligibility requirements, and that states have some flexibility in designing their Medicaid program benefits, it is not clear that a Medicaid waiver eliminates the "nominal" amount requirement.[56]

PhRMA argues that Vermont attempted to use the Medicaid laws to impose an "illegal burden on prescription drug manufacturers", and notes that the Social Security Act "does not permit states to collect rebates on drugs that are not paid for by the Medicaid program".[57] The Secretary of Health and Human Services may require Medicaid rebate payments only where there is a State "payment" under Medicaid law. Although a number of other state pharmaceutical assistance programs have long required drug manufacturers to pay "Medicaid-type" rebate to the state, the PDP is seeking Medicaid rebates (as a Medicaid waiver demonstration project), not Medicaid-like rebates.

To participate in the Medicaid program, a drug manufacturer must enter into agreement with the U.S. Department of Health and Human Services (HHS). An agreement between the manufacturer and HHS is not required for state pharmaceutical assistance programs that mandate rebates. Under Medicaid, the federal government will reimburse states only for drugs subject to HHS rebate agreement. that requires the manufacturer to pay rebates for their prescription drugs dispensed to Medicaid participants.. Rebates required by traditional state-funded direct benefit programs have not been challenged, although some believe it will be increasingly difficult for state programs to negotiate meaningful rebates from drug manufacturers, particularly in light of the economic conditions resulting from the September 11, 2001, tragedies in New York and Washington D.C..

When Vermont was granted its original section 1115 waiver, the state properly enlarged its Medicaid eligibility pool based on savings enacted when Vermont implemented managed care to provide Medicare services. PDP differed in payment structure to potential Medicaid beneficiaries and in the amount paid by those beneficiaries. Managed care savings allowed Vermont to establish a budget neutral program that served a larger population without an increase in state or federal funding.

Clearly Vermont's experience, and other states', indicates that states may utilize a Medicaid section 1115 waiver to expand the population served by Medicaid, which includes prescription drug benefits. Where the program beneficiary pays "more than a nominal sum" as in Vermont's PDP, the results are less predictable. An expanded Medicaid program has good news and bad news. The good news is that any expansion of Medicaid is required to be budget neutral, no extra state or federal funds are expended, yet services or population served may

increase. The bad news is the creation of an entitlement. Using a Medicaid waiver to establish a demonstration program may provide some assistance to a state's low to moderate-income residents who have no drug benefits. If Vermont's PDP is allowed to continue, it is uncertain whether the program would create an entitlement. States will have to await a final court ruling on not only Vermont's Pharmacy Discount Program, but also the Healthy Maine Prescription Program. Policy makers should not hold their breath.

Endnotes

1. Margaret Reinschant and Darlene Shores Lynch, *Final Report of the Task Force on Improving Access to Prescription Drugs for the Elderly*, submitted to State of Maine Legislature, Office of Policy and Legal Analysis (Augusta, ME.: February 17, 1998), at 1.

2. *Final Reports of the Task Force on Improving Access to Prescription Drugs for the Elderly*, the Commission to Study Bulk Purchasing of Prescription Drugs and Medical Supplies, and the Joint Select Committee to Study the Creation of a Public/Private Purchasing Alliance to Ensure Access to Health Care for All Maine Citizens were submitted to the State of Maine Legislature in 1998, 1999, and 2000, respectively. The various groups reviewed other states' programs and heard about specific and general inadequacies of the current the Elderly Drug Program. The Final Reports are found at <http://www.state.me.us>.

3. Governor Angus King signed Public Law 786 on May 12, 2000.

4. On January 5, 2001, DHS submitted to the Health Care Financing Administration of the U.S. Department of Health and Human Services Maine's proposal for a "demonstration project to expand Medicaid eligibility for prescription drugs to all individuals up to 300% of the Federal Poverty Level (FPL) without Medicaid or other third party prescription drug coverage benefits." Since the proposed project intended to offer only a "partial prescription drug benefit", Maine sought a waiver of section 1902(a)(B) and 42 C.F.R. sections 440.230-250, requiring that the amount, duration, and scope of service be equally available to all recipients. Maine also sought a waiver of Section 1902(a)(34) and 42 C.F.R. 435.914 to eliminate the requirement of retroactive eligibility for demonstration recipients; and sections 1902(a)(17), 1902(a)(10)(A)(ii)(I), and (11) and 42 C.F.R. part 435, subparts G, H, and I to eliminate asset limits. A section 1115(a)(2), was requested so that Maine's Prescription Program expenditures of Maine Rx would be regarded as expenditures under the State's Medicaid plan. *See* Letter from Kevin Concannon, Commissioner, Maine Department of Human Services, to Timothy Westmoreland, Director, Center for Medicaid and State Operations, Health Care Financing Administration, U.S. Department of Health and Human Services, January 5, 2001.

5. As a Medicaid waiver demonstration program, however, the Prescription Program requires participants to meet income qualifications, thus serving a smaller population than Maine Rx's intended target. Healthy Maine Prescriptions was "designed to make prescription drugs more affordable for more than 200,000 Maine citizens." Found at <http://www.state.me.us/bms/hmpwebsite>.

6. Because the law establishing the Healthy Maine Prescription Program provides little detail on the operation of the program, information on eligibility, benefits, and other features of the programs is based largely on information in Maine's Medicaid Waiver request of January 5, 2001.

7. Individuals in both programs receive a single certificate of eligibility entitling them to benefits of both programs. *See* 22 Maine Revised Statutes, section 258.

8. Individuals who have full Medicaid coverage also are not eligible for the Low Cost Drugs for the Elderly or Disabled component of the Healthy Maine Prescriptions Program. *See* 36 Maine Revised Statutes, section 6121-B.

9. According to information on Healthy Maine Prescriptions website, the program covers "all drugs from companies with signed agreements with the federal government". This would mean that prescription drugs available under Medicaid (which requires a manufacturers rebate agreement with the U.S. Department of Health and Human Services as a condition of participation) are available at discounted prices to Prescription Program participants. *Note,* however, in response to "What drugs are covered by the Healthy Maine Prescriptions Program", the Frequently Asked Questions portion of the Healthy Maine Prescriptions website states that "Almost all prescription drugs from companies with contracts with the federal government area covered by the program". See information on Healthy Maine Prescriptions found at <http://www.state.me.us/bms/hmpwebsite/coveredservices.html> and <http://www.state.me.us/bms/hmpwebsite/faqs.html>.

10. DHS's website advises consumers that their physician or pharmacist can provide information on medicines covered and assistance in getting any required prior authorizations. DHS must grant or deny prior authorization requests within 24 hours of receipt of a doctor's request for approval. An "override" may allow a 34-day supply of the drug if the physician cannot be reached by the pharmacy and it is a new prescription. Otherwise, participants may receive a 72-hour supply if the physician cannot reach DHS. *Id.*

11. DHS declared that the Prescriptions Program "does not require state or federal tax dollars to support". *See* Maine Department of Human Services, Press Release, January 19, 2001. Maine contends that drugs covered by the Prescriptions Program are subject to the Medicaid rebate program requirements, and that drug manufacturers that participate in Medicaid are required to pay rebates to the State for drugs sold to Healthy Maine Prescriptions Program participants.. The Elderly Program's basic coverage, a component of the Prescription Program, continues to be financed by state funds. The Elderly Program also uses manufacturer rebates to lower program costs for both basic coverage and supplemental coverage.

12. *See* Letter from Kevin Concannon, Commissioner, Maine Department of Human Services, to Timothy Westmoreland, director, Center for Medicaid and State Operations, Health Care Financing Administration, U.S. Department of Health and Human Services, January 5, 2001.

13. Effective May 1, 1992, reimbursement was denied for drugs from manufacturers who do not enter an Elderly Low Cost Drug Program rebate agreement with DHS. Rebate amounts were statutorily defined from October 1, 1992, until October 1, 1998, when DHS was required to "seek to achieve an aggregate rebate amount from all rebate agreements that is 67 percentage points higher" than the earlier defined amount, "provided such rebates result in a net increase in rebate revenue available to the elderly low cost drug program." *See* 22 Maine Revised Statutes, section 254.

14. As of August 1, 1999, income eligibility was expanded to 185% of the FPL and the age criteria for disabled individuals was lowered from 55 to 19. A supplemental drug benefit was added. As of August 2000, the program was expanded to included all generic drugs and a cap on catastrophic prescription drug expenses was added, initially $1,000 per year. *See* Letter from Kevin Concannon, Commissioner, Maine Department of Human Services, to Timothy Westmoreland, Director, Center for Medicaid and State Operations, Health Care Financing Administration, U.S. Department of Health and Human Services, January 5, 2001.

15. *See* 22 Maine Revised Statutes, section 25.

16. Before August 1, 1999, income level was determined by reference to the Maine Residents Property Tax Program and was not expressed as a percentage of the Federal Poverty Level (specifically the definition of "elderly household" in Title 36, section 6201, and the income ceilings of elderly households in section 6206 of Maine Revised Statutes). Currently, the income limits are $1,790 per month for a couple or $1,325 per month for an individual. *See Prescription Drug Assistance—A Guide for Maine Elders and Adults with Disabilities* found at <http://www.state.me.us/dhs/beas/medbook.htm>. *See* also 22 Maine Revised Statutes, section 254 2-A.

17. The commissioner determines the "extent and the magnitude of the program" based on the "calculated need of the recipient population and the available funds". *See* 22 Maine Revised Statutes, section 254.

