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NOTE

AN RX FOR REFORM: A MEDICARE PRESCRIPTION DRUG BENEFIT

Jennifer Rak[†]

SENIORS IN THE UNITED STATES are boarding buses to Canada to buy prescription drugs.¹ Faced with expenditures for medications that place an increasing demand on their limited income, many elderly persons are getting tickets on rented buses to visit Canadian physicians and pharmacies.² They can save as much as ninety percent on needed medications, with a busload of fifty seniors saving as much as \$48,000 a year.³ This strange trend is likely to continue as the elderly in the United States search for a way to pay for their prescription drug expenses, not covered by Medicare, the government health insurance program for the aged.

INTRODUCTION

The Medicare program is facing serious problems in controlling costs and providing adequate coverage, including the prospect of future insolvency of the Medical Insurance Trust Fund.⁴ However, reform prospects are hampered by political

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¹ See Susan Jaffe, *More Buses Head North for Prescription Drugs*, PLAIN DEALER, Sept. 4, 2001, at B3.

² See *id.* Filling prescriptions in Canada to bring to the United States is not illegal, but requires that the person first visit a Canadian physician to prescribe the medication. *Id.*

³ *Id.*

⁴ See Kathryn L. Moore, *Raising the Social Security Retirement Ages: Weighing the Costs and Benefits*, 33 ARIZ. ST. L.J. 543, 544 (2001) (predicting that the Social Security program will become insolvent by 2037 "unless corrective action is taken"); see also BD. OF TRS. OF THE FED. OLD-AGE AND SURVIVORS INS. AND DISABILITY INS. TRUST FUNDS, THE 2000 ANNUAL REPORT 3-4 (2000) (noting how long various trust funds are expected to be in operation before becoming insolvent).

and theoretical differences on how to “save” Medicare.⁵ Over the next few years, one area of Medicare reform that is likely to receive much attention and debate is the provision of outpatient prescription drug coverage under Medicare. This Note reviews four proposals for adding a prescription drug benefit to Medicare that are presently before Congress.⁶ Each of these proposals is the result of earlier efforts at Medicare reform, and as such, provides a perspective on policy development.⁷ These proposals offer an opportunity to compare various structural and theoretical approaches to a federal prescription drug program for the elderly and Medicare reform more generally.

As prescription drug expenses grow, they increasingly impact the elderly.⁸ Because the federal government has been slow to respond with Medicare legislation, the States have started to experiment with various types of drug assistance programs.⁹ These state programs offer examples and lessons for a federal response. Yet they also demonstrate the need for a more uniform and encompassing approach to coverage of drug costs for the elderly.

This Note examines the need for prescription drug coverage for Medicare beneficiaries. It reviews previous efforts at introducing a drug benefit to Medicare with a particular emphasis on the difficulties of enacting major Medicare legislation. The next section focuses on state efforts to provide prescription drug coverage and assistance, and analyzes the benefits and limita-

⁵ See Robin Toner, *Major Battle Looms Over Medicare*, N.Y. TIMES, Feb. 11, 2001, at A34.

⁶ These include two from the Senate, S.10, 107th Cong. (2001) and S. 358, 107th Cong. (2001), and two from the House of Representatives H.R. 339, 107th Cong. (2001) and H.R. 803, 107th Cong. (2001).

⁷ See generally Mark McClellan et al., *Designing a Medicare Prescription Drug Benefit: Issues, Obstacles, and Opportunities*, HEALTH AFF., Mar.-Apr. 2000, at 26, 28-29 exh.1 (outlining the key features of the bills that have been introduced in Congress); MICHAEL E. GLUCK, THE HENRY J. KAISER FAMILY FOUND., A SIDE-BY-SIDE COMPARISON OF SELECTED MEDICARE PRESCRIPTION DRUG COVERAGE PROPOSALS (Aug. 2000) (same), available at http://www.kff.org/content/2000/1601/sideby_side.pdf.

⁸ U.S. DEP'T OF HEALTH AND HUMAN SERVS., REPORT TO THE PRESIDENT: PRESCRIPTION DRUG COVERAGE, SPENDING, UTILIZATION, AND PRICES, at exec. summ. (Apr. 2000) (discussing how the rising costs of newly developed prescription drugs are preventing elderly and disabled Medicare beneficiaries from acquiring such drugs) [hereinafter REPORT TO THE PRESIDENT], available at <http://aspe.os.dhhs.gov/health/reports/drugstudy/>.

⁹ Robert Pear, *States Creating Plans to Reduce Costs for Drugs: Benefit for the Elderly*, N.Y. TIMES, Apr. 23, 2001, at A1.

tions of state action, concluding that federal action is necessary. The next section discusses the major policy concerns and establishes a framework for considering various aspects of a Medicare benefit. This is followed by a review and evaluation of the proposals within the policy framework. From this analysis, the Note offers a perspective on which aspects are best suited for providing prescription drug coverage under Medicare.

The discussion and analysis of adding a prescription drug benefit to Medicare may be useful in considering broader Medicare reforms. While describing specifics of a prescription drug benefit, the analysis highlights a number of themes in the debate about Medicare reform more generally. These include whether Medicare should be viewed as a social insurance benefit program, or whether in order to control costs, it should be treated more like a welfare program. Another theme is the role that the government or private markets should play in the structure and functioning of the Medicare program. Finally, the addition of a prescription drug benefit exemplifies the tension of attempting to control the growing costs of providing needed medical care while ensuring that needed care is available.

THE NEED FOR PRESCRIPTION DRUG COVERAGE AMONG MEDICARE BENEFICIARIES

As the federal health insurance program for the elderly, Medicare provides coverage for inpatient medical services under Medicare Part A.¹⁰ It also covers many outpatient medical services with voluntary enrollment under Medicare Part B, in which most Medicare recipients opt to enroll.¹¹ Medicare does not cover outpatient prescription drugs as a part of the covered mandated benefits package.¹²

A. The Rise of Prescription Drug Use

When Medicare was enacted in 1965, prescription drug coverage was not a common component of health insurance.¹³

¹⁰ THEODORE MARMOR, *THE POLITICS OF MEDICARE* 201 (Aldine De Gruyter, 2d ed. 2000).

¹¹ *See id.*

¹² MICHAEL E. GLUCK, NAT'L ACAD. OF SOC. INS., A MEDICARE PRESCRIPTION DRUG BENEFIT, BRIEF NO.1, at 1 (Apr. 1999), available at <http://www.nasi.org/Medicare/Briefs/medbr1.htm>.

¹³ REPORT TO THE PRESIDENT, *supra* note 8, at 1.

Drug therapies were not as prevalent or as effective as they are now.¹⁴ They have become an increasingly important part of health care coverage.¹⁵ As one study describes:

From a clinical perspective, the lack of a prescription drug benefit when Medicare was implemented did not constitute as much of a barrier to effective health care as it does today. In the late 1960s comparatively few of the prescription drugs available had clinically significant effects on the chronic diseases that are prevalent among the elderly. Since then, however, researchers have made much progress in understanding the pathophysiology of many chronic diseases. Combined with major advances in our ability to identify and create new pharmaceutical products, this has resulted in an enormous increase in the number of drugs that are available for both chronic and acute diseases.¹⁶

Over the last century, vaccine development and drug treatment have revolutionized medicine.¹⁷ Diseases such as smallpox and polio have essentially been eradicated due to vaccines. Drug treatments for many diseases and ailments have been developed. Drug therapies can replace surgeries, lower cholesterol and provide chronic pain relief.¹⁸ Drug therapies may substitute for more expensive medical interventions¹⁹, provide previously unavailable treatment²⁰, or facilitate the use of other medical interventions.²¹

In recent years, the use of drug therapies has rapidly expanded, increasing the dependence on this form of treatment.²² One measure of this explosion is the dramatic growth in spending on prescription drugs. Between 1993 and 1998, drug spend-

¹⁴ See Earl P. Steinberg et al., *Beyond Survey Data: A Claims-Based Analysis of Drug Use and Spending by the Elderly*, HEALTH AFF., Mar.-Apr. 2000, at 198, 199.

¹⁵ Sharon Levine et al., *Kaiser Permanente's Prescription Drug Benefit*, HEALTH AFF., Mar.-Apr. 2000, at 185.

¹⁶ Steinberg, et al., *supra* note 14, at 199.

¹⁷ See Jerry Stanton, Comment, *Lesson for the United States from Foreign Price Controls on Pharmaceuticals*, 16 CONN. J. INT'L L. 149, 152 (2000).

¹⁸ REPORT TO THE PRESIDENT, *supra* note 8, at 1.

¹⁹ See Stanton, *supra* note 17, at 152 (listing various examples).

²⁰ See REPORT TO THE PRESIDENT, *supra* note 8, at 1 (promising more innovative therapies in biotechnology and genetic research).

²¹ See *id.*

²² See Steinberg, et al., *supra* note 14, at 199.

ing increased by eighty-four percent.²³ During the year 2000, prescription drug spending increased by 17.3% to \$121.8 billion.²⁴ The increased spending on drug therapies is driven in part by volume, although prices are also a factor.²⁵ According to a report by the National Institute for Health Care Management Foundation, there are three factors contributing to this rise in spending.²⁶ The first is an increase in the number of prescriptions written by physicians.²⁷ This accounts for nearly forty-two percent of the increase in spending.²⁸ The second is the use of more expensive and popular drugs, accounting for about thirty-six percent of the increase in spending.²⁹ As popular drugs account for greater market share control, pharmaceutical companies increasingly use advertising, which in turn leads to higher costs.

Finally, general price increases have contributed to the overall increase in spending.³⁰ These cost increases have led to higher premiums for health insurance.³¹ They have also increased demands on, and the cost of, Medicaid programs, the state health care programs for the poor.³²

Another indication of the growth in the use of prescription drugs is the number of new drugs being approved by the Food and Drug Administration. Between 1966 and 1970, the first five years of Medicare's existence, the Food and Drug Administra-

²³ THE NAT'L INST. FOR HEALTH CARE MGMT. FOUND., FACTORS AFFECTING THE GROWTH OF PRESCRIPTION DRUG EXPENDITURES, ISSUE BRIEF 1 (July 1999), available at <http://www.nihcm.org/FinalText3.PDF>.

²⁴ Katharine Levit et al., *Inflation Spurs Health Spending in 2000*, HEALTH AFF., Jan.-Feb. 2002, at 172, 173-74.

²⁵ THE NAT'L INST. FOR HEALTH CARE MGMT. FOUND., PRESCRIPTION DRUG EXPENDITURES IN 2000: THE UPWARD TREND CONTINUES 2 (May 2001), available at www.nihcm.org/spending2001.pdf [hereinafter NIHCM].

²⁶ *Id.* at 3.

²⁷ *Id.* at 2-3, 9-10.

²⁸ *Id.* at 2, 10.

²⁹ *Id.* at 2-3, 10.

³⁰ *Id.* at 2-3, 11-12.

³¹ See Bradley C. Strunk et al., *Tracking Health Care Costs: Hospital Care Surpasses Drugs as the Key Cost Driver*, HEALTH AFF., Sept. 26, 2001 (examining trends in outpatient, inpatient, physician, and prescription drug spending), at <http://130.94.25.113/readergent.php?ID=/usr/local/apache/sites/healthaffairs.org/htdocs/Library/v20n6/s2.pdf>.

³² See NIHCM, *supra* note 25, at 3-4 (stating that in early 2001, twenty-five States reported that their fiscal year 2002 Medicaid budgets were going to be exceeded, due partly to the increasing amount of money spent on prescription drugs).

tion approved sixty-two new drugs.³³ Between 1994 and 1998, 149 new drugs were approved.³⁴ The reliance on drug therapies has grown in line with the increased presence. Alan F. Holmer, the president of the Pharmaceutical Research and Manufacturers of America (PhRMA), recently observed that these increases show that people believe that prescription medicines are "the best value in health care today, allowing patients to stay out of the hospital, off the surgery table, on the job and in the home."³⁵

The continued advances of research offer more and improved drug therapies. The advantages of drug therapies are increased life spans and better health.³⁶ This presents a paradox of the dominant use of drug therapies and interventions. As drug therapies replace costly surgeries and hospital stays, life spans increase.³⁷ People live longer and they are susceptible to new diseases and ailments that require more treatments. Alternatively, the drug treatment may be required for long periods of time or for life.³⁸ Drug therapies may offer cost effectiveness over other therapies but may also naturally increase health care costs.³⁹ This paradox reflects the difference between two often-confused terms: cost effectiveness and cost savings. The former is a cost-benefit analysis and the latter is a measure of the amount of money saved.

The pharmacoeconomic benefit of drug interventions, both cost effectiveness and cost savings of drug therapies as compared to other therapies, is difficult to evaluate. Recent press reports suggest that for every \$1 spent on drugs there is a \$3.65 saving on hospital spending.⁴⁰ At the same time, Health Mainte-

³³ GLUCK, *supra* note 12, at 1.

³⁴ *Id.*

³⁵ Robert Pear, *Spending on Prescription Drugs Increases by Almost 19 Percent: Doctors Are Using More of Costliest Medicines*, N.Y. TIMES, May 8, 2001, at A1.

³⁶ Stanton, *supra* note 17, at 149.

³⁷ See J.D. Kleinke, *Just What the HMO Ordered: The Paradox of Increasing Drug Costs*, HEALTH AFF., Mar.-Apr. 2000, at 78, 82.

³⁸ See *id.* (noting how it can take up to ten years for the cost savings associated with a cholesterol-lowering program to take effect).

³⁹ See Peter J. Neumann et al., *Are Pharmaceuticals Cost-Effective? A Review of the Evidence*, HEALTH AFF., Mar.-Apr. 2000, at 92, 92-93 (examining the argument that money spent on pharmaceuticals can decrease hospital costs, and describing evidence that limiting the number of prescriptions which the elderly could fill would subsequently increase hospital costs).

⁴⁰ Robert Pear, *Clinton Will Seek a Medicare Change on Drug Coverage*, N.Y. TIMES, June 8, 1999, at A1.

nance Organizations (HMOs) are complaining of increased pharmaceutical costs for new drugs with no additional benefits.⁴¹

Cost effectiveness is a comparative evaluation; it therefore offers a way to evaluate one type of intervention with regard to another. The comparison of the two interventions results in a cost-benefit analysis, where the benefits would likely be measured as an estimate of life years and/or health status following each type of intervention.⁴² An example is the comparison of using anti-viral therapies in patients with herpes zoster virus infection versus no therapy for the infection. A comparison of the health care costs incurred in both these situations and the health status under both these scenarios produces a comparative value of the costs to the adjusted benefits for drug therapy versus no intervention.⁴³

A cost-effective drug intervention is one that is as effective as another but at a lesser cost. However, a more useful definition given the complexity of potential benefits, suggested by Peter J. Neumann and colleagues, includes not only less costly and as effective therapies, but also therapies that are "more costly and more effective, as long as society is willing to pay for the QALYs⁴⁴ gained or other health outcomes produced."⁴⁵

Cost savings may be complicated to determine as well. A preventative therapy may have initial cost increases that may be offset only at a much later time. For example, medicines for high cholesterol require initial investment which will lead to reduced high cost care for heart attacks and strokes many years later. The cost savings of later high cost care may not be realized for many years. While the presence of and reliance on drug therapy is clear, the additional costs and cost-benefits to this transformation in medical treatment is less clear.

⁴¹ See Kleinke, *supra* note 37, at 82 (discussing HMO complaints against the "highly profitable" pharmaceutical industry).

⁴² There are a number of methods used to evaluate this benefit. Each has inherent limitations. More popular methods include life years added, quality adjusted life year (QALY), and disability adjusted life year (DALY) measures.

⁴³ See Neumann et al., *supra* note 39, at 98 exh.3.

⁴⁴ QALYs stands for quality-adjusted life years. *Id.* at 94.

⁴⁵ *Id.* at 98.

What is clear though is that prescription drug costs continue to soar in the United States.⁴⁶ Prescription drug spending has been growing disproportionately compared to the rest of the health sector.⁴⁷ Prescription drug spending as a percentage of health care spending grew from 5.6% in 1993 to 7.9% in 1998.⁴⁸ In 1999, drug costs rose between 14% and 18% while the rest of health care spending increased by only 5.3%.⁴⁹ Drug prices grew 2.4 times the overall Consumer Price Index, at an annual rate of 6.1% in 1999.⁵⁰ This dramatic growth in health care spending is due to a number of factors including: the prevalence and volume of prescription drug use;⁵¹ the development of new and more costly drugs;⁵² the marketing of drugs to the public;⁵³ and, inflation and price increases.⁵⁴

B. Prescription Drug Use and the Medicare Population

The elderly are particularly impacted by the increased presence of prescription drugs in the health sector. According to a study by the American Association of Retired Persons, eighty percent of retired persons take a prescription medication daily.⁵⁵ Although the elderly (sixty-five years old and older) comprise about twelve percent of the population, they account for a third of prescription drug spending.⁵⁶ The majority of health care costs are incurred by the elderly population, as are the costs for

⁴⁶ See Pear, *supra* note 9 (reporting the more health care dollars are being spent on prescription drugs).

⁴⁷ See NIHCM, *supra* note 25, at 3 (noting that drug spending has contributed disproportionately to increased health insurance premiums and increased health care costs).

⁴⁸ GAIL SHEARER, CONSUMERS UNION, PRESCRIPTION DRUGS FOR MEDICARE BENEFICIARIES: 10 IMPORTANT FACTS 4 (Apr. 2000), <http://www.consumer.org/pdf/meddrugs.pdf>.

⁴⁹ GLUCK, *supra* note 12, at 1.

⁵⁰ SHEARER, *supra* note 48, at 4.

⁵¹ See NIHCM, *supra* note 25, at 2-3, 9-10.

⁵² See *id.* at 2-3, 10; Michael S. Wilkes et al., *Direct-to-Consumer Prescription Drug Advertising: Trends, Impact and Implications*, HEALTH AFF., Mar.-Apr. 2000, at 110, 112.

⁵³ See NIHCM, *supra* note 25, at 12-13.

⁵⁴ See *id.* at 12.

⁵⁵ *Ways to Make Prescription Drugs More Affordable for Seniors*, Hearing Before the Subcommittee on Health, House Ways and Means Committee (Feb. 15, 2000) (statement of Dr. Beatrice Braun, Board of Directors, AARP) [hereinafter Braun testimony], available at <http://www.aarp.org/press/testimony/2000/021500b.html>.

⁵⁶ *Id.*

prescription drugs. The prevalence of prescription drug therapies is particularly evident among Medicare beneficiaries and has also increased the costs of medical care.⁵⁷

Many Medicare beneficiaries have unreliable, inadequate, or no drug coverage.⁵⁸ Nearly one-third of beneficiaries have out-of-pocket health care expenditures greater than ten percent of their income.⁵⁹ Besides premium payments, prescription drug spending is the largest out-of-pocket health care spending among seniors, and “[o]n average, these beneficiaries spend as much out-of-pocket for prescription drugs . . . as for physician care, vision services, and medical supplies combined.”⁶⁰

Prescription drug expenses for beneficiaries are quite variable. Further, the payment sources for these expenses are equally varied. In 1999, outpatient drug spending averaged \$942 a year per beneficiary.⁶¹ This was paid almost equally by insurers and out-of-pocket by beneficiaries.⁶² However, this average does not reflect the uneven distribution of spending among beneficiaries. Many beneficiaries do not spend much on prescription drugs while a smaller group of beneficiaries have large drug costs.⁶³ This is better demonstrated in the median cost per beneficiary of \$200, where half of beneficiaries spend less for out-of-pocket expenditures.⁶⁴ One reason for this spread can be

⁵⁷ See generally Robert W. Dubois et al., *Explaining Drug Spending Trends: Does Perception Match Reality?*, HEALTH AFF., Mar.-Apr. 2000, at 231, 232 (examining the underlying drivers of drug spending trends).

⁵⁸ See Bruce Stuart et al., *Dynamics in Drug Coverage of Medicare Beneficiaries: Finders, Losers, Switchers*, HEALTH AFF., Mar.-Apr. 2001, at 86 (discussing how “Medicare alone offers no protection from the vicissitudes of the market for outpatient prescription drugs”); Nadereh Pourat et al., *Socioeconomic Differences in Medicare Supplemental Coverage*, HEALTH AFF., Sept.-Oct. 2000, at 186 (reporting on “[l]arge income-related disparities” in the type of supplemental insurance).

⁵⁹ GAIL SHEARER, CONSUMERS UNION, HIDDEN FROM VIEW: THE GROWING BURDEN OF HEALTH CARE COSTS (1998), <http://www.consumersunion.org/health/0122exec.htm>.

⁶⁰ Braun testimony, *supra* note 55.

⁶¹ GLUCK, *supra* note 12, at 1 (using data from the 1995 Medicare Current Beneficiary Survey (MCBS) projected forward to 1999).

⁶² REPORT TO THE PRESIDENT, *supra* note 8, at 39 (but noting that the amount of out-of-pocket expenses can vary considerably, from fifty-eight percent for those who have Medigap coverage to twenty percent for those with Medicaid coverage).