18. Participants pay $2 or 20% of the cost of generic drugs, whichever is greater. Generic or chemically equivalent drugs are required unless otherwise prescribed. *See* 22 Maine Revised Statutes, section 254 4-A

19. Although some prescriptions require prior approval before they may be dispensed, DHS states that "most drugs" do not. Brand name drugs are subject to a 34-day supply limitation, while generic drugs may be dispensed as 90-day supplies. *See* information on Elderly Program found at <http://www.state.me.us/bms/hmpwebsite/coveredservices.html> and <http://www.state.me.us/bms/hmpwebsite/faqs.html>.

20. *See* 22 MRSA, section 254 8-A. Earlier law denied payment for drugs from nonparticpating manufacturers; current law denies payment.

21. Maine, Department of Human Services, Press Release, June 1, 2001.

22. *See* 22 Maine Revised Statutes, section 258.

23. PhRMA claims that the program violates Medicaid laws. PhRMA's legal action to halt Healthy Maine is similar to the action it filed to stop Vermont's Pharmacy Discount Program, also a Medicaid demonstration project. A month before PhRMA's lawsuit against CMS, a federal appeals court ruled in PhRMA's favor that the Secretary of Health and Human Services improperly approved Vermont's PDP.

    PhRMA contends that HCFA did not have authority to grant Maurs waiver giving Medicaid pricing to a "non-poor population not otherwise eligible for Medicaid services". *Pharm Research and Manufacturers of America v. Tommy G. Thomphson*, U.S. Court of Appeals for the District of Columbia, No. 01-5029 (June 8, 2001).

24. The Maine Resident Low Cost Prescription Drug Program was never implemented; it appears to be an earlier version of Maine Rx.

25. *See* 22 Maine Revised Statutes, section 2681.

26. A pharmacy benefit manager is defined to mean an entity that procures prescription drugs at a negotiated price under a contract. *See* 22 Maine Revised Statutes, section 2681. Because pending litigation has prevented implementation of Maine Rx, the Healthy Maine Prescription Program (discussed above) was established as a Medicaid waiver demonstration project to target a similar population: Maine residents without drug benefits.

27. The Department of Human Services is required to establish procedures to determine eligibility and issue enrollment cards to qualified residents. By definition, a "qualified resident" is "a resident of the State who has obtained from the department a Maine Rx enrollment card." *See* 22 Maine Revised Statutes, section 2681 2-F.

28. Drug manufacturers or labelers that participate in the Elderly Low Cost Drug Program or "any other publicly supported pharmaceutical assistance program" are required to enter into a rebate agreement with DHS and to make rebate payments to the State. *See* 22 Maine Revised Statutes, section 2681 3.

29. The initial rebate amount was anticipated to be the Medicaid rebate amount or better, while rebates "taking effect no later than October 1, 2001", were hoped to equal or be greater than prices for prescription drugs bought by the federal government, presumably Federal Supply Schedule price. *See* 22 Maine Revised Statutes, 2681 2.

30. In addition to Maine Rx, DHS is directed to administer "other medical and pharmaceutical assistance programs under this Title in a manner that is advantageous to the programs and to the enrollees in those programs." DHS is authorized to coordinate other programs with Maine Rx to enhance efficiency, reduce drug costs and maximize benefits to the programs and the enrollees, "including providing the benefits of this program to enrollees in other programs". *See* 22 Maine Revised Statutes, section 2681 13.

31. The "average wholesale price" of prescription drugs is defined by Maine Rx law to mean "the wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in a nationally recognized drug pricing file." *See* 22 Maine Revised Statutes, section 2681 2-A. The Commissioner also sets the amount of professional fees paid to participating retail pharmacies. *See* 22 Maine Revised Statutes, section 2681 6-D.

32. The Department is required to set discount prices for "drugs covered by a rebate agreement and shall promote the use of efficacious and reduced-cost drugs, taking into consideration reduced prices for state and federally capped drug programs, differential dispensing fees, administrative overhead and incentive payments." Pharmacies were expected to offer initial discounted prices by January 1, 2001, and secondary discounted prices no later than October 1, 2001. *See* 22 Maine Revised Statutes, section 2681 0-5.

33. The Commissioner is directed to use "best efforts" to obtain an initial rebate equal to or greater than the Medicaid rebate amount, and an amount equal to or greater than the amount of any discount, rebate or price reduction for prescription drugs provided to the Federal Government. *See* 22 Maine Revised Statutes, section 2681.

34. Maximum retail prices may be established to achieve the public health purposes in 22 Maine Revised Statutes, section 2691. Section 2691 provides that the Act is enacted as a positive measure to make prescription drugs more affordable for qualified Maine residents, thereby increasing the overall health of Maine residents, promoting healthy communities and protecting the public health and welfare of Maine residents.

35. *See* 22 Maine Revised Statutes, section 2693.

36. PhRMA's challenged the constitutionality of provisions of Maine Rx that require manufacturers' rebates, mandate prior authorization in Medicaid for nonparticpating drug manufacturers, punish manufacturers who rearrange distribution channels to minimize their exposure in Maine, and require manufacturers who participate in Medicaid to also participate, beginning January 1, 2001, in the rebate program of Elderly Low Cost Drug Program. Complaint for Declaratory, Injunctive and Other Relief, *PhRMA v. Kevin Concannon, et al.* (U.S.D.C. Maine No. 00-1578).

    PhRMA's sought to prohibit implementation and enforcement provisions relating to rebate agreements and rebate amounts; action with regard to nonparticipants (Medicaid prior authorization requirement and public disclosure), the prohibition against profiteering in prescription drugs, and mandatory participation in rebate program of the Elderly Low Cost Drug Program beginning January 1, 2001, for all manufacturers and labelers that participate in Medicaid. Plaintiff's Motion for Preliminary Injunction, *PhRMA v. Kevin Concannon, et al.* (U.S.D.C. Maine No. 00-1578).

37. Defendants' Memorandum of Law in Opposition to Plaintiff's Motion for Preliminary Injunction, *PhRMA v. Kevin Concannon, et al.* (U.S.D.C. Maine No. 00-1578).

38. *Id.*

39. There is no definition of "state pharmaceutical assistance program" in the law creating the best price exemption. *See* 42 U.S.C. section 1396r-8(c)(i)(III).

40. The Department of Prevention, Assistance, Transaction and Health Access of the Office of Vermont Health Access is required to "establish application, eligibility, coverage and payment standards". The Department is also directed to administer the program. *See* 33 Vermont Statutes Annotated, section 1992(a).

41. *See* 33 Vermont Statutes Annotated, section 1992(e).

42. Letter from Michael M. Hash, Acting Administrator, HCFA, U.S. Department of Human Services to Eileen I. Elliott, Commissioner, Vermont Department of Social Welfare dated November 3, 2000.

43. PhRMA appealed. *See PhRMA v. Thompson*, No. 01-5029, U.S. Court of Appeals (D.C. Circuit), June 8, 2001.

44. The rebate for calendar year 2001 was to be 17.5%. *See Vermont Health Access Plan Pharmacy Programs*, found at <www.dsw.state.vt.us/districts/ovha/ovha9.htm>.

45. *See Pharmacy Discount Program (PDP) History*, found at <www.dsw.state.vt.us/districts/ovha/ovha9.htm>.

46. PhRMA challenged "approval of Vermont's demonstration project requiring manufacturers to rebate a portion of the price of drugs purchased directly by certain individuals who are not otherwise covered by the state's Medicaid program." Because PhRMA members have entered into Medicaid rebate agreements with the Department of Health and Human Services, they are required to pay rebates to Vermont under the PDP. *See PhRMA v. Thompson*, No. 01-5029, U.S. Court of Appeals (D.C. Circuit), June 8, 2001.

47. In seeking a preliminary injunction, PhRMA also argued that while U.S. Department of Health and Human Services could block them from Medicaid participation, Vermont could stand behind sovereign immunity to avoid PhRMA's lawsuit to recover rebates paid. The Secretary of HHS did not deny that the drug manufacturers could be prohibited from participating in Medicaid if they did not pay PDP rebates. Similarly, Vermont's Secretary of Human Services did not deny that sovereign immunity barred PhRMA's potential recovery of rebates paid. *Id.*

48. *Id.*

49. *See PhRMA v. United States and the State of Vermont*, No. 2000-2990, D.D.C. (January 17, 2001) (order denying preliminary injunction).

50. The court commented "Our task, however, is neither to evaluate the PDP's policy justification nor to determine whether the program best serves the pharmaceutical needs of the poor…We face a straightforward legal issue: Did the Department exceed its statutory authority by authorizing Vermont to require pharmaceutical manufacturers to make rebates under the PDP?" *See PhRMA v. Thompson*, No. 01-5029, U.S. Court of Appeals (D.C. Circuit), June 8, 2001.

51. Congress intended "payment" to mean "payment with funds appropriated for Medicaid purposes", and "payment" does not include expenditures that are fully reimbursed by manufacturer rebates. In 2000, Vermont received a rebate of approximately 18%. Vermont would pay pharmacies the rebate amount, then bill the drug manufacturer for that amount. Thus, the court reasoned, "PDP benefits would be paid not with funds appropriated by Congress and the states for Medicaid services", but by beneficiaries and drug manufacturers.

    Specifically, the court's opinion states: "[B]ecause Congress imposed the rebate requirement in order to reduce the cost of the Medicaid program and because no Medicaid funds are expended under the Vermont demonstration project and thus no Medicaid savings produced by the required rebates, we conclude that the

Department lacked authority to approve the project. We therefore reverse the district's decision to the contrary and remand for further proceedings." *Id.*

52. Medicaid waiver demonstration programs are required to be budget neutral as a condition of approval. Arguably, state monies are used to pay some PDP administrative costs since the program was administered by the state agency that administers Vermont's Medicaid program.