⁶³ GLUCK, *supra* note 12, at 1 (estimating from 1995 MCBS data prepared by Actuarial Research Corporation for the National Academy of Social Insurance).

⁶⁴ *Id.*

directly attributed to differences in spending between beneficiaries with coverage and beneficiaries without coverage.⁶⁵

Presently, approximately sixty-five percent of Medicare beneficiaries have some form of prescription drug coverage.⁶⁶ This is usually in one of four forms: employer-sponsored coverage, Medicaid, Medicare HMO (Medicare+Choice Plans) or Medigap policies.⁶⁷ Nearly thirty-three percent of Medicare beneficiaries have supplemental health care insurance through employer-sponsored policies.⁶⁸ This coverage is for both working and retired beneficiaries.⁶⁹ Through this supplemental insurance, eighty-six percent have a prescription benefit (twenty-eight percent of total beneficiaries).⁷⁰ The benefits offered for prescription drug coverage through this employer-provided insurance are often the most comprehensive outpatient drug coverage benefits available, offering lower deductibles than other sources.⁷¹ This type of coverage has been declining, both in terms of numbers of beneficiaries covered and the level of benefits.⁷² The decline is attributable to fewer employers offering continued supplemental insurance for their retirees, and to the use of managed care plans that limit drug benefits.⁷³ A Medicare prescription drug coverage policy might further threaten the use of these plans as employers opt against offering supplemental insurance because it is available through Medicare.

⁶⁵ See John A. Poisal & Lauren Murray, *Growing Differences Between Medicare Beneficiaries With and Without Coverage*, HEALTH AFF., Mar.-Apr. 2001, at 74, 74.

⁶⁶ GLUCK, *supra* note 12, at 3 tbl.2; see also REPORT TO THE PRESIDENT, *supra* note 8, at 9 (finding that in 1996, sixty-nine percent of Medicare beneficiaries had drug coverage for at least one month during the year but only fifty-three had coverage for the entire year).

⁶⁷ REPORT TO THE PRESIDENT, *supra* note 8, at 11.

⁶⁸ See *id.*

⁶⁹ See GLUCK, *supra* note 12, at 4.

⁷⁰ *Id.* at 3. tbl.2.

⁷¹ *Id.* at 3.

⁷² See REPORT TO THE PRESIDENT, *supra* note 8, at 13 (citing recent employer surveys showing a decrease in providing health benefits to retirees and Medicare eligible retirees); HEWITT ASSOCIATES, HENRY J. KAISER FAMILY FOUNDATION, RETIREE HEALTH COVERAGE: RECENT TRENDS AND EMPLOYER PERSPECTIVES ON FUTURE BENEFITS 3 (Oct. 1999) (noting that some employers have dropped coverage from employer-sponsored health plans for retirees altogether, and fewer new employers are adding such coverage), available at <http://www.kff.org/content/1999/1540/Retiree.pdf>.

⁷³ See GLUCK, *supra* note 12, at 4 & tbl.3.

Beneficiaries with low incomes may be eligible for Medicaid coverage of prescription drugs.⁷⁴ Approximately twelve percent of Medicare beneficiaries are Medicaid eligible.⁷⁵ Ninety-one percent of those eligible for Medicaid receive their prescription drug coverage through Medicaid.⁷⁶ This represents eleven percent of all beneficiaries.⁷⁷ Medicaid covers most prescription drug costs (depending on the state plan and involvement of HMOs).⁷⁸ However, between 1990 and 1999, Medicaid spending on prescription drugs more than tripled.⁷⁹

Some Medicare+Choice plans, the Medicare HMO alternative, have been able to offer a prescription drug coverage benefit.⁸⁰ This is likely to change due to limits in payments from the federal government to Medicare+Choice plans.⁸¹ Most plans offer the drug coverage now, and nearly all Medicare beneficiaries covered by these plans have prescription drug coverage through them.⁸² However, recent news suggests drastic cuts by HMOs in their drug coverage for Medicare beneficiaries.⁸³

⁷⁴ See *id.* at 2. This discussion includes "Qualified Medicare Beneficiaries" (QMBs) or "Specified Low-Income Medicare Beneficiaries" (SLMBs). QMBs are low-income Medicare beneficiaries who receive assistance with Medicare cost-sharing and Part B premiums but are not covered for prescription medications. SLMBs are low-income beneficiaries who receive assistance with Part B premiums only.

⁷⁵ See Margaret Davis et al., *Prescription Drug Coverage, Utilization, and Spending Among Medicare Beneficiaries*, HEALTH AFF., Jan-Feb. 1999, at 231, 235 exh.1 (citing 1995 data on the distribution of noninstitutional Medicare beneficiaries by type of supplemental insurance and presence of drug coverage).

⁷⁶ *Id.* at 237 exh.2 (citing 1995 data on the percentage of Medicare beneficiaries using prescription drugs by the type of supplementary insurance coverage and presence of drug coverage).

⁷⁷ See *id.* at 235 exh.1.

⁷⁸ See GLUCK, *supra* note 12, at 2-3.

⁷⁹ NIHCM, *supra* note 25, at 4.

⁸⁰ See Stephen B. Soumerai & Dennis Ross-Degnan, *Inadequate Prescription-Drug Coverage for Medicare Enrollees—A Call to Action*, 340 NEW ENG. J. MED. 722, 724-25 & tbl.1 (1999) (noting, however, that the state programs vary considerably in their income requirements, the kinds of drugs covered, and the sources of program funding).

⁸¹ See GLUCK, *supra* note 12, at 3.

⁸² See Davis et al., *supra* note 75, at 231 (stating that 65% of Medicare beneficiaries have at least some prescription drug coverage, and that 95% of Medicare health maintenance organization enrollees have drug coverage).

⁸³ See Milt Freudenheim, *Many H.M.O.'s For the Elderly Cut or Abolish Drug Coverage*, N.Y. TIMES, Jan. 25, 2002, at C1 (reporting that some insurers are either eliminating drug coverage or are requiring higher payments from plan members).

Under federal law, there are ten Medigap policies available for supplemental insurance for Medicare enrollees. Only three of these plans offer prescription drug coverage, and offer it in limited form. The Medigap Plans H, I, and J offer this coverage, but the premiums for these plans are double that of some of the other Medigap plans.⁸⁴ This difference in premium levels is attributable to the prescription drug coverage benefit.⁸⁵ Moreover, the coverage for drug prescriptions in these plans is also very limited.⁸⁶ There is a \$250 deductible and the plans only pay half of the costs up to either \$1,250 or \$3,000, depending on the plan.⁸⁷ Medigap premiums also increase with age.⁸⁸ The coverage is more expensive as enrollees become increasingly likely to be sick, and as they have less income. Almost thirty percent of Medicare enrollees are covered under a Medigap supplemental insurance policy.⁸⁹ Of these, only twenty-nine percent have prescription drug coverage, which represents only eight percent of all enrollees.⁹⁰ Finally, eight percent of Medicare beneficiaries have no supplemental insurance at all.⁹¹

⁸⁴ See CTRS. FOR MEDICARE AND MEDICAID SERVS., U.S. DEP'T OF HEALTH AND HUMAN SERVS., 2001 GUIDE TO HEALTH INSURANCE FOR PEOPLE WITH MEDICARE: CHOOSING A MEDIGAP POLICY TO SUPPLEMENT THE ORIGINAL MEDICARE PLAN 54 (2001) (discussing the basics of these plans), available at <http://www.medicare.gov/Publications/Pubs/pdf/lpguide.pdf>.

⁸⁵ GLUCK, *supra* note 12, at 4.

⁸⁶ See REPORT TO THE PRESIDENT, *supra* note 8, at 15 (noting that some carriers do not offer drug coverage, and those that do may not cover if the applicant is "high-risk"; also commenting that there are limited enrollment periods, as well as some practices known as attained-age rating).

⁸⁷ See *id.* at 14.

⁸⁸ Thomas Rice et al., *The Impact of Policy Standardization on the Medigap Market*, 34 INQUIRY 106, 113 (1997) (noting that the practice of raising premiums as beneficiaries get older is called "attained-age" rating).

⁸⁹ See Davis et al., *supra* note 75, at 237 exh. 2 (reporting 1995 data, where 70% of all persons had no supplemental drug coverage—having FFS Medicare only).

⁹⁰ AARP, OUT-OF-POCKET SPENDING ON HEALTH CARE BY MEDICARE BENEFICIARIES AGE 65 AND OLDER: 1999 PROJECTIONS, ISSUE BRIEF # 41, at 3 fig.3 (Dec. 1999).

⁹¹ *Id.* at 4.

Table 1. Prescription Drug Coverage Description for Medicare Beneficiaries, 1995.⁹²

Type of Coverage	Percent of Beneficiaries with Specified Type of Coverage	Percent with Prescription Drug Coverage	Percent of All Beneficiaries with Drug Coverage
Employer Sponsored	33%	86%	28%
Medicaid	12	90	7
Medicare Risk HMO	7	95	8
MediGap	29	29	3
Other Forms	11	89	6
No Insurance	8	0	0
Total	100		65

Medicare beneficiaries who lack a prescription drug benefit pay more for prescription medications than those who have coverage.⁹³ They lack access to the savings available to insurers and government purchasers, who have greater negotiating strength because of purchasing power.⁹⁴ In 1996, average out-of-pocket expenditures for prescription drugs for those without coverage was \$463 as compared to \$253 for those who had coverage.⁹⁵ Findings of the House of Representatives Committee on Government Reform described price discrimination for seniors. Seniors without coverage were shown to be paying more than twice the price that insurance companies and government buyers were paying for needed medications.⁹⁶

Although Medicare beneficiaries without prescription drug coverage pay more for prescriptions, this lack of coverage creates the larger problem of decreased use of needed medications by those without the prescription coverage.⁹⁷ One study found that Medicare beneficiaries who did not have drug coverage got fewer medications and had spent less on prescription medica-

⁹² This table is adapted from GLUCK, *supra* note 12, at 3 tbl.2.

⁹³ See John A. Poisal & George S. Chulis, *Medicare Beneficiaries and Drug Coverage*, HEALTH AFF., Mar.-Apr. 2000, at 248.

⁹⁴ Richard G. Frank, *Prescription Drug Prices: Why Do Some Pay More Than Others Do?*, HEALTH AFF., Mar.-Apr. 2001, at 115, 121-22.

⁹⁵ Poisal & Chulis, *supra* note 93.

⁹⁶ SHEARER, *supra* note 48, at 3.