53. *See* 42 U.S.C. section 1315(a)(1); *PhRMA v. Thompson*, No. 01-5029, U.S. Court of Appeals (D.C. Circuit), June 8, 2001.

54. *See* 42 U.S.C. section 1315(a).

55. *PhRMA v. Thompson*, No. 01-5029, U.S. Court of Appeals (D.C. Circuit), June 8, 2001 (emphasis added, citing 42 U.S.C. section 1315(a)(1)).

56. Under the PDP, the court noted, participants would pay 82% of the cost of each prescription, and drug manufacturers would pay the remaining 18% (the amount of the rebate). *Id.*

57. Brief for Appellant PhRMA, *PhRMA v. Thompson*, No. 01-5029, U.S. Court of Appeals (D.C. Circuit), June 8, 2001, at 13.

Chapter 9

OTHER OPTIONS TO LOWER PRESCRIPTION DRUG COSTS

Introduction

In addition to state-funded direct benefit and discount prescription drug assistance programs, some states have used or authorized other options aimed at increasing access to affordable prescription drugs. These options include regulating private sector prescription drug discount card or buyer's club programs; expanded use of federally qualified health centers able to take advantage of 340B discount drug prices; programs to coordinate information on public and private programs that promote consumer awareness and facilitate participation[1]. Most programs discussed in this chapter involve little or no state funding.

Regulation of Private Discount Drug Plans, Buyer's Clubs, or Both

There are a number of private discount drug card plans that offer discounts on some or all prescription drugs. Although these plans are not established or usually regulated by state law, New Hampshire, South Dakota, and Texas recently enacted laws to regulate pharmacy discount cards or buyers clubs to protect consumers. A few representative discount card programs are described briefly below. Buyer's clubs or cooperatives operate much the same way as discount drug cards

AARP Prescription Savings Service—Nonprofit, AARP Insureds

Sponsored by the American Association for Retired Persons (AARP), the AARP Prescription Savings Service is a free program available only to AARP Health Care Options insureds. Benefits terminate when participation in AARP Health Care Option ends. The plan averages "15% off of brand name drugs and 50% - 55% off of generic alternative drugs" for mail order drugs[2] and establishes a Personalized Medication Review to track the prescriptions participants purchase through the service to avoid potentially harmful drug interaction.

YOURxPLAN—Pharmaceutical Manufacturer Managed Care, No Eligibility Requirements

Run by Merck-Medco Managed Care, YOURxPLAN gives members discounts or savings up to 40% on "virtually all brand-name and generic drugs". Members who buy a brand name drug from the "List of Selected Drugs" receive an additional 10% cash-back bonus (based on the price paid, minus the sales tax) every three months.[3] Members pay an enrollment fee of $25 for an individual and $40 for a family membership. Merck-Medco offers discount prices based on their relationships with participating retail pharmacies and "arrangements with most

pharmaceutical manufacturers under which it may receive favorable pricing, payments for dispensing drugs included on the List of Selected Drugs, payments based on changes in market share or other compensation."

Citizens Health Corp—Nonprofit, Uninsured/Underinsured in Certain States Only

Citizens Health Corp. was formed on September 25, 2001 as a prescription drug discount program for people who pay full retail price for some or all of their prescriptions. Members pay an annual fee of $12 for individuals or $28 for families, and receive discounts at participating pharmacies in Connecticut, Massachusetts, and Rhode Island, with deeper savings on certain drugs ordered by the Citizens Health mail service pharmacy. All prescription drugs are included, but over the counter medications are not. Discounts are based on the "group buying power of its members" and extra discounts offered by the program's two drug company sponsors, Bristol-Myers Squibb Company and GlaxoSmithKline. Citizens Health uses Express Scripts, one of the largest PBMs, to administer the program.

GlaxoSmithKline Drug Manufacturer—Low-Income Medicare Beneficiaries with No Drug Benefits

On October 2001, GlaxoSmithKline a pharmaceutical manufacturer launched the Orange Card discount program for low-income (300% or below the FPL) Medicare beneficiaries without drug benefits, or approximately 11 million potential eligibles. Administered by Express Scripts Specialty Distribution Services, the free program covers GlaxoSmithKline outpatient products only, promising discounts that average 30% off the usual cash price and that may reach 40%. Members present their Orange Card when filling their prescription to receive the discount.

State responses to the increase in the number of private discount card or buyer's club programs include:

New Hampshire

- Effective January 1, 2002, consumer protection rights are extended to users of certain discount cards that are not insurance, but "purport" to offer discounts or access to discounts for prescription drug purchases.
  - Requires registration with Consumer Protection and Antitrust Bureau of the New Hampshire Department of Justice;
  - Requires express notice that discount available only at participating pharmacies; and
  - Violation constitutes an unfair or deceptive act or practice.

South Dakota

- Prohibits deceptive trade practices regarding prescription discount cards:
  - Cards must state that discounts are not insurance;
  - Discounts must be specifically authorized by a separate contract with each pharmacy listed; and
  - The discount or access to discounts offered must not be "misleading, deceptive, or fraudulent, regardless of the literal wording".

Texas

- Requires Texas Health Information Council (Council) to develop criteria for evaluating drug purchasing cooperatives and create an evaluation form for consumers;
- Requires Council to distribute evaluation forms to state agencies and compile information to help consumers make an informed choice in choosing buying cooperative.

Development of Clearinghouse/Education/Outreach Programs

Many individuals who do not have prescription drug benefits may not be aware of the public and private programs that provide or help provide prescription drugs at free or low cost. In recognition that many such programs are under enrolled, several states have enacted legislation aimed at increasing consumer and provider awareness of available public and private programs and facilitating participation.

Maryland

- Created MedBank, a clearinghouse program that links residents to manufacturers' free drug programs.
- State funds pay administrative costs and "interim" supplies of drugs until a person is determined eligible for the free drugs.

Virginia[4]

- Required Commissioner of Health Department to establish a resource and referral program with a toll free phone number to provide information on drug manufacturers' free patient assistance drug programs.
  - Information shall include available drugs, participating companies, application procedures, and dispensing methods.
  - May contract with public or private organizations to administer the program.
- Law does not become effective until funds are appropriated or available for this purpose.

Expand Use of Federally Qualified Health Centers and 340B Discount Drug Program

Section 340B of the Public Health Service Act created a federal discount drug program for federally qualified health centers (FQHC). These safety net providers play a crucial role in providing health care, including prescription drugs, to low-income individuals, many of whom lack drug coverage. Several states have authorized or are considering an expanded use of FQHCs to increase access to low cost drugs.[5] In addition, the U.S. Department of Health and Human Services has announced a recent initiative to potentially expand the program's reach to a greater number of needy individuals. Approved demonstration projects allow an increased number of pharmacies where prescriptions can be dispensed to expand and improve patient access to affordable medications.

Maryland

- Authorized the Department of Human Services to request from the federal government medically-underserved area designations, and other designation or approval to establish FQHCs to use the federal supply schedule for prescription drugs.
- Subject to the availability of funds.

Miscellaneous Options

In addressing the cost of prescription drugs, state legislators have introduced legislation that includes a number of alternatives to the traditional state-funded or discount prescription drug assistance programs. Legislation introduced, but not enacted, includes proposals to regulate pharmaceutical benefit managers, allow medical savings accounts for prescription drug, establish a prescription drug reimportation program, require drug manufacturers to disclose advertising

and marketing costs, and require all health plans to issue a card containing uniform prescription drug information.

Recently, Oklahoma passed legislation authorizing the distribution of unused prescription drugs to low-income residents without drug benefits; Vermont and other states are instituting a formulary, or list of preferred drugs to keep pharmaceutical expenditures down and avoid reducing benefits in a number of public programs.

Oklahoma

- Directs the State Board of Health and state agencies to develop a pilot program that allows transfer of certain unused prescription drugs to health departments or county pharmacies for distribution to the medically indigent.

Vermont

- Directs the state to establish a Pharmacy Best Practices and Cost Control program to be implemented for Medicaid and V-Script beneficiaries; may be implemented for any public or private plan that agrees to participate.

- Contract with a Pharmacy Benefit Manager (PBM) to develop a "preferred list" or formulary for prescription drugs, with utilization review, including prior authorization procedures.

- Permit doctors to require the dispensing of a higher cost drug if the lower cost drug is not effective or may result in adverse reactions.

- Goal to operate by 2002.

Federal Government as the Solution?

On July 12, 2001, President George Bush announced a Medicare endorsed drug discount card for Medicare beneficiaries. The plan was supported by large pharmacy benefit management companies and strongly opposed by pharmacy organizations who filed a lawsuit in U.S. District Court for the District of Columbia on July 17, 2001. Enrollment was anticipated to begin approximately November 1, 2001, but was halted by federal court ruling on September 7, 2001, granting the pharmacy trade groups' request for a preliminary injunction.[6] In early November, the injunction was lifted to allow the plan to be revised. The future of the President's discount drug card is uncertain.

Although several states have passed or are considering resolutions requesting the U.S. Congress to pass a Medicare prescription drug benefit, congressional action is also uncertain in light of the events of September 11, 2001, and U.S. actions that followed. Some say U.S. efforts

against terrorism, revenue lost from tax cuts, and the recession make it less likely that proposals dealing with spending increases, especially the creation or expansion of entitlements will succeed.[7]

Access to affordable prescription drugs is an issue facing serious obstacles. At a recent forum on health issues for state government officials, health related officials stated that while prescription drugs, tobacco prevention, health care costs, and Medicaid are high priority issues, the main concern for many states is the budget and revenue shortfalls.[8] For example, in Florida a special legislative session cut $22 million from the $30 million prescription drug assistance program that was approved in 2000. As a result, the program will now help only about 8,000 residents instead of the initial prediction of 30,000.