⁹⁷ *Id.* at 6.

tions presumably because they could not afford them.⁹⁸ Another study found that small price increases in the out-of-pocket cost for hypertension medicine resulted in fewer purchases of that drug.⁹⁹

The need for a prescription drug benefit among the Medicare population is exacerbated by two factors. The first is the growth of the Medicare population due to the baby-boomers entering this group.¹⁰⁰ The second is the decline in employer-sponsored supplemental insurance.¹⁰¹ Absent a change in drug benefits, the combination of these factors will lead to an increased number of Medicare beneficiaries without prescription drug coverage in the coming years.

C. Previous Government Efforts and Recent Private Measures to Assist the Elderly with Prescription Costs

While the need for a prescription drug benefit for the elderly is increasing, this is not a new issue. Previous efforts at providing a Medicare prescription drug benefit have failed largely due to political pressures.¹⁰² In 1988, Congress expanded Medicare coverage for catastrophic expenses under the Medicare Catastrophic Coverage Act of 1988 (MCCA).¹⁰³ This law mainly expanded inpatient coverage but it also provided for prescription drug coverage.¹⁰⁴ This was enacted during the 1980s when fiscal conservatism had refocused efforts on controlling government spending and the Act "highlights the connection between Medicare's interest group politics and the new

⁹⁸ See Poisal & Chulis, *supra* note 93, at 248, 251-252, exh.2 (indicated that those without drug coverage averaged 16.01 prescriptions and spent \$463 on those prescriptions annually, while those with drug coverage averaged 21.14 prescriptions and spent \$769 on those annually).

⁹⁹ See Jan Blustein, *Drug Coverage and Drug Purchases by Medicare Beneficiaries with Hypertension*, Health Aff., Mar.-Apr. 2000, at 219.

¹⁰⁰ See Victor R. Fuchs, *Health Care for the Elderly: How Much? Who Will Pay for It?*, HEALTH AFF., Jan.-Feb. 1999, at 11, 11 (citing a one percent more rapid growth in elderly population than the rest of the population as one reason for the increase in the cost of health expenditures for the elderly).

¹⁰¹ See REPORT TO THE PRESIDENT, *supra* note 8, at 13 (discussing drops in coverage and distinguishing between active workers versus retirees).

¹⁰² MARMOR, *supra* note 10, at 110.

¹⁰³ Pub. L. No. 100-360, 102 Stat. 683. This law was enacted in June 1988, became effective on January 1, 1989, and was terminated on November 30, 1989 by the Medicare Catastrophic Repeal Act of 1989, Pub. L. No. 101-234, 103 Stat. 1979.

¹⁰⁴ See Pub. L. No. 100-360, sec. 202, 102 Stat. 683, 702.

politics of deficit reduction.”¹⁰⁵ The new Act was to be financed by increases in premiums paid by Medicare beneficiaries.¹⁰⁶ This upset some beneficiaries, particularly wealthier enrollees who had drug coverage but did not want to pay higher Medicare premiums.¹⁰⁷ The MCCA was overturned the next year, leaving Congress frustrated from the experience of major Medicare legislation.¹⁰⁸

The election of President Clinton in 1993 led to serious consideration of health care reform, including Medicare reform.¹⁰⁹ As part of his health care plan President Clinton intended to provide a prescription drug benefit to Medicare beneficiaries, mostly in the hopes of gaining support for his program from the elderly.¹¹⁰ The Clinton health care plan did not get passed due to its complexity and resulting political problems.¹¹¹ The Republican-held Congress in 1995 made a similar effort at larger scale health care reform. This largely consisted of a plan to move Medicare to the use of vouchers for purchasing health care needs. Although President Clinton vetoed this measure at the time, it set the stage for two years of partisan disagreement between Congress and the White House that eventually ended in the passage of the Balanced Budget Act of 1997, which included some large Medicare changes.¹¹²

In 1997, the Balanced Budget Act introduced more private sector market measures into the Medicare system, including allowing beneficiaries to enroll in private plans, but it also included greater government control over reimbursement amounts and increased charges to beneficiaries. Further, the 1997 Balanced Budget Act created a group to study Medicare called the National Bipartisan Commission on the Future of Medicare (NBCFM). Senator John Breaux (D-La.) and Congressman Bill Thomas (R-Cal.) led this commission of seventeen members. The NBCFM worked for eighteen months to make recommendations on Medicare reform. These recommendations largely

¹⁰⁵ MARMOR, *supra* note 10, at 110.

¹⁰⁶ Pub. L. No. 100-360, sec. 103, 211, 102 Stat. 683, 687.

¹⁰⁷ MARMOR, *supra* note 10, at 111.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.* at 126-132.

¹¹⁰ *Id.* at 134.

¹¹¹ See generally John K. Iglehart, *Medicare and Prescription Drugs*, 344 NEW ENG. J. MED. 1010 (2001) (noting how the Clinton proposal failed in 1994 and discussing the greater potential for coverage in the current political landscape).

¹¹² Pub. L. No. 105-33, 111 Stat. 251.

suggested the introduction of market reforms into the Medicare structure. These were very similar to a voucher system earlier proposed by the Republican Congress. However, the recommendations required a supermajority approval of the committee, which was never gained. Following the dissolution of the NBCFM without official recommendation, both Breaux and Thomas worked to modify plans to introduce in their respective Houses.¹¹³ The Clinton administration and many liberal Democrats who were largely opposed to the Breaux-Thomas plan, offered alternative plans.¹¹⁴ In part because of the differences in approach, no proposals were enacted and there remained no prescription drug benefit for Medicare. However, the problem of a lack of or inadequate prescription drug coverage among the elderly remains.

Many pharmaceutical companies offer reduced pricing or free prescription coverage to low-income persons.¹¹⁵ Recently, Pfizer Inc., the largest drug company in the world, implemented one of the more major of these assistance programs, the Pfizer Share Card. Pfizer will offer low-income seniors Pfizer prescriptions for a flat rate of \$15 per month per prescription.¹¹⁶ This follows in a line of similar actions by other pharmaceutical companies such as GlaxoSmithKline and Novartis A.G., offering reduced rates for low-income U.S. seniors.¹¹⁷ The Pfizer discount, at seventy-five percent savings to seniors is a much larger discount.¹¹⁸ Further, the program may assist as many as seven million Medicare recipients.¹¹⁹ While this can clearly be viewed as a political move, intended to improve the image of the pharmaceutical industry and soften congressional activity when it revisits Medicare prescription drug coverage in the up-

¹¹³ See NATIONAL ACADEMY OF SOCIAL INSURANCE, FINAL REPORT OF THE STUDY PANEL ON MEDICARE'S LONG TERM FINANCING – FINANCING MEDICARE'S FUTURE ch.2 (Marilyn Moon & Michael E. Gluck eds., 2000), available at http://www.nasi.org/usr_doc/med_report_financing_NO.pdf.

¹¹⁴ See *id.*

¹¹⁵ See Pharmaceutical Research and Manufacturers of American, PhRMA, *Directory of Prescription Drug Patient Assistance Programs 2002* (listing forty-eight pharmaceutical companies which offered various drug assistance programs), at <http://www.phrma.org/searchcures/dpdpap/>.

¹¹⁶ Robert Pear & Melody Petersen, *Pfizer Plans to Offer Prescriptions to Elderly for a Monthly \$15 Fee*, N.Y. TIMES, Jan. 16, 2002, at C1.

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

coming election session, the program does provide seniors with some access to needed medications.

Over the last thirty years, drug therapy and treatment have dramatically gained importance in health care. This importance is revealed in the prevalence of use and effectiveness as well as the economic impact on the health care sector. There has been a disproportionate impact on the elderly, particularly the Medicare population. The lack of a prescription drug benefit in Medicare coverage causes large out-of-pocket expenses for this population, and also compromises the health care of those most in need of many drug therapies.

STATE PROGRAMS FOR ELDERLY ACCESS TO PRESCRIPTION DRUG COVERAGE

In response to the growing need for prescription drug coverage for the elderly and the lack of a federal measure to address this need, States are experimenting with various programs to offer aid to seniors for prescription medicines.¹²⁰ Presently, twenty-six states have implemented some form of prescription drug assistance for the elderly and many States are considering options for assistance.¹²¹ (See Table 1.) While state programs demonstrate a number of potential methods of providing aid for prescription medicines, they also reinforce the need for a federal response in part because of the legal challenges to the state programs.

Although there are a number of proposals for adding a drug benefit to the Medicare program, recent political and economic developments have slowed congressional action and interest.¹²²

¹²⁰ See Pear, *supra* note 9 (reporting that twenty-six states have authorized a pharmaceutical assistance program).

¹²¹ See SENIOR LIVING, PRESCRIPTION MEDICATION COST COVERAGE BY STATE (n.d.) (listing various programs and their eligibility requirements), at <http://seniorliving.about.com/library/weekly/aa092500b.htm?terms=%22prescription+Medication+cost+coverage+by+state%22> (last visited Jan. 24, 2002); HENRY J. KAISER FAMILY FOUND., STATE HEALTH FACTS ONLINE: SENIOR PHARMACEUTICAL ASSISTANCE PROGRAMS, 2000 (same) [hereinafter STATE HEALTH FACTS ONLINE].

¹²² See generally Robin Toner, *Congressional Budget Battle Centers on Older Americans*, N.Y. TIMES, Jan. 21, 2002, at A1 (stating that the 2002 Congressional elections "will play out amid the increasing strains of an aging society, a sluggish economy, a resurgence in health care costs and a disappearing budget surplus"); Robert Pear, *Bipartisan Medicare Panel to Call for More Spending: Pressure on Congress to Reject Bush's Cuts*, N.Y. TIMES, Jan. 21, 2002, at A10 (noting reasons why the White House wants to slow the growth of Medicare); Jackie Koszczuk, *Efforts to Subsidize Prescription Costs for Elderly May be Resuscitated*, KNIGHT RID-

These developments include the recently passed tax-cut,¹²³ new estimates for the cost of adding a program,¹²⁴ differences about whether to cover all beneficiaries or only low-income beneficiaries,¹²⁵ and President Bush's Interim Immediate Helping Hand proposal to encourage state actions.¹²⁶ Further, it appears that spending on prescription drugs will continue to increase causing further demand for coverage. It is estimated that from the years 1998 to 2000, there was a forty percent increase in drug spending.¹²⁷ Over the last year, prescription drug spending increased 18.8%.¹²⁸ States feel the impact of these demands more immediately, as they cause increased pressure on Medicaid programs and on efforts to secure the health of their citizens.

The States are taking a cue from the Bush Administration's Immediate Helping Hand Proposal. The Bush Administration offers a two-stage proposal for Medicare Reform.¹²⁹ The first stage is the early initiative for providing low-income Medicare beneficiaries with coverage by offering direct aid to the States that participate in providing assistance. Under this plan, there would be a total of \$48 billion provided to the States over four years.¹³⁰ The second part of Bush's Medicare reform plan is based on the Federal Employees Health Benefit Program and recommendations of the NBCFM. Although this plan for estab-

DER/TRIBUNE BUS. NEWS, Jan. 24, 2002 (discussing House Speaker Dennis Hastert's prescription drug plan proposal).

¹²³ See Koszczuk, *supra* note 122 (discussing the cut in the context of the Congressional Budget Office's fiscal projection of a budget deficit).

¹²⁴ Robert Pear, *CBO Issues New Estimates for Medicare Prescription Drugs*, N. Y. TIMES, Feb. 2001.

¹²⁵ See Anjetta McQueen, Associated Press, *Lawmakers Consider Medicare Reform Plans* (Feb. 15, 2001), available at <http://archive.nandotimes.com/noframes/story/0,2107,500310200-500498649-503508602-0,00.html>.

¹²⁶ See WHITE HOUSE, A BLUEPRINT FOR NEW BEGINNINGS, DEPARTMENT OF HEALTH AND HUMAN SERVICES, # 21, HIGHLIGHTS OF 2002 FUNDING, at <http://www.whitehouse.gov/news/usbudget/blueprint/bud21.html> (last visited Feb. 23, 2002) (outlining the basics of the Immediate Helping Hand Program); see also AM. FED'N OF STATE, COUNTY AND MUN. EMPLOYEES, SUMMARY OF PROPOSED BUSH TAX AND SPENDING PLAN § 3 (describing the program as providing states with federal funds to establish new pharmaceutical assistance programs) [hereinafter AFSCME], <http://www.afscme.org/action/bushtax.htm> (last visited Feb. 23, 2002).

¹²⁷ Pear, *supra* note 35.

¹²⁸ *Id.*

¹²⁹ The text of President Bush's announcement of Medicare Reform proposals is available at NewsHour with Jim Lehrer, *Medicare Overhaul* (July 12, 2001), http://pbs.org/newshour/health/prescriptions/bush_7-12.html.

¹³⁰ AFSCME, *supra* note 126, § 3.

lishing a benefit modeled from the recommendations of the NBCFM was endorsed by Tommy Thompson, the Secretary of Health and Human Services, it is opposed by two high-power Republicans, Bill Thomas (R-Cal.) who chairs the House Ways and Means Committee and Senator Chuck Grassley (R-Iowa) who chairs the Senate Finance Committee. Both favor Medicare inclusion of a prescription drug benefit over expanding state coverage.¹³¹

The range of state actions to protect seniors from the high costs of prescription drug use is very broad. In general, States are using one of two methods, either a form of subsidy for prescription medications or state-mandated discounts for prescription drugs to seniors.¹³² The subsidies can come in the form of direct payments for part of each prescription, as in Pennsylvania.¹³³ There are similar programs in Illinois, New York, and New Jersey.¹³⁴ In the last year, New York, Illinois, and Massachusetts have doubled the size of their programs by expanding enrollment eligibility.¹³⁵ All of the subsidy programs by the States are income-based, so they do not offer broad coverage of Medicare beneficiaries.¹³⁶ Michigan and Missouri use a tax rebate to subsidize the cost of prescriptions.¹³⁷ These provide a model for the use of tax-rebate measures in federal proposals. Nevada, under its Senior Rx program, is using subsidies to allow seniors to purchase private insurance from Fidelity Security Life Insurance.¹³⁸ This insurance provides drug benefits.¹³⁹ A number of States are using money received from the tobacco

¹³¹ See Iglehart, *supra* note 111, at 1012-13 (stating that both oppose state-based pharmacy assistance programs).

¹³² See Pear, *supra* note 9.

¹³³ See PA. STAT. ANN. tit. 72, § 3761-509 (West Supp. 2002).

¹³⁴ See 320 ILL. COMP. STAT. ANN. 25/4(f) (West 2001); MASS. GEN. LAWS ANN. ch. 118E, § 16B (West Supp. 2002); N.J. STAT. ANN. § 30:4D-45; N.Y. EXEC. LAW §§ 547a-547m (McKinney 1996 & Supp. 2001).

¹³⁵ Pear, *supra* note 9.

¹³⁶ See *id.*

¹³⁷ See MICH. COMP. LAWS ANN. § 550.2003 (West Supp. 2001); MO. ANN. STAT. § 135.095 (West 2000).

¹³⁸ See NEV. REV. STAT. ANN. § 439.665(1) (Michie 2000), amended by 2001 Nev. Stat. 529; see also Nevada Senior Rx Program, *Medicines for a Healthy Nevada* (2002) (discussing program funding under the Fidelity/Professional Risk and Assessment Management Insurance Services (PRAM)), at <http://nevadaseniorr.com/>.

¹³⁹ See generally Nevada Senior Rx Program, *supra* note 138 (indicating that the Nevada Department of Human Services determined the most frequently prescribed drugs in order to target the program).

company settlements to pay for drug benefits in the form of subsidies.¹⁴⁰

State discounts for prescription drug purchases also come in a variety of forms. California and Florida have passed laws limiting the amount pharmacies can charge elderly customers.¹⁴¹ In California, any Medicare card carrier can show the card to a pharmacy and pay the amount that the Medicaid program pays for the drugs.¹⁴² This results in an average saving of twenty-four percent for prescriptions.¹⁴³ States like Washington, West Virginia, Iowa, and New Hampshire have started collective bargaining groups for aiding low-income elderly.¹⁴⁴ These States have created purchasing cooperatives to negotiate for drug discounts.¹⁴⁵ This idea is being followed and expanded by States that are considering ways to create interstate negotiating blocks for drug discounts.¹⁴⁶

Perhaps the most controversial of the state programs are the ones implemented by Maine and Vermont. These States have recently gained permission to expand their Medicaid program coverage to assist with the prescription drug costs of individuals who do not currently qualify for Medicaid in the state.¹⁴⁷ Pharmaceutical manufacturers have challenged these programs for their impact on interstate commerce, violation of the Supremacy Clause, and violation of the Medicaid Act. The challenges are

¹⁴⁰ See e.g., IND. CODE ANN. § 4-12-8-2 (West 2002); N. Y. PUB. HEALTH LAW § 2807-v(1)(n) (McKinney 2002).

¹⁴¹ See CAL. HEALTH & SAFETY CODE §§ 130401-130404 (West 1996 & Supp. 2002); FLA. STAT. ANN. § 409.9066 (West Supp. 2001).

¹⁴² CAL. HEALTH & SAFETY CODE § 130404 (West 1996 & Supp. 2002).

¹⁴³ Pear, *supra* note 9.

¹⁴⁴ See *id.* However, Washington's AWARDS program was invalidated by a Superior Court ruling on May 5, 2001. This program was started by Governor Gary Locke. Similar proposals are being put forward in the Washington State Congress. The New Hampshire program was scheduled to end January 1, 2002. Iowa's program is not fully a state program as it is a demonstration project using federal funds.

¹⁴⁵ Pear, *supra* note 9.

¹⁴⁶ *Id.*

¹⁴⁷ See 1999 Me. Laws 786, § A-3 (stating that the goal of the legislation is "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"); see also ME. REV. STAT. ANN. tit. 22, § 2681 (West Supp. 2001) (outlining the Maine Rx Program); Pharm. Research & Mfrs. of Am. v. United States, 135 F. Supp. 2d 1 (D.D.C. 2001) (describing Vermont's application to the Dept. of Health and Human Services for expansion of their prescription drug pilot program), *rev'd*, Pharm. Research & Mfrs. of Am. v. Thompson, 251 F.3d 219 (D.C. Cir. 2001).

creating complicated and potentially divisive law in the Federal Circuit courts as well as generating a multitude of differing state regulations with regard to prescription drug coverage and expenses for state citizens.

On May 11, 2000, Maine enacted an Act to Establish Fairer Pricing for Prescription Drugs (Maine Rx Program).¹⁴⁸ This program was established to allow state residents who were not Medicaid eligible to purchase prescription drugs from participating pharmacies at discounted prices.¹⁴⁹ The premise of the legislation was that large purchasers of prescription medications, such as Health Maintenance Organizations, insurance companies, and the Medicaid program, were able to negotiate less costly prices for medications through volume purchasing. Citizens not covered by these groups paid significantly more (eight-six percent) for their prescription medications.¹⁵⁰ The statute required pharmaceutical manufacturers to rebate a portion of the price for providing these drugs in order to participate in the State Medicaid program.¹⁵¹ The plan required manufacturers to provide the State with a negotiated rebate on the sale of drugs by pharmacists to uninsured persons. One penalty for manufacturers who were unwilling to participate was having their drugs placed on a prior authorization list for Medicaid participants.¹⁵² The law also defined "illegal profiteering" as manufacturers requiring an "unconscionable price", or prices or terms that lead to any "unjust or unreasonable profit" or actions which "intentionally prevent[], limit[], lessen[] or restrict[] the sale or distribution of prescription drugs in this State in retaliation for the provisions" of the statute.¹⁵³ Pharmaceutical Research and Manufacturers of America (PhRMA), an association representing drug manufacturers, challenged the Maine Rx Program in the United States District Court of Maine.¹⁵⁴ This group represented about seventy-five percent of brand name drug sales in the United States.¹⁵⁵ All of the manufacturers represented by

¹⁴⁸ ME. REV. STAT. ANN. tit. 22, § 2681 (West Supp. 2001).

¹⁴⁹ *Pharm. Research & Mfrs. of Am. v. Comm'n, Maine Dep't of Human Servs.*, 2000 U.S. Dist. LEXIS 17363 at *2.

¹⁵⁰ *Id.* at *2 n.2.

¹⁵¹ ME. REV. STAT. ANN. tit. 22, § 2681(3)-(4) (West Supp. 2001); *see also* 1999 Me. Laws 786, § A-3.

¹⁵² *See* 1999 Me. Laws 786, § A-3.

¹⁵³ *Id.*

¹⁵⁴ *See Pharm. Research & Mfrs. of Am.*, 2000 U.S. Dist. LEXIS 17363.

¹⁵⁵ *Id.* at *4.