Economists predict that the current recession is likely to last for many months, with high levels of unemployment, and large and small companies going bankrupt. As state and national economies falter, however, the pharmaceutical industry continues to report strong profits.[9] Although the high prices of prescription drugs boosts the earnings of drug manufacturers, they often make needed medications unattainable for low-income seniors, disabled, and other individuals who lack prescription drug benefits.

The chief advantage of the several options discussed in this chapter is the low cost to the state, an advantage of no little significance—particularly in light of economic conditions that prevail in many states as a result of the terrorist attacks of September 11, 2001. Although programs that coordinate information on public and private programs and facilitate participation, laws to regulate private discount drug plans, or other options discussed herein do not solve entirely the problem of affordable drugs, they are initial steps that are worthy of consideration.

Endnotes

1. Vermont and Washington introduced legislation to fund countermarketing or counterdetailing programs to educate physicians, other prescribers, and consumers. These programs are intended to "balance the effect of pharmaceutical company marketing behavior." *See* National Conference of State Legislatures, *2001 Prescription Drug Discount, Bulk Purchasing, and Price-Related Legislation*, Updated: December 18, 2001, (hereafter NCSL Discount Legislation) found at <http://www.ncsl.org/programs/health/drugdisc01.htm>.

2. AARP Pharmacy Services website found at <http://www.aarp.pharmacy.com>.

3. For 14 of the most commonly prescribed brand name drugs for seniors, actual savings ranged from 0% to 40% using YOURxPLAN's convenient Home Delivery Pharmacy, and from 0% to 30% at participating retail pharmacies. The program claims its Home Delivery Pharmacy prices averaged 18% lower than retail prices; and participating retail pharmacies averaged 11% lower than retail prices for the 14 brand name drugs. *See* <http://www.yourxplan.com>.

4. Missouri, Oregon, Texas, and Virginia have created or authorized similar programs.

5. In addition to Maryland, Arkansas, and Texas also have passed legislation to use FQHCs for expanded prescription drug coverage. Other states have similar legislation pending. *See* NCSL Discount Legislation.

6. Judge Paul Friedman found that the U.S. Department of Health and Human Services did not have legal authority to create the program and that the Department had not followed the proper rules in adopting regulations. *Judge Blocks Prescription Discount Plan*, Washington Post, September 7, 2001, p. A 1.

7. *Drug Coverage Advocates Fear Losing Ground Because of War Effort*, Newhouse News Service, December 19, 2001.

8. Mary Guiden, *State Health* Experts *Cite Budget Woes a Major Concern*, November 20, 2001, found at <http://www1.stateline.org/index.do;jsessionid=h1118m8rg1>.

9. *Rx prices soar as economy plummets*, The Capital (Annapolis, MD), December 9, 2001, E-5.

Chapter 10

SUMMARY AND RECOMMENDATIONS

In recent years, affordable prescription drugs was a key issue in most state legislatures. As of January 7, 2002, thirty-one states have established or authorized some type of prescription drug program. Although state governments and consumers alike continue to face increasing expenditures for prescription drugs, prescription drugs do not appear in the anticipated top ten legislative issues for 2002. The National Conference of State Legislatures predicts that the war on terrorism, the changing economy, and a pivotal election year will play major roles in defining this year's legislative activities.

In the best of times, there is no one size fits all answer to the problem of rising drug costs. In today's climate, a meaningful answer is even more difficult. State-funded direct benefit programs providing drugs at nominal cost continue to predominate, with newer state-funded programs often requiring higher cost sharing by participants. To minimize state funding, recently established programs tend to require a somewhat higher co-payment or co-insurance amount, and may impose deductibles, benefit caps, or both as cost control tools. Discount prescription drug programs, voluntary buyers clubs, and other options such as bulk purchasing within and across states are being explored as less costly to states. Most of the state prescription drug assistance programs established or authorized in the last two years are not yet operational, or are so new that their value to participants has not been established. Bulk purchasing implementation, for example, has been slow because states have taken some time to agree on administrative and other program details. The value of discount drug card programs, however, was disputed by a recent U.S. General Accounting Office report that found drug discount cards do not result in significant price reductions for seniors buying brand name drugs, averaging savings of less than 10%.[1]

A number of states are poised to request a Medicaid waiver to establish a prescription drug benefit program similar to Vermont's Pharmacy Discount Program and in 2001, approximately twenty-seven states introduced legislation modeled on Maine Rx. However, pending federal court proceedings initiated by drug manufacturers to block implementation of both of these programs makes their future uncertain. Other recent attempts to control drug costs and increase access by imposing required rebates and discounts, prior authorization, formularies, or preferred drug lists have faced strong opposition from drug manufacturers, pharmacy groups, or both. Lawsuits to halt pharmaceutical assistance or Medicaid programs using these approaches have also been filed in Florida, Washington, and Michigan.[2] In addition, although most types of pharmaceutical assistance programs rely on negotiated or mandatory rebates from drug manufacturers to keep program costs down, some feel that the future of rebates as a cost control tool or financing mechanism is in question.[3] Some programs, both new and established, are being forced to redesign themselves to remain viable.[4]

The price paid for prescription drugs depends in large part on who is doing the buying. The recently formed in-state and across-state bulk purchasing alliances have concluded that the volume of their aggregated pharmaceutical purchases will result in greater rebates. Voluntary

buyer's clubs and prescription drug discount card programs share that belief. While bulk purchasing or buyer's clubs may achieve some price reductions, state-funded direct benefit programs have a higher value to participants. A key consideration in price determination is the buyer's ability to drive market share toward specific brand name products. The more ability a pharmaceutical buyer has to drive market share toward use of particular drugs, the more willing the drug manufacturer is to offer that buyer significant rebates or discounts.[5]

Although volume is not irrelevant, market share is also driven through use of preferred drug lists or formularies and, to a certain extent, cost sharing tools in the form of co-payments or co-insurance. Despite the litigation facing Medicaid programs attempting to impose preferred drug lists or formularies, state pharmaceutical assistance programs should give serious consideration to using formularies or preferred drug lists. Generally, Medicaid programs are required to cover drugs from manufacturers who have signed a rebate agreement with the U.S. Department of Health and Human Services. State pharmaceutical assistance programs have no similar mandate. While many state-funded direct benefit programs cover only those drugs from manufacturers who enter a rebate agreement with the program, state prescription drug assistance programs may, and should, develop a list of preferred drugs covered by the program as a cost containment tool and as a device to move market share, influence physicians' prescribing habits, and gain a significant rebate from participating manufacturers. In addition to having the freedom to impose a preferred drug list, traditional state direct benefit programs are eligible to receive discounts even greater than Medicaid programs because of their Medicaid best price exemption.

Programs that tie prescription drug prices for state programs to foreign or federal prices are likely to encounter difficulties. In addition to constitutional issues raised, federal laws influence federal prices, giving federal buyers an advantage not available to states. Unless a state establishes a pharmaceutical assistance program that qualifies for the Medicaid best price exemption,[6] a state is not likely to receive prescription drug prices equal to, much less better than, Federal Supply Schedule (FSS) prices. Since FSS prices are lower than Medicaid prices, manufacturers will not offer FSS prices to nonfederal buyers who do not have a Medicaid best price exemption because federal law would require them to offer the same price (the new "best price") to all Medicaid programs.

Eligible Hawaii residents, often low-income uninsureds, may get low cost prescription drugs at community health centers that benefit from federal laws. The Hawaii Primary Care Association's Medicine Bank transfers donated prescription drugs to community health centers for distribution to their patients; the Medicine Bank cannot provide medications directly to patients.[7] Hawaii's federally qualified health centers, community health centers, and other section 340B covered entities or safety net providers should seek federal approval to participate in the U.S. Department of Health and Human Services' new initiative aimed at expanding the ability of these safety net providers to improve access to prescription drugs at lower costs for a greater number of uninsured patients.

The Veteran Administration's (VA) national contract price success, probably the lowest prices offered to any pharmaceutical buyer, is not likely to be duplicated by Hawaii. The Federal Ceiling Price and FSS give VA its initial advantage over state buyers. But, the VA's drug formulary also gives it a price containment and negotiation tool lacking in most state programs.

The formulary increases VA's ability to influence its physician prescribing habits, increasing VA's ability to move the market share with its large number of potential buyers. Finally, the VA is an integrated health care system that uses VA pharmacies in VA hospitals to dispense prescriptions written by VA doctors according to the VA formulary. Middlemen are eliminated, market share is moved, and costs are saved for VA and patients.

As an alternative to or in addition to state prescription drug programs, several states are establishing programs to educate consumers, prescribers, or both about using cost effective prescription drugs without compromising quality of care. Some programs act as clearinghouses and facilitate access to manufacturers patient assistance programs. Studies over the past twenty-five years have recognized physicians' unfamiliarity with the cost of prescription drugs. Physicians often receive prescription drug information largely through personal visits by drug manufacturer representatives; patients also are educated by drug manufacturers, through direct to consumer advertising campaigns.[8] A clearinghouse program with an educational component for prescribers and patients that provides information promoting therapeutic and cost effective use of prescription drugs without compromising quality of care is an indirect but significant step in providing greater access to affordable prescription drugs. A clearinghouse program could also provide information about benefits and requirements of public and private prescription drug assistance programs, facilitating participation by matching individuals to any eligible prescription drug benefit and assisting patients and prescribers with enrollment procedures. A clearinghouse to assist patients and prescribers would not require a large investment of state revenues, but could provide a significant benefit for many.

Some prescription drug assistance programs are not yet operational; some are so new that they have no track record, their effectiveness is unproven. Traditional state-funded direct benefit programs have long provided a significant benefit to participants, with programs often expanding in membership or benefits over the years. Because each state's experience is different, however, transplanting a program from one state to another is not easily achieved. Given the economic impact of the September 11, terrorist attacks and the related federal spending on homeland security, the war on terrorism, and economic stimulus, a federal solution to the problem of expensive prescription drugs does not appear likely in the near future.

Similarly, current economic problems are likely to hamper most states' ability to establish new prescription drug assistance programs. Although Hawaii's successful Med-Quest has reached its enrollment limits, before September 11, public programs were under enrolled in some states. Drug manufacturers' patient assistance programs can provide prescription drugs made by their company to uninsured patients, but participation is not simple for patients with little income, no health care provider, and no insurance. A number of existing private prescription drug discount cards may offer some price relief for nominal enrollment fees. Veterans' benefits and safety net providers provide prescription drugs to certain populations. States will look to creative programs that take advantage of existing resources, programs that educate consumers and prescribers about cost effective use of prescription drugs, options that will increase access to affordable prescription drugs without a significant investment of state revenues.

A lack of reliable data on the potential target population in Hawaii, the sometimes conflicting interests of stakeholders, problems facing established and new prescription drug programs, pending litigation, and the sagging economy, both State and national, make designing a state pharmacy assistance program a formidable task for Hawaii lawmakers at this time.

Recommendations

Traditional state-funded direct benefit prescription drug programs have an established record of support and success. Generally, the use of state revenues, combined with rebates and discounts, allows these programs to provide a significant benefit to a specific population, most often low-income seniors and sometimes the disabled. To establish a state pharmaceutical assistance program that would provide prescription drugs at the lowest cost to a target population (presumably, the neediest population), the Bureau recommends the traditional state-funded direct benefit model.[9] A prescription drug assistance clearinghouse to assist and educate patients and prescribers on various prescription drug issues as well as an expanded use of safety net providers are two additional recommendations that can be implemented fairly quickly and inexpensively. The Bureau suggests that legislators consider a discount type program as a less costly alternative to a state-funded direct benefit program.

In searching for alternatives, the Bureau believes that a cautious approach should be taken concerning the development of a pharmaceutical assistance program based solely on the Maine Rx discount program or Vermont's Pharmacy Discount Program, a Medicaid waiver demonstration project, because of the unresolved issues that are pending in the respective federal court actions. Pending litigation does not mean that Hawaii should ignore Maine and Vermont's innovative programs or adopt a "do nothing" strategy; it means that any Hawaii program that is based on either of these two programs should have, at the very least, a future effective date that takes the pending litigation into consideration. Legislation relating to the Bureau's recommendations are attached as Appendices B, D, E, and F.

- A state-funded direct benefit program can provide the neediest population access to prescription drugs at the lowest cost.
  - This type of program provides the most significant benefit to participants, but also requires the most significant investment of state funds.
- A state-sponsored prescription drug discount card program may produce somewhat lower prescription drug prices for participants and require little or no state funds.
  - Depending on the program's structure, the benefit to participants may be limited.
  - If state revenues subsidize at least a token amount of each prescription, the program <u>may</u> claim a Medicaid "best price" exemption as a "state

pharmaceutical assistance program". Whether this model would qualify as an exempt state pharmaceutical assistance program is uncertain.

- Use of a preferred drug list for any state created prescription drug assistance program is recommended as a cost containment tool and an aid in negotiating rebates.

- Two of the most significant alternatives to a state pharmaceutical assistance program are:

  - A clearinghouse program to educate consumers and health care providers and to facilitate participation in existing prescription drug programs; and

  - Expand use of federally qualified health centers, safety net providers, or "covered entities" that qualify for the 340(B) drug discount program.

  Establishment of one or both of these two programs does not exclude the establishment of any type of state pharmaceutical assistance program.

- Legislators should monitor closely the prescription drug and Medicaid programs that are in litigation, as well as the success of several newly authorized bulk purchasing and the federal discount card program.

- Consumer protection law should be examined to determine whether additional protection is needed for consumers in connection with private discount drug cards, buyer's clubs, or purchasing cooperatives.

A. State-Funded Direct Benefit Pharmaceutical Assistance Program (*Appendix B*)

- The Bureau recommends the establishment of a state-funded direct benefit prescription drug program for residents who meet age and income requirements.

  - State-funded direct benefit programs have an established record of success and support, and provide the most benefit to the neediest population.

  - Target population recommended: seniors and disabled residents not eligible for Medicaid with incomes less than X% (a percentage to be designated by the Legislature) of the Federal Poverty Level, i.e., the neediest population.

  - Qualifies for Medicaid best price exemption crucial to negotiating steep rebates—a significant advantage.

- ❖ Formularies, preferred drug lists, or prior authorization requirements are recommended for consideration as cost control tools also used in negotiating manufacturer rebates.

- ❖ To minimize state subsidy, require higher cost sharing by participants (perhaps co-insurance instead of co-payments) and employ cost control tools such as benefit caps or deductibles.

- ❖ Creation of a program through general enabling legislation is suggested because of the large number and wide variety of important issues for decisionmakers' consideration.

- ❖ Enabling legislation would allow the Legislature to set program parameters, while giving the responsible administering agency some flexibility in program design.

- ❖ See *Appendix C* for key considerations for a variety of program issues.

- ❖ Start small, expand as program succeeds and funds are available – e.g., limit coverage to neediest population and cover drugs or conditions most frequently used by that population.

- ❖ Consider adding catastrophic coverage with higher income eligibility.

- ❖ Plan for potential Medicare prescription drug benefit.

- ❖ Mail service pharmacies may offer deeper discounts for prescriptions, but retail pharmacies should not be excluded.

- ♦ Legislation to establish a Prescription Discount Drug Card program is included as *Appendix D,* without further discussion.

B. Establish a Clearinghouse/Education Program on Prescription Drugs (*Appendix E*)

There is a small number of existing public and private programs that provide prescription drugs to certain low-income individuals. The Bureau recommends the establishment of a clearinghouse and educational program to provide information on these sometimes under used public and private prescription drug assistance programs, to facilitate participation, and to provide both consumers and prescribers with other cost savings tips and educational information relating to prescription drugs, particularly the use of generic drugs.

- ♦ Require the Department of Human Services to establish a Hawaii Prescription Drug Clearinghouse program to facilitate awareness of and participation in public and private prescription drug assistance programs.

- ❖ Consumer education component to include cost containment strategies that include use of generics, when appropriate, i.e., pill splitting, etc.

- ♦ Outreach and education should include health care providers, social service agencies, and media to promote the program.

- ♦ Program should establish a toll free hotline and internet website for consumers and health care providers to provide information on options available, qualifications, and procedures to enroll or obtain benefits.

- ♦ Prescriber education component should include information on prescription drugs that includes information on cost of brand name and generic drugs and aids prescribers in choosing a cost effective drug therapy for patients that does not sacrifice quality of care.

- ♦ Authorize the Department of Human Services to contract with private organization to develop, implement, or administer the program.

- ♦ Alternatively, a clearinghouse program that provides information and assistance to Medicare beneficiaries only could be established in the Department of Health's Executive Office on Aging.

C. Expand Use of Federally Qualified Health Centers, Safety Net Providers, and Other Entities that Qualify as Covered Entities for 340B Discount Drug Program

(*Appendix F*)

Section 340B of Public Law 102-585, the Veterans Health Care Act of 1992, limits the cost of drugs to federal purchasers and to certain federally funded grantees, some disproportionate share hospitals, and other organizations (collectively "covered entities"). Significant savings, averaging 25% to 40% on discounted outpatient prescription drugs, are available for entities that participate in this program. A new initiative announced in June by the U.S. Department of Health and Human Services allows community health centers and other safety-net providers to develop new ways to expand their ability to buy drugs through the section 340B discount drug program and improve access to prescription drugs at lower costs for patients.[10]

The Bureau recommends that the Legislature increase the use of safety net providers or other covered entities to expand the 340B drug pricing availability to more patients.

- ♦ Authorize the Department of Health or appropriate organization or entity to request federal designation of medically underserved areas and any other designation or approvals requiring to establish FQHCs or other entities permitted to purchase prescription drugs through the federal supply schedule or the 340B drug discount program.

- Authorize or request existing section 340B covered entities to apply to U.S. Department of Health and Human Services for demonstration project status to expand patient's access to low cost drugs.

Endnotes

1. GAO, the investigative arm of Congress, collected information on prices charged to seniors with drug discounts and to those who simply walked in to a retail pharmacy without a card. In some cases, GAO found that people using discount cards paid more for a drug than consumers without cards. Health policy experts generally believe that issuers of public discount cards, whether federal or state agency sponsored, will be unable to influence physicians' prescribing habits. If the discount cards sponsor cannot deliver large amounts of business to drug manufacturers (or "affect market share"-see fn. 6), manufacturers have no incentive to offer substantial discounts, making the value of the card questionable. *Drug Discount Cards Give the Elderly Small Savings*, The New York Times On The Web, January 4, 2002, found at <http://www.nytimes.com>.

2. Washington's AWARDS discount drug program was terminated this year after a state court ruled that the executive branch lacked authority to implement the program without statutory authority. Litigation in the other states is pending at the time of this writing.