PhRMA were located outside of the Maine.¹⁵⁶ PhRMA challenged three aspects of the program: (1) the prohibition on excessive pricing by drug manufacturers, (2) the prohibition against manufacturers changing their distribution schemes to avoid Maine's law, and (3) the requirement that manufacturers pay a rebate when uninsured citizens purchased prescription drugs.¹⁵⁷ The U.S. District Court for the District of Maine held that the Maine Rx Program violated the Dormant Commerce Clause with regard to the illegal profiteering regulations because the extraterritorial effects of the statute were to regulate commerce that occurred completely outside the State boundaries.¹⁵⁸ The court also held that the penalty for not participating in the rebate program, the prior authorization of those drugs for Medicaid participants, violated the Supremacy Clause.¹⁵⁹ The court found this type of prior authorization was not authorized by the Medicaid Act and therefore was prevented by preemption by federal law.¹⁶⁰ The court granted a preliminary injunction, preventing Maine from implementing these sections of the Maine Rx Program, stating that the "plaintiff's likelihood of success on the merits of most of its constitutional challenges to be overwhelming."¹⁶¹

On appeal to the United States Court of Appeals for the First Circuit, Maine challenged the injunction as to whether the program violated the Federal Medicaid program and whether the extraterritorial reach of the regulation as to the sale of drugs by out-of-state pharmaceutical manufacturers to out-of-state distributors violated the Dormant Commerce Clause.¹⁶² The Court of Appeals found that the prior authorization requirement was consistent with the Medicaid Program, specifically the Medicaid regulation permitting prior authorization, which says States may 'subject to prior authorization any covered outpatient drug.'¹⁶³ However, the court concluded that its opinion did not prejudice PhRMA's right to re-challenge Medicaid preemption after program was implemented, if Medicaid recipients

¹⁵⁶ *Id.* at *5.

¹⁵⁷ *Id.* at *3.

¹⁵⁸ *Id.* *6-7.

¹⁵⁹ *Id.* at *20.

¹⁶⁰ *Id.* at *19.

¹⁶¹ *Id.* at *24.

¹⁶² *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, (1st Cir. 2001), *cert granted*, No. 01-188, 2002 WL 1393606 (U.S. June 28, 2002).

¹⁶³ *Id.* at 75 (quoting 42 U.S.C. § 1396r-8(d)(1)(A) (Supp. V. 1999)).

were harmed by the prior authorization requirement.¹⁶⁴ Secondly, the Court of Appeals found that the Maine Rx Program did not violate the Dormant Commerce Clause. In evaluating which level of review to apply to the state regulation, the court found that the regulation was not per se invalid nor was it subject to strict scrutiny review for regulating with discriminatory purpose, but instead should be evaluated under low level scrutiny as the statute regulated evenhandedly with only incidental effects on interstate commerce.¹⁶⁵

The court's rationale for choosing the level of review deserves some consideration as that selection dramatically alters the outcome of this type of challenge. The court found that the regulation was not per se invalid because the regulation did "not interfere with regulatory schemes in other states."¹⁶⁶ The regulation was only on activity that occurred in the state such as purchase of the prescription medications that led to the rebate, rebate price negotiations, and the penalties the State imposed for not participating.¹⁶⁷ However the court pointed out that one consideration in this analysis would be the impact of other States enacting similar legislation.¹⁶⁸ The court stated that the "most apparent effect of similar statutes being passed in other states would be a loss in profits for manufacturers" which might lead to "inconsistent obligations" or price-linking between states.¹⁶⁹ The court also dismissed the strict scrutiny test because the regulation was not discriminatory on its face or in its effects. While this court found these activities to be predominately within the State, other courts may interpret differently the fact that all the manufacturers and almost all of the distributors were located outside of the state. Finally, in the balancing test of interests, the court found that Maine's stated purpose to protect its citizens' ability to purchase prescription medications outweighed the incidental effect on commerce.¹⁷⁰ As the Court of Appeals concludes, this is a "close case," but the value of State experimentation should be preserved.¹⁷¹

¹⁶⁴ *Id.* at 78.

¹⁶⁵ *Id.* at 80-85.

¹⁶⁶ *Id.* at 82.

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ *Id.* at 82-83.

¹⁷⁰ *Id.* at 84.

¹⁷¹ *Id.* at 85.

PhRMA also challenged Vermont's Medicaid expansion plan to assist with the costs of prescription medications. In this challenge though, PhRMA challenged the federal government's approval of a State Medicaid waiver.¹⁷² PhRMA filed suit against the Department of Health and Human Services and Vermont intervened. Vermont's Pharmacy Discount Program (PDP) is a prescription drug subsidy program, which is an expansion of the pilot Medicaid project known as the Vermont Health Access Plan (VHAP).¹⁷³ Vermont applied for a Medicaid waiver from the federal government to expand the pilot project to provide coverage for 70,000 Vermont residents who do not have prescription drug coverage.¹⁷⁴ Under this program, Vermont pharmacies charge eligible beneficiaries the Medicaid discounted prices for prescriptions.¹⁷⁵ The beneficiaries are expected to pay 82.5% of the Medicaid discounted price and then the state would initially pay the remaining 17.5%.¹⁷⁶ However, the state would later bill the manufacturers for this 17.5%.¹⁷⁷ The manufacturers claim that this violates the Medicaid statute because it imposes more than nominal co-payments on beneficiaries and because the State does not provide medical assistance because no payment is made under the state plan.¹⁷⁸ The court held that PhRMA lacked standing for the co-payment challenge.¹⁷⁹ It also held that the Secretary, in approving the expanded plan recognized the State's initial payments as payments for medical care within the meaning of the statute.¹⁸⁰ The Court denied the injunction to suspend the waiver. However, the United States Court of Appeals for the District of Columbia held that the State was not making payments within the meaning of 42 U.S.C. § 1396r-8 and therefore the Secretary did not have authority to grant the Medicaid waiver.¹⁸¹ The court held that only Congress had the authority to permit States to require a

¹⁷² See *Pharm. Research & Mfrs. of Am. v. United States*, 135 F. Supp. 2d 1, (D.D.C. 2001) *rev'd*, *Pharm. Research & Mfrs. of Am. v. Thompson*, 251 F.3d 219, (D.C. Cir. 2001).

¹⁷³ *Id.* at 5.

¹⁷⁴ *Id.*

¹⁷⁵ *Id.*

¹⁷⁶ *Id.* at 6.

¹⁷⁷ *Id.*

¹⁷⁸ *Id.* at 9.

¹⁷⁹ *Id.* at 10.

¹⁸⁰ *Id.* at 13-15.

¹⁸¹ *Pharm. Research & Mfrs. of Am. v. Thompson*, 251 F. 3d 219 (D.C. Cir. 2001).

rebate where the State did not itself make payment.¹⁸² This again highlights the need for a federal response. The court reversed the decision and remanded for further proceedings.

These decisions reflect the variety of challenges that pharmaceutical manufacturers make to state plans to expand coverage of Medicaid plans to assist citizens with prescription drug costs. The Maine decision also reflects the potential for alternative holdings on similar fact patterns based on interpretation by other Circuit courts. Further, pharmaceutical manufacturers are not the only affected groups that may challenge state plans. In *Wal-Mart Stores v. Knickrehm*,¹⁸³ Wal-Mart challenged an Arkansas reimbursement formula, which established a two-tiered reimbursement system for prescription drug-costs. While the State was not attempting to expand its Medicaid coverage, it was attempting to control costs by charging different prices to chain pharmacies and independent pharmacies.¹⁸⁴ The court found the system violated the Medicaid Act and the Equal Protection Clause.¹⁸⁵ This demonstrates another way that States might be limited in the manner in which they are able to offer prescription drug cost assistance.

As the varieties of state programs suggest, there are a number of methods being used by the States to address the needs of the elderly for drug coverage. Although this permits experimentation in approaches, the variety highlights the need for federal action. The wide array of state programs is burdensome not only for drug manufacturers, wholesalers, and distributors but also for the elderly. The programs vary in who may be covered, and in the amount of coverage provided under the particular state program. (See Table 2). This leads to uneven benefits in different States. It may also cause seniors to migrate to States with the most coverage. This creates a large burden on States with a high demand on their programs. State negotiations and collective state negotiations with drug companies may lead to regional lockouts of certain types of drugs. Further, the drug companies may be forced into price discrimination based on regions or power of the bargaining groups.

¹⁸² *Id.* at 226.

¹⁸³ 101 F. Supp. 2d 749 (E.D. Ark. 2000).

¹⁸⁴ *Id.* at 750.

¹⁸⁵ *Id.* at 764.

Although President Bush would like to utilize state programs in covering prescription drug expenses, especially in light of the restrictions that the recent tax-cut places on the possibility of federal action on expanding Medicare,¹⁸⁶ the laboratory of state action may be more harmful than helpful. President Bush has offered the states \$48 billion dollars over the next four years to aid seniors, including the provision of some drug benefits.¹⁸⁷ Given the recent spikes in drug spending, the costs to the States to provide this coverage will be very high.¹⁸⁸ As Ray Scheppach, executive director of the National Governors Association, stated to a Senate committee hearing on Medicare, the States have shouldered much of the burden of providing prescription drug coverage to the elderly.¹⁸⁹ He concluded that if a universal benefit is created, it must be a federal benefit.¹⁹⁰

Table 2. State Prescription Drug Programs and Elderly Assistance, 2001.¹⁹¹

State	Pharm. Assistance Available?	Type	Eligibility	Enrollment
AL	No			
AK	No			
AZ	No			
AR	No			
CA	Prescription Drug Discount Program for Medicare Recipients	Discount	Discount price for 65+/disabled and a processing fee for Medicare cardholders	
CO	No			

¹⁸⁶ See *Bush Tax Cut "Will Halt Medicare Rx Benefit,"* MARKETLETTER (Marketletter Publications, London, Eng.), Mar. 19, 2001 (arguing that President Bush's tax cut will prevent Congress from passing "a meaningful Medicare seniors' prescription drug benefit") [hereinafter *Bush Tax Cut*].

¹⁸⁷ AFSCME, *supra* note 126, § 3.

¹⁸⁸ See Pear, *supra* note 35.

¹⁸⁹ *Finding the Right Fit: Medicare, Prescription Drugs, and Current Coverage Options: Hearing Before the Senate Fin. Comm.* (Mar. 4, 2001) (statement of Ray Scheppach, Executive Director, National Governors Association), <http://www.nga.org/nga/legislativeUpdate/testimonyDetailPrint/1,1419,1949,00.html>.

¹⁹⁰ *Id.*

¹⁹¹ This table has been adapted from STATE HEALTH FACTS ONLINE, *supra* note 121.