3. It is also important to be aware that rebates are usually associated with newer, brand name drugs and may create a false economy by detracting from the most cost effective drug choices. David Kreling, *What Strategies Can States Use to Control Costs and How Effective are They?* Wisconsin Family Impact Seminars, at 4.

4. Pennsylvania's Pharmaceutical Assistance Contract for the Elderly, a state-funded direct benefit program established nearly twenty years ago, faces the possibility of a $360 million deficit in three years, unless drastic program changes are made. Funded by lottery profits that are stagnant, the program's costs continue to escalate. Pennsylvania's Secretary of Aging recently submitted a report to the Legislature, with cost-cutting recommendations for lawmakers' consideration. *Subsidized Drugs for Seniors Facing Deficit,* Pittsburgh Post-Gazette, November 28, 2001.

   A new program, California's 1999 Discount Prescription Medication Program for Medicare beneficiaries was financed initially through retail pharmacy discounts required as a condition of Medicaid participation. On October 10, 2001, the Governor signed S.B. No. 696, renaming and revising the program. Now called the Golden Bear State Pharmacy Assistance Program, the program continues to require Medicaid pharmacies to charge discount prices based on Medicaid, but recent changes include negotiated drug manufacturer rebates, with pharmacy reimbursement based on the rebates, and voluntary participation for Medicare beneficiaries, pharmacies, and drug manufacturers. The new Golden Bear State Pharmacy Assistance Program will be implemented only if all necessary federal approvals (Medicaid waivers) are obtained and a sufficient number of manufacturer rebates are negotiated.

5. Pharmacy benefit managers, HMOs, and others get rebates because they can influence the use of drugs by using a formulary for their patient base. Hospitals, clinics, and HMOs that buy drugs directly from manufacturers get rebates because they are able to influence the prescribing patterns of their physicians. Kaiser Permanente and the U.S. Department of Veterans Affairs (VA) are two integrated health systems that have been successful in managing use and cost of prescription drugs by formularies, prescriber education, and other methods. Most believe that health care systems lacking their own physicians, hospitals, and pharmacists could not as successfully employ methods used by Kaiser and the VA. For example, most physicians deal with formularies from a number of managed care organizations or HMOs, whereas Kaiser and VA physicians have a single formulary.

6. Traditional state-funded direct benefit programs that provide prescription drugs at a nominal cost to participants have long been considered eligible for the Medicaid best price exemption for "state pharmaceutical assistance programs". *See* 42 U.S.C. 1396r-8.

7 The Medicine Bank's prescription drugs are most often samples donated by physicians. The Medicine Bank also has provided assistance to a few individuals seeking prescription drugs through drug manufacturers patient assistance programs. These individuals had an established relationship with a physician and called Medicine Bank for help. Telephone interview with Allison Ciszek, Executive Director, Medicine Bank, Hawaii State Primary Care Association, by Lynn Merrick, on January 9, 2002. More than 40,000 Hawaii residents benefited from medications donated to the Medicine Bank in FY99. More than $1 million (wholesale value) in donated medication were distributed to 13 community health centers and other facilities. *Medicine Bank helps some 40,000,* Honolulu Star Bulletin, April 7, 2000.

8. A recent study confirmed physicians' limited knowledge about the cost of medications they commonly prescribe; nearly 90% of the surveyed physicians underestimated the price of brand drugs, while generic drugs were overestimated in more than 90% of the responses. The study also reported the surveyed physicians stated that regular access to information on prescription medication costs would help them prescribe more cost-effectively. Patients often request drugs they see advertised on television. *Prescription Medication Costs A Study of Physician Familiarity,* Archives of Family Medicine, Vol. 9, No. 20, November/December 2000.

9. U.S. Department of Health and Human Services, *New HHS Initiative Will Expand Access to Prescription Drugs for Safety-Net Patients* , HHS News Press Release, June 18, 2001.

Report Title: Mandated Benefit Advisory Taskforce; Pharmaceutical Assistance Program Study.

HOUSE OF REPRESENTATIVES

TWENTY-FIRST LEGISLATURE, 2001

STATE OF HAWAII

H.C.R. NO. 129 H.D. 1 S.D. 1 C.D. 1

HOUSE CONCURRENT

RESOLUTION

REQUESTING THE INSURANCE COMMISSIONER TO CONVENE A MANDATED BENEFIT ADVISORY TASKFORCE AND REQUESTING THE LEGISLATIVE REFERENCE BUREAU TO CONDUCT A STUDY ON THE FEASIBILITY OF A STATE PHARMACEUTICAL ASSISTANCE PROGRAM.

WHEREAS, across the nation, the cost of health insurance coverage has been constantly rising; and

WHEREAS, each year, the Legislature introduces health insurance mandated benefits and regulations, and expands the eligible provider list, thus further increasing the cost of health care in our islands; and

WHEREAS, many of these mandated benefits are passed without knowing the social or financial implications or needs; and

WHEREAS, although the Auditor is required to report on financial implications, this report does not gather input from others in the health care industry such as providers or payers of these benefits---the business community; and

WHEREAS, prescription drugs are an increasingly significant component in modern health care as new medications improve health outcomes and quality of life, replace surgery and other invasive treatments, quicken recovery for patients who receive these treatments, and prevent serious and costly hospitalization; and

WHEREAS, prescription drug prices are rising twice as fast as inflation, with annual percent increases in prescription expenditures surpassing most other aspects of personal health care expenditures in the past decade; and

WHEREAS, individuals without drug coverage pay a higher price at the retail pharmacy than the total price paid on behalf of those with drug coverage, thereby forcing those most in need to face the highest prices; and

WHEREAS, one in four Americans (70 million citizens) do not have drug coverage; and

WHEREAS, the percentage of Hawaii residents lacking even the most basic health insurance has been steadily growing in recent years, from 7 percent in 1996 to 11 percent in 1999; and

WHEREAS, a study by Boston University School of Public Health researchers estimate that 19 percent of Hawaii's population (228,000 residents) do not have drug coverage, and given that employers are required to provide health insurance but not drug coverage, the percentage of residents without drug coverage may be even higher; and

WHEREAS, one in three Medicare recipients do not have drug coverage; and

WHEREAS, Hawaii's elderly population has been growing (13.2 per cent of total population in 1997) and is expected to increase dramatically in the near future with the first baby boomers turning 65 years old in 2011; and

WHEREAS, seniors consume one-third of all prescription drugs, averaging ten prescriptions prescribed per year versus three per year for those under 65, and often live on fixed incomes, yet have minimal drug coverage; and

WHEREAS, an April 2000 study by the U.S. Department of Health and Human Services found that fewer employers offer health benefits to future retirees, making declines in drug coverage more likely; and

WHEREAS, rebates are such a common practice that most, if not all, third-party insurers secure rebates from pharmaceutical manufacturers to bring discounted prices to their members; and

WHEREAS, 26 states have enacted varying forms of state pharmaceutical assistance programs for uninsured residents; and

WHEREAS, four states have established programs to pool together the uninsured and negotiate discounted prices through manufacturer rebates on their behalf; now, therefore,

BE IT RESOLVED by the House of Representatives of the Twenty-first Legislature of the State of Hawaii, Regular Session of 2001, the Senate concurring, that the Insurance Commissioner is requested to establish a mandated benefit advisory task force (task force); and

BE IT FURTHER RESOLVED that the Insurance Commissioner appoint the members, which shall include but not be limited to representatives for licensed registered nurses, licensed physicians, alternate complementary care service providers, professional medical associations, health plans, consumer advocate groups, and members of the business community; and

BE IT FURTHER RESOLVED that the task force advise the 2002 Legislature on the problems surrounding Hawaii's mandated benefits and the legislative process enacting them; and

BE IT FURTHER RESOLVED that the task force recommend legislation on the mandated benefit process as well as recommend legislation for the establishment of a permanent advisory panel to review mandated benefits; and

BE IT FURTHER RESOLVED that the taskforce report its findings to the Legislature no later that twenty days prior to the convening of the Regular Session of 2002; and

BE IT FURTHER RESOLVED that the Legislative Reference Bureau is requested to:

(1) Compile data on the status of prescription drugs in Hawaii to include the number and percentage of uninsured residents, the scope of available programs, and access to prescription drugs;

(2) Contact other states that have enacted state pharmaceutical assistance programs, or organizations familiar with them, and request any and all pertinent information relating to their experience with the development and implementation of the programs;

(3) Contact relevant parties in Hawaii and request any and all pertinent information relating to their experience with pharmaceuticals and health care;

(4) Submit proposed legislation for a state pharmaceutical assistance program for uninsured residents of Hawaii;

and

BE IT FURTHER RESOLVED that the Legislative Reference Bureau study the feasibility of a state pharmaceutical assistance program and assist the advisory panel in reviewing health care regulations; and

BE IT FURTHER RESOLVED that the Legislative Reference Bureau report its findings to the Legislature no later that twenty days prior to the convening of the Regular Session of 2002; and

BE IT FURTHER RESOLVED that certified copies of this Concurrent Resolution be transmitted to the Director of Health, the Insurance Commissioner, and the Acting Director of the Legislative Reference Bureau.

Appendix B

Report Title:
State Pharmaceutical Assistance Program

Description:
Directs the department of human services to establish a state funded direct benefit prescription drug program that provides prescription drugs to low income seniors and disabled residents; authorizes the department to contract with private entity to implement and administer the program.

Appendix B

TWENTY-FIRST LEGISLATURE, 2002
STATE OF HAWAII

.B. NO.