CT	Connecticut Pharmaceutical Assistance Contract to the Elderly and Disabled Program (ConnPACE)	Subsidy	Assistance for 65+/disabled with incomes below \$15,000 individual/18,100 couple. Co-pay-\$12. Annual-\$25. Additional assistance avail.	31, 666
DE	1. Nemours Health Clinic Pharmaceutical Assistance Program (Private) 2. Delaware Prescription Assistance Program (DPAP) (Public)	1. Discount 2. Subsidy	1. Nemours- Discount for 65+/disabled with incomes below \$12,500 individual/17,125 couple. Co-pay-20% 2. DPAP- Assistance for 65+/disabled with incomes between \$12,500-16, 488 individual/17,125-22,128 couple. Co-pay-\$5 or 25%	1. Nemours 26,000 2. DPAP 3,577
DC	No			
FL	1. Pharmaceutical Expense Assistance for Low Income Elderly Individuals Program 2. Medicare Prescription Discount Program	1. Subsidy 2. Discount	1. Assistance for 65+/disabled with incomes between \$7,517-10,222 individual; Medicaid/Medicare eligible. Co-pay-10%. Monthly limit 2. Discount for Medicare eligible. Dispensing fee	1. Not operational as of 12/31/01 2. NA
GA	No			
HI	No			
ID	No			

IL	Illinois Circuit Breaker and Pharmaceutical Assistance Program	Subsidy	Assistance for 65+/ disabled with incomes below \$21,218 individual/35,740 couple. Co-pay-income based. Annual-\$5-25. Cap-\$2,000/yr. then 20% co-pay	53,555
IN	HoosierRx	Subsidy	Refund assistance for 65+ with incomes below \$11,280 individual/15,192 couple	6, 401 COT
IA	No ¹⁹²	(Discount)		
KS	Senior Pharmacy Assistance Program	Subsidy	Assistance for 67+ with incomes below \$12,885. Co-pay-30%. Annual limit	Not operational as of 12/31/01
KY	No			
LA	No			
ME	1. Maine Low Cost Drug for the Elderly or Disabled Program 2. Maine Rx Program	1. Subsidy 2. Discount	1. Assistance for 62+/19+disabled with incomes below \$15,358 individual/20,460 couple. Co-pay-\$2-20% 2. Discount for any senior or other who lacks drug coverage.	1. 41,000 2. Not operational as of 12/31/01

¹⁹² Received a 1 million federal demonstration grant to establish a prescription drug purchasing cooperative, however this is federally funded cooperative.

MD	<p>1. Maryland Pharmacy Assistance Program (MPAP)</p> <p>2. Short term Subsidy Plan</p>	<p>1.Subsidy</p> <p>2. Subsidy</p>	<p>1. Assistance for all non-Medicaid with incomes below \$9,650 individual / 10,450 couple. Co-pay</p> <p>2. Medicare+Choice supplement enrollees. Co-pay. Limited enrollment to 15,000. Annual limits</p>	<p>1. 34,000</p> <p>2. Not operational as of 12/31/01</p>
MA	<p>Pharmacy Program (and former Pharmacy Plus Program) with Catastrophic Prescription Drug Insurance Program</p>	<p>Subsidy</p>	<p>Assistance for 65+ with incomes below \$15,492 individual / 20,769 couple. Co-pays based on drug. Annual fee and limits. Catastrophic protection enacted to limit out-of-pocket to \$2000/year or 10% of income.</p>	<p>69,170 (CPDI not operational as of 12/31/01)</p>
MI	<p>1. Michigan Emergency Pharmaceutical Program for Seniors (MEPPS)</p> <p>2. Elder Prescription Insurance Coverage Program (EPIC)</p>	<p>Subsidy (Tax)</p>	<p>EPIC replaced MEPPS in 10/01- MEPPS was a voucher system for low income. EPIC-insurance program for low income. Annual fee-\$25. Co-Pay-based on income and generic. Tax credit-\$600 for Michigan seniors</p>	<p>1. MEPPS 12,591</p> <p>2. EPIC Not operational as of 12/31/01</p>

MN	Minnesota's Pre-prescription Drug Program	Subsidy	Assistance for 65+ with incomes below \$10,308 individual/13,932 couple. Deductible-\$35/month	5000
MS	No			
MO	Tax Credit	Subsidy (Tax)	65+ and income less than \$15,000/year. Tax credit equal to total amount spent on drugs minus reimbursements from other sources, with some income reductions.	44, 6372
MT	No			
NE	No			
NV	Nevada's Senior Rx (Basic and Enhanced Plans)	Subsidy	62+ with income below \$21,500 State subsidy for pharmaceutical-only insurance, assistance based on income and plan preference (Basic Plan or Enhanced Plan)	Not operational as of 12/31/01
NH	Senior Prescription Drug Discount Program. Scheduled to End 1/2002	Discount	Drug discounts for 65+ with 40% discount for generics and 15% for brand-name drugs.	Not operational as of 12/31/01

NJ	Pharmaceutical Assistance for the Aged and Disabled (PAAD)	Subsidy	Assistance for 65+/-disabled with incomes below \$19,238 individual/23,589 couple. Co-pay-\$5-\$5+cost difference	188,000
NM	No			
NY	Elderly Pharmaceutical Insurance Coverage Program (EPIC)	Subsidy	Assistance for 65+ with incomes below \$35,000 individual/50,100 couple. Fee Plan for incomes of less than \$20,000 individual/\$26,000 couple. Deductible Plan for remaining income groups. Co-Pay-\$3-20 for both plans	203,251
NC	Prescription Drug Assistance Program	Discount	Program is for 65+ diagnosed with cardiovascular disease or diabetes with income less than \$12,885-Medicaid discounted rate. Co-pay-\$6	2,070
ND	No			
OH	No			
OK	No			

OR	No			
PA	1. Pharmaceutical Assistance Contract for the Elderly (PACE) 2. PACE Needs Enhancement Tier (PACENET)	Subsidy	1. Assistance for 65+w/ incomes below \$14,000 individual/17,200 couple.Co-pay-\$6 2. Assistance for 65+ with incomes between \$14-16,000 individual/17,200-19,200 couple. Co-pay-\$8-15. Annual Deductible-\$500	1. PACE 208,000 2.PACENET 22,000
RI	Rhode Island Pharmaceutical Assistance for the Elderly (RIPAE)	Subsidy	Assistance for 65+ with incomes below \$35,000 individual/40,100 couple. Scaled Co-pay system based on income	31,000
SC	SILVERxCard	Subsidy	Assistance for 65+ with incomes below \$14,612 individual/19,678 couple Deductible-\$500/year for full coverage. Generic purchasing requirements	Not operational as of 12/31/01
SD	No			
TN	No			
TX	No			
UT	No			

VT	1. VScript 2. Vermont Health Access Program-Pharmacy (VHAP-Pharmacy) 3. Pharmacy Discount Program (PDP)	1.Subsidy 2.Subsidy 3.Discount	1. Assistance for 65+/disabled w/ incomes \$15,033-21,375. Co-pays. Annual-\$24 2. Assistance for 65+/disabled with incomes below \$12,885 individual/17,415 couple. Co-pays 3. Provides the Medicaid Discount Rate for Medicare eligible lacking drug coverage; income below \$12,885 individual	1. 5, 588 2. 9,012 3. Not operational as of 12/31/01
VA	No			
WA	Washington Alliance to Reduce Prescription Drug Spending (AWARDS) AWARDS invalidated by Superior Court ruling on 5/25/01	Discount	Discount for 55+ Buyers' club card for annual fee of \$15 individual/25 couple used by state employees	Not operational as of 12/31/01
WV	Senior Prescription Assistance Network II (SPAN II)	Discount	Discounts for 65+ with incomes below \$25,050 individual/33,750 couple	2000
WI	No			

WY	Minimum Medical Program	Subsidy	Assistance for non Medicaid eligible with incomes below \$8,350. Co-pay-\$25. Limit co-pay-\$75/month	550
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MEDICARE PRESCRIPTION DRUG COVERAGE POLICY QUESTIONS

The implementation of an outpatient prescription drug program for Medicare presents a number of challenging practical and theoretical issues. While this Note does not address every issue, it outlines some of the major policy questions facing the design of the drug program for Medicare. This discussion is intended to provide a framework for considering the various proposals before Congress. It is also intended to identify some of the characteristics that will be essential to other Medicare reform plans and distinguish features that are unique to the question of providing outpatient prescription drug coverage to Medicare beneficiaries.

There are both structural and theoretical issues involved in developing a Medicare prescription drug coverage policy. The structural issues include issues related to coverage such as who will be covered, what drugs will be included and how the drugs will be provided. Another set of structural issues are related to the costs of the program and include what beneficiaries will be responsible for paying (co-payments, deductibles, and premium amounts), the pricing or reimbursement amounts for the drugs, how the program will be administered, and how the costs of the program will be covered.

There are also a number of theoretical issues. These issues are intertwined with the structural questions. One of the first of these is the fundamental question of whether Medicare should be viewed as a social insurance program or benefit program. A social insurance program is one in which the recipient is perceived to have "paid-in" for their benefits.¹⁹³ For example, like

¹⁹³ MARMOR, *supra* note 10, at 25.

social security, benefit programs are often linked to a history of employment or contribution.¹⁹⁴ Welfare programs are programs for those who lack the opportunity or resources for their own care. Welfare programs are often means-tested, based on income, and are considered “give-away” programs.¹⁹⁵ While Medicare is often considered a benefit program and Medicaid a welfare program, the broad coverage of the elderly under Medicare raises concerns that aspects of the program should be treated more as a welfare program. These concerns include the costs of the program, the fact that not all those covered “contributed” and the fact that the contributions are less than the demands made on the program by the beneficiaries.¹⁹⁶ How Medicare is characterized in terms of its benefits defines the depth of coverage that should be applied, and the questions of redistribution, or the reallocation of “benefits and burdens among broad socioeconomic population groups.”¹⁹⁷

Another issue is whether the government should highly regulate the program, or use prescription drug price controls. This focuses the consideration of the level of government regulation needed to administer the set goals. A corollary to this issue is whether more market-oriented controls should be used, such as competition. This leads to the ways competition can be used and how the competition may need to be regulated. A final theoretical question is the place of the proposed measure with reference to larger policy concerns such as health care access, cost-containment, and reform. These questions will be addressed in the context of the structural issues in laying out a framework to understand the proposals for prescription drug coverage.

In developing a policy for prescription drug coverage an initial question asks whether the benefit should be available to all beneficiaries or only to lower income or extraordinary-use beneficiaries.¹⁹⁸ This is a question of universal eligibility or targeted eligibility, which “reflects a trade-off between uninsurance and limiting government costs.”¹⁹⁹ The three options for designing benefit coverage are coverage for all beneficiaries,

¹⁹⁴ *Id.*

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ McClellan et al., *supra* note 7, at 29.