A BILL FOR AN ACT

RELATING TO PRESCRIPTION DRUGS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. The legislature finds that thirty-one states have established or authorized a state pharmaceutical assistance program to provide prescription drug assistance for a target population, generally low income seniors or disabled individuals who are not eligible for Medicaid prescription drug benefits. State subsidized direct benefit programs are the most common, with twenty six state programs using state revenues to subsidize program benefits.

State funded direct benefit programs that provide drugs at a significantly reduced price have an established record of support and success. They are an effective tool to increase access to affordable drugs to vulnerable populations. State funded direct benefit prescription drug assistance programs qualify for a Medicaid "best price" exemption. This exemption grants this model of prescription drug assistance programs a significant advantage that allows drug manufacturers to offer significant discounts to a program without being required to provide the same discount to Medicaid programs.

The purpose of this Act is to direct the department of human services to establish a state pharmaceutical assistance program that provides prescription drugs to residents not eligible for Medicaid prescription drug benefits, who are age sixty-five or are disabled according to the standards of the Social Security Act and who have annual incomes that do not exceed three hundred per cent of the federal poverty level.

SECTION 2. Chapter 346, Hawaii Revised Statutes, is amended by adding a new part to be appropriately designated and to read as follows:

"**PART . PRESCRIPTION DRUG ASSISTANCE PROGRAM**

§346-A Prescription drug assistance program. (a) The department of human services shall establish a prescription drug assistance program to provide prescription drugs at discount prices for eligible state residents. The program shall be funded through negotiated rebates and discounts from pharmaceutical manufacturers and retail pharmacies and state revenues.

(b) The program shall offer prescription drugs at discounted prices to any state resident who:

(1) Is at least sixty-five years or older, or disabled according to the standards of the Social Security Act;

(2) Is not eligible for prescription drug benefits under Medicaid; and

(3) Has an annual income that does not exceed three hundred per cent of the federal poverty level.

(c) To minimize state funding, the program shall require cost-sharing by program participants in the form of coinsurance payments, deductibles, and benefit caps.

(1) Separate coinsurance requirements for generic drugs and brand name drugs shall reflect cost differences and encourage cost effective prescriptions without compromising quality of care;

(2) The deductible amount that participants must pay out of pocket before benefits begin and the annual benefit limit shall reduce the State's financial investment, but shall not prohibit participation or render the program's intended benefit meaningless.

(d) The program shall adopt a preferred drug list that ensures participants will receive the most effective prescription drug available at the best possible price. Prescribers may designate a brand name drug as medically necessary, but only prescription drugs from pharmaceutical

manufacturers or labelers who enter into a rebate agreement with the program administrator will be covered by the program.

(e) As a state funded pharmaceutical assistance program with an express Medicaid "best price" exemption, the program administrator shall use the administrator's best efforts to negotiate a rebate amount better than rebates required for the Medicaid program under 42 U.S.C. section 1396r-8.

(f) Over the counter drugs are not included in the program. For purposes of this part, an "over the counter drug" means any packaged, bottled, or non-bulk chemical, drug, or medicine that may be lawfully sold without a prescription.

(g) Participating pharmacies shall offer participants a discount price set by negotiations with the program administrator, and shall receive (or "may charge") a dispensing fee based on the Medicaid dispensing fee.

(h) In establishing the program, the department shall contact and involve all stakeholders, including physicians, pharmacists, advocates for seniors and the disabled, pharmaceutical manufacturers, and other relevant health care providers or potential participants.

§346-B Outreach, education, and enrollment. (a) The program shall include an outreach and education component for consumers and health care providers.

(b) A single page application and enrollment form that imposes a minimum burden shall be established as part of the outreach program.

(c) Eligible participants shall be issued an enrollment card annually by the administrator.

§346-C Prescription drug assistance program special fund. There is established in the state treasury a prescription drug assistance program special fund to receive revenues appropriated or allocated by the legislature, federal moneys, grants, or gifts, and revenues from manufacturer rebates. The funds shall be expended by the department for the purposes of this part.

§346-D Rules; waivers. The department shall adopt rules under chapter 91, and shall seek any waivers from the Centers on Medicare and Medicaid Services necessary to implement this part.

§346-E Contracts. The department may contract with a public agency or a private organization for the development, implementation, and administration of all or part of the prescription drug assistance program.

§346-F Prescription drug assistance program data base. The program administrator shall develop and maintain a data base to allow an annual review of the program. After the program becomes operational, an annual report shall be submitted to the legislature no later than twenty days before the convening of each regular session.

§346-G Prescription drug assistance program operation. Subject to funding and the negotiation of sufficient rebates and discounts, the prescription drug assistance program shall begin operation by July 1, 2004.

SECTION 3. A progress report on the program's implementation shall be submitted by the department no later than twenty days before the convening of the regular session of 2003.

SECTION 4. There is appropriated out of the general revenues of the State of Hawaii the sum of $, or so much thereof as may be necessary for fiscal year 2002-2003, for the department of human services.

SECTION 5. In codifying the new sections added by section 2 of this Act, the revisor of statutes shall substitute appropriate section numbers for the letters used in designating the new sections in this Act.

SECTION 6. This Act shall take effect upon its approval.

Appendix C

Initial Considerations in Designing a State Pharmacy Assistance Program

- Input of all stakeholders in program design is important to success.
- Permanent funding source critical for traditional programs.
  - What financial eligibility level can program sustain?
- Cost control is key task.
  - Income requirements and scope of benefits impact program costs.
  - Participant cost sharing by co-payment, co-insurance, and deductibles are significant cost containment tools.
- Medicaid procedures and experience may be useful.
- Initial outreach is key to program success.
  - Avoid raising unrealistic expectations for new program.
  - Simplicity of enrollment enhances participation.
- Scope of benefit.
  - Broad target population or generous benefits (depth v. breadth).
  - Start small, then grow.
  - Realistically, can't cut benefits, once given.
  - Assume that programs inevitably grow; costs increase.
- Potential Medicare prescription drug benefit must be considered; wrap around.
  - No maintenance of effort.
  - State as payor of last resort.
  - Give state option to administer.
  - Automatic enrollment current participants in state program in Medicare.
  - Mandate coordination of benefits; especially if administered through pharmacy benefit managers.
- Importance of pharmacy access.
- Strong program administration vital.
  - Skilled administrator.
  - Advisory organization involving all stakeholders should be included in program development.
  - Effective data and claims processing system.
  - Timely payment to pharmacies important.
  - Coordination of drug program with other programs.

Considerations Regarding *Who* Should Qualify

- Seniors or any age
  - Include disabled?
- Income level
  - Income requirement by fixed amount or as % of Federal Poverty Level
  - Use eligibility level for other low-income programs?
  - Asset requirement
  - Higher level income allowed if catastrophic coverage.
- Prescription drug benefit coverage
  - Other coverage allowable?
  - Ineligible if have equal or better pubic or private coverage.
- Residency
  - How long and when-e.g., 6-months immediately prior to applying for benefits or any consecutive 6-months.

Considerations Regarding What *Benefits* to Include

- What drugs or conditions will be covered?
  - Maintenance drugs v. limits by disease or condition.
  - Generic v. brand name
  - Dispensing dosage
  - Over the counter medications and medical supplies.
  - Lifestyle/nonessential drugs covered weight loss, baldness, and tobacco.
- Catastrophic coverage available

Considerations Regarding *Cost Containment* Tools

- Enrollment fee
- Co-payment or coinsurance
  - $ flat fee v. co-payment, or whichever higher/lower.
  - Tiered cost sharing for generic and branded drugs higher co-pay if brand name not required.

- Deductibles, benefit cap, or both.
- Amount of cost sharing varies by income?
- Rebates and discounts.
    - Negotiated or set
    - Coverage requires rebate agreement.
- Formulary or preferred drug list.
    - Prior authorization if no rebate agreement or not on formulary.
    - Medical necessity or exceptions allowed.

Considerations Regardung *Administrative Duties*

- Participant enrollment and eligibility.
- Provider enrollment
- Outreach and Customer Relations
- Claim Processing and Reimbursement
- Drug Utilization Review
- System Development and support
- Rebate invoicing (receipt, process, audit rebate payments)
- Recovery of third party payments.
- State agency as Administrator.
    - Human Services
    - Health
    - Aging
    - State as Pharmacy Benefit Manager (PBM)
- Private PBM as Administrator
    - All or part of program administration.

Consideration Regarding *Program Controls*

- Drug Utilization Review
- Prospective (point of sale?)
    - Reject point of sale claims based on .
    - ID of potentially severe drug interaction.
    - Therapeutic duplication
    - High dose

- ❖ Early refill

♦ Retrospective

- ❖ Reviews of all recently dispensed prescriptions.
- ❖ ID potentially severe drug interaction, therapeutic duplication, use of multiple pharmacies and prescribers.
- ❖ Contact prescriber when necessary.

Appendix D

Report Title:
Prescription Drug Discount Card; Uninsureds

Description:
Directs DHS to establish a drug discount card program for uninsureds; discounts based on negotiated rebates and discounts; state subsidizes $1 for each covered generic drug and $2 for brand name prescription. Includes outreach/education component. Authorizes contracting out implementation and administration.

Appendix D

TWENTY-FIRST LEGISLATURE, 2002
STATE OF HAWAII

.B. NO.

A BILL FOR AN ACT

RELATING TO A PRESCRIPTION DISCOUNT DRUG CARD PROGRAM.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. The legislature finds that individuals who lack prescription drug insurance benefits pay for their medications out of their own pockets, often paying two or three times more than those with drug benefits for the same drug. Persons with prescription drug insurance benefits generally pay only a fraction of the actual costs of their drugs, often a nominal co-payment amount for each prescription. Those with the fewest resources are thus faced with the highest costs for prescription drugs, causing them to incur significant out-of-pocket expenditures or forego needed medications.

The purpose of this Act is to establish a prescription discount drug card program for residents who do not have prescription drug insurance coverage, do not qualify for Medicaid prescription drug benefits, and have annual incomes less than three hundred per cent of the federal poverty level.

SECTION 2. Chapter 346, Hawaii Revised Statutes, is amended by adding a new part to be appropriately designated and to read as follows:

"PART . HAWAII PRESCRIPTION DISCOUNT DRUG CARD

§346-A Hawaii prescription discount drug card program; establishment. (a) The department shall establish a Hawaii prescription discount drug card program that offers prescription drugs at discount prices to eligible state residents.

(b) The program shall be open to state residents who:

(1) Do not qualify for Medicaid;

(2) Have an annual income of not more than three hundred per cent of the federal poverty level; and

(3) Have no other public or private drug coverage benefits.

(c) In establishing the program, the department shall contact and involve all stakeholders, including physicians, pharmacists, advocates for seniors and the disabled, pharmaceutical manufacturers, and other health care providers or potential participants or stakeholders as the department deems advisable.

(d) The program is not an entitlement and is not an insurance program.

§346-B Program benefits. (a) Drugs from manufacturers who enter a rebate agreement with the Hawaii prescription discount card program shall be available to participants.

(b) Participants shall pay discounted prices based on the amount of the manufacturer rebates and retail pharmacy discounts negotiated by the program administrator.

(c) State revenues shall subsidize participant costs for covered drug prescriptions in the amount of $1 for each generic prescription and $2 for each brand name prescription dispensed.

(d) Participating pharmacies shall offer prescription drugs at negotiated discount prices to participants, which may include a dispensing fee based on the Medicaid dispensing fee.

§346-C Enrollment fee. The department may require an annual enrollment fee of not more than $25 for each participant. Enrollment fee revenues may be used to reduce administrative costs of the program.

§346-D Preferred drugs. (a) The program shall adopt a preferred drug list that ensures participants will receive the most effective prescription drug available at the best possible price.

(b) The use of generic drug equivalents shall be encouraged where quality of care is not compromised.

§346-E Outreach, education, and enrollment. (a) The program shall include an outreach, education, and enrollment component to facilitate participation by consumers and health

care providers. This component shall also provide information on eligibility requirements, benefits or coverage available, and enrollment procedures for other public and private prescription drug assistance programs, and shall assist residents in obtaining any prescription drug benefits for which the resident is eligible.

(b) The department shall develop a single page application, and enrollment procedures that are easily understood and completed by applicants.

(c) Participants shall be issued program cards that will entitle them to discounts on covered prescription drugs at participating pharmacies.

§346-F Hawaii prescription discount drug card program special fund. There is established in the state treasury a Hawaii prescription discount drug card program special fund to receive revenues appropriated or allocated by the legislature, federal moneys, grants, or gifts, and revenues from manufacturer rebates. The funds shall be expended by the department of human services for the purposes of this part.

§346-G Rules; waivers. The department shall adopt rules under chapter 91, and shall seek any waivers from the Centers on Medicare and Medicaid Services necessary to implement this part.

§346-H Contracts. The department may contract with a public agency or a private organization for the development, implementation, and administration of all or part of the Hawaii prescription discount drug card program.

§346-I Hawaii prescription discount drug card program data base. The program administrator shall develop and maintain a data base to allow an annual review of the program. After the program becomes operational, an annual report shall be submitted to the legislature not later than twenty days before the convening of each regular session.

§346-J Hawaii prescription discount drug card program operation. Subject to funding and the negotiation of sufficient rebates and discounts, the Hawaii prescription discount drug card program shall begin operation by July 1, 2004."

SECTION 3. A progress report on the program's implementation shall be submitted by the department to the legislature no later than twenty days before the convening of the regular session of 2003.

SECTION 4. There is appropriated out of the general revenues of the State of Hawaii the sum of $, or so much thereof as may be necessary for fiscal year 2002-2003, for the development and implementation of a Hawaii prescription discount

drug card program to provide discounted prescription drug prices for eligible state residents who lack drug coverage insurance benefits.

SECTION 5. The sum appropriated shall be expended by the department of human services for the purposes of this Act.

SECTION 6. This Act shall take effect upon its approval.

Appendix E

Report Title:
Hawaii Prescription Drug Clearinghouse

Description:
Directs department of human services to establish Hawaii prescription drug clearinghouse to educate and assist consumers and health care providers about eligibility, enrollment, and benefits available in public and private prescription drug assistance programs.

Appendix E

TWENTY-FIRST LEGISLATURE, 2002
STATE OF HAWAII

.B. NO.

A BILL FOR AN ACT

RELATING TO A HAWAII PRESCRIPTION DRUG CLEARINGHOUSE.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. Chapter 346, Hawaii Revised Statutes, is amended by adding a new part to be appropriately designated and to read as follows:

"**PART . HAWAII PRESCRIPTION DRUG CLEARINGHOUSE**

§346-A Hawaii prescription drug clearinghouse. (a) The department shall establish a Hawaii prescription drug clearinghouse to educate Hawaii consumers and health care providers about public and private prescription drug assistance programs available to state residents. As part of the clearinghouse program, the department shall develop and distribute educational and informational materials relating to prescription drug assistance programs for consumers and prescribers, explaining their rights and responsibilities, and promoting therapeutic and cost effective utilization of prescription drugs by consumers and prescribers.

(b) The clearinghouse shall:

(1) Provide information and assistance on:

(A) Eligibility requirements and coverage provided by publicly funded prescription drug benefit programs administered by the department of human services; and

(B) The process for applying to receive publicly funded prescription drug benefits;

(2) Provide information, in an organized and easily understood manner, to patients, physicians, pharmacists, and pharmacies regarding patient qualifications for public and private prescription drug assistance programs;

(3) Increase awareness of the public and private prescription drug assistance programs available to state residents;

(4) Establish a toll-free hotline and internet website to increase public awareness of the Hawaii prescription drug clearinghouse and to provide public access to the information and services provided through the program; and

(5) Adopt procedures to assist consumers in applying to pharmaceutical companies or other prescription drug assistance programs for free or discounted

prescription drug medications if the patient is not eligible for any publicly funded prescription drug benefit program.

(b) In establishing the Hawaii prescription drug clearinghouse, the department may contract with one or more public or private organizations to develop, implement, or administer all or part of the program.

§346-B Evaluation. To assist in the efficacy of the Hawaii prescription drug clearinghouse established under this part, the department shall provide to the legislature, on an annual basis no later than thirty days before the convening of each regular session, measurable data to identify the progress and success of the program, including the number of individuals served, length and type of assistance, follow-up, and program evaluation."

SECTION 2. There is appropriated out of the general revenues of the State of Hawaii the sum of $, or so much thereof as may be necessary for fiscal year 2002-2003, for the Hawaii prescription drug clearinghouse program of the department of human services.

SECTION 3. The sum appropriated shall be expended by the department of human services for the purposes of this Act.

SECTION 4. In codifying the new sections added by section 1 of this Act, the revisor of statutes shall substitute appropriate section numbers for the letters used in designating the new sections in this Act.

SECTION 5. This Act shall take effect on July 1, 2002.

Appendix F

Report Title:
Prescription Drugs; Safety Net Providers

Description:
Authorizes the department of health to request the federal government to approve demonstration programs in federally funded safety net providers to increase access to affordable prescription drugs and to designate medically underserved areas and to secure other designation or approvals necessary to establish or expand federally qualified health centers.

Appendix F

TWENTY-FIRST LEGISLATURE, 2002
STATE OF HAWAII

.B. NO.

A BILL FOR AN ACT

RELATING TO PRESCRIPTION DRUGS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF HAWAII:

SECTION 1. (a) The legislature finds that the drug discount program created by section 340B of Public Health Service Act, 42 U.S.C. Section 256b, (section 340B) limits the cost of outpatient prescription drugs for clinics, health departments, hospitals and other safety net health care providers (collectively "covered entities") that receive funds from the U.S. Public Health Service. Section 340B requires drug manufacturers to provide discount prices on outpatient drug purchases to federally funded safety net providers and programs that care for some of the most vulnerable in our patient population. These safety net providers, critical in providing access to health care to many low income residents who lack drug coverage, purchase drugs for their patients at discount prices approximately nineteen per cent lower than Medicaid net prices. In June 2001, the U.S. Department of Health and Human Services announced a new initiative that allows community health centers and other covered entities to develop new ways to expand their

ability to buy drugs and improve access to prescription drugs at lower costs for patients.

The legislature further finds that the development and expansion of federally qualified health care centers will improve access to health care services for residents in medically underserved areas. Expansion of prescription drug services by safety net providers that qualify as covered entities under the section 340B drug discount program will allow uninsured and underserved individuals to obtain their prescription drugs at affordable prices.

The purpose of this Act is to increase access to affordable prescription drugs by authorizing the department of health to:

(1) Obtain the necessary federal designation and approvals to establish and expand federally qualified health centers to improve access to health care, including prescription drugs; and

(2) Obtain federal approval to establish demonstration projects that expand access to section 340B discount price drugs for federally funded safety net providers that qualify as covered entities under the section 340B drug discount program.

SECTION 2. Within forty-five days of the effective date of this Act, the department of health shall initiate proceedings, subject to the availability of funds, to secure the necessary designations and approvals described in section 1(b) of this Act.

SECTION 3. The department of health shall submit a report of its progress to the legislature no later than twenty days before the convening of the regular session of 2003.

SECTION 4. This Act shall take effect upon its approval.