¹⁹⁹ *Id.*

coverage for low-income beneficiaries only, and coverage for individuals with extraordinary drug expenses only.²⁰⁰ The main concern with the low-income-targeted or extraordinary-use-targeted coverage is that it leaves many beneficiaries uninsured.²⁰¹ The main trade-off for universal coverage is that it will be the most costly.²⁰²

Universal coverage, regardless of income or need, is generally the most consistent with the Medicare program. This was one of the main reasons for the successful enactment in 1965.²⁰³ As Theodore Marmor writes:

The selection of the aged as the problem group is comprehensible in the context of American politics, however distinctive it appears in comparative perspective. Unlike America, no other industrial country in the world has begun its government health insurance program with the aged. The typical pattern has been the initial coverage of low-income workers, with subsequent extensions to dependents and then to higher-income groups. Insuring low-income workers, however, involves use of means tests, and the cardinal assumption of social security advocates in America has been that the stigma of such tests must be avoided. In having to avoid both general insurance and humiliating means tests, the Federal Security Agency strategists were left with finding a socioeconomic group whose average member could be presumed to be in need. The aged passed this test easily; everyone intuitively knew the aged were worst off.²⁰⁴

The targeted approach to benefit coverage requires means testing, and is inconsistent with the federal social insurance nature of Medicare.

Coverage only for low-income beneficiaries or extraordinary drug expenses would not protect the interests of the covered beneficiaries and there are increasing numbers of beneficiaries that would fall between the gaps. While extraordinary use

²⁰⁰ See *id.* at 29-30 (discussing the merits of targeted eligibility versus universal eligibility for prescription drug benefits).

²⁰¹ *Id.* at 29.

²⁰² *Id.* at 33.

²⁰³ MARMOR, *supra* note 10, at 11.

²⁰⁴ *Id.*

coverage would limit excess out-of-pocket costs, beneficiaries would still be responsible for costs up to the deductibles and any co-insurance. However, many elderly have found difficult even paying these amounts and with expected increases in prescription drug costs, more will find meeting these requirements difficult.²⁰⁵ Low-income benefit coverage would also leave many without drug coverage. Further, one study found that lack of coverage was not overwhelmingly coordinated with income.²⁰⁶ Many States are still finding populations left without prescription coverage even when they offer coverage for low-income individuals. Universal coverage, while being the most expensive, would provide the most secure coverage in a manner consistent with the present Medicare program.

Another question of coverage is that of voluntary or mandatory enrollment. There are two interrelated issues with voluntary or mandatory enrollment. The first is whether people should be able to opt-out. The second is whether people should be allowed to buy supplemental insurance from the private sector. The value of voluntary enrollment is that it may save the program some expense by allowing beneficiaries to compare and opt out of the Medicare benefit. Higher income beneficiaries may desire more elaborate prescription drug plans and may elect to pay for them. This would have the effect of a Medicare prescription drug plan providing more targeted coverage for lower to moderate income beneficiaries without the associated drawbacks of a targeted program. Further, beneficiaries requiring more expensive care may opt for supplemental insurance that would also offset some of the costs. Although there may be concerns that employer-sponsored insurance may decrease with the availability of a Medicare benefit or that beneficiaries would choose the available benefit through Medicare over additional costs,²⁰⁷ incentive programs could be devised to encourage employers and supplemental insurance coverage to continue. One way to do this is to offer subsidies to employers and private insurers carrying Medicare beneficiaries presently to continue to offer their drug coverage.²⁰⁸ A voluntary universal coverage program would be the most comprehensive with some potential savings.

²⁰⁵ See SHEARER, *supra* note 48, at 4.

²⁰⁶ McClellan et al., *supra* note 7, at 29-30 & exh. 2.

²⁰⁷ *Id.* at 32.

²⁰⁸ *Id.*

Allowing beneficiaries to opt-out permits beneficiaries to elect the level of their benefits while still providing a basic package of benefits. This is similar to Medicare Part B, which although voluntary, is still used by most Medicare enrollees.²⁰⁹ While this opt-out provision provides a potential for cost-savings, it is more protective of ensuring that all beneficiaries can be covered. It provides at least some benefit for seniors' medicine expenses. The issue of permitting supplemental coverage, presumably from the private sector, allows for individual assessment of needs. It also keeps the program in competition with private insurers for quality and offering. While this may lead to segregation in care levels based on income, Medicare is not intended to equalize all health care. Medicare is meant to insure that there is a basic level of care available to beneficiaries.

A next series of structural questions address the types of drugs and medications that should be covered by the plan. For many common drug therapies, there are multiple drugs available including generic versions. At the other end of the spectrum there are drugs that may be new and/or more limited in design. In between are various combinations of drugs that may be similarly classified in their results, but act in different manners.²¹⁰ Or there may be drugs that have alternative uses to their common use, which offer a particular patient a better result.²¹¹

Equivalently, there is a spectrum of possible coverage options. At the extreme is the decision to cover all prescribed drugs under any circumstances of prescription. This would be very costly but would allow for the maximum coverage. Under this inclusive policy, it would be necessary to consider ways to control costs including fixed reimbursements and incentives for selecting lower cost drugs. This would likely require Medicare to determine reimbursable prices for pharmaceuticals. This would be a heavy administrative action and would involve price setting of pharmaceuticals by the federal government.²¹² Such an action would likely meet stiff opposition by the pharmaceutical industry and would be a difficult measure for Congress to

²⁰⁹ MARMOR, *supra* note 10.

²¹⁰ See Haiden A. Huskamp et al., *The Medicare Prescription Drug Benefit: How Will the Game be Played?*, HEALTH AFF., Mar.-Apr. 2000, at 8, 13-14.

²¹¹ See *id.* at 13.

²¹² See *id.* at 14 (stating that these decisions would presumably be made by the Food and Drug Administration).

pass. A more limited option along this spectrum would be to use drug formularies. Drug formularies are lists of reimbursable drugs when there are multiple drugs available. Formularies allow for cost-savings by limiting the choice of drugs, forcing manufacturers to compete based on prices.²¹³ The Medicare plan could use formularies designed by the program administration itself. However, there are concerns about formularies, particularly with those designed by the federal government. Formularies may not protect beneficiary needs and interests sufficiently as they might limit access to needed medications. Also, formularies established by the federal government may cause controversy in limiting access to FDA-approved treatments. Medicaid programs were prohibited from using formularies under the Omnibus Reconciliation Act of 1990. However, the public benefit in coverage and cost containment available might mitigate these concerns.

A popular method presently used by private insurance programs that Medicare could adopt is to contract with pharmaceutical management firms. These firms are known as pharmaceutical benefit management companies (PBMs). PBMs negotiate with drug manufacturers, wholesalers and pharmacies largely based on drug formularies, saving money through rebates and discounts. One of the drawbacks of the use of PBMs is that they have the potential to create regional monopolies under Medicare contracts, potentially leading to unintended repercussions, like limiting which medications are available to beneficiaries in a region based on the contracts established.²¹⁴

Another consideration for policy is how coverage for a drug benefit will be provided. This is intricately linked to measures and theories of cost-containment. This presents the conflict between government regulation and market-oriented tactics to control costs. The primary method of government regulation would be the use of price controls to set the price paid for various drugs. This approach would be similar to prospective payment methods used for both outpatient and inpatient Medicare coverage. In this way, Medicare could set prices or reimbursements for prescription medications and pay pharmacies or drug

²¹³ See *id.* at 13.

²¹⁴ See Patricia M. Danzon, *Pharmaceutical Benefit Management: An Alternative Approach*, HEALTH AFF., Jan.-Feb. 2000, at 24, 24 (discussing the benefits of using competing pharmacy benefit managers in Medicare programs as opposed to the traditional monopoly PBM).

providers based on these values. While this method may be the most effective for controlling costs, it is also likely to meet with greater resistance from pharmaceutical companies and pharmacists, creating an impediment to the successful passage of a proposal for drug benefits.

Market-based approaches to cost-containment focus on competition. Two models of competition have been proposed for prescription drug benefit programs. The first is competition among eligible providers of drug benefits (like PMBs) for enrollees.²¹⁵ The second is competition for contracts to be a regional provider of prescription benefits.²¹⁶ Competition for enrollees presents adverse selection problems while regional contract competition creates anti-competitive disadvantages and antitrust problems.²¹⁷ Further, regional contract competition relies on providers limiting drug selection to reduce costs. One paper suggested the use of tiered incentive pricing to avoid this problem. Tiered pricing would allow companies to scale prices in a way that encourages use of lowest cost drugs while maintaining choice.²¹⁸

Cost is a major factor in considering a prescription drug benefit. Although predicting the cost of a future program is difficult, cost estimates may provide a starting point for a cost benefit weighing of various aspects of the proposals. In 2000, Medicare covered thirty-nine million beneficiaries at a cost of \$220 billion.²¹⁹ These costs were split between Medicare Part A, which was responsible for about sixty percent, and Medicare Part B, which were responsible for about forty percent.²²⁰ A portion of the Social Security payroll tax pays for Medicare Part A. Medicare Part B is financed from a mixture of general revenues and premiums paid by enrollees. The premiums contribute only about twenty-five percent of the costs of Medicare Part B.²²¹

²¹⁵ See Huskamp et al., *supra* note 210, at 10-12.

²¹⁶ See *id.*

²¹⁷ *Id.*

²¹⁸ See *id.* at 11.

²¹⁹ CONG. BUDGET OFFICE, AN ANALYSIS OF THE PRESIDENT'S BUDGETARY PROPOSALS FOR FISCAL YEAR 2001, at 23 (Apr. 2002), available at http://www.house.gov/budget_democrats/pres_budgets/fy2001/cbo_analysis_presbud01.pdf.

²²⁰ *Id.*

²²¹ *Id.* at 40 tbl.2-5.

Medicare costs increased dramatically from its beginnings, growing faster than the economy for twenty years.²²² The rising costs of the Medicare program have only recently begun to slow down.²²³ Over the next few years, the baby-boomers will begin to become part of the Medicare population. This will lead to a greater demand on Medicare resources. The work force population will shrink and not be able to match the financial demands on the Medicare program resulting from this growth. Although recent slowing of Medicare's inflation has encouraged benefit expansion consideration, there are serious concerns about the future demands on Medicare and its limited ability to meet the added costs.

Estimating the costs of the proposals is difficult given the limited data and uncertainty, but a study by the National Academy of Social Insurance used five scenarios to compare benefit proposals.²²⁴ In their study, they found that estimated costs were less over time for a benefit program that had a maximum benefit level than for a program that had a maximum out-of-pocket liability (i.e., a catastrophic loss protection).²²⁵

Their study also showed that a lower deductible and a higher percentage of co-insurance combined had the best effect in slowing the growth in costs of a program.²²⁶ In this study they compared deductibles of \$200 with \$500. They compared co-insurance contributions of twenty percent with fifty percent. As might be expected the most effective combination of controlling costs was a \$200 deductible and a fifty percent co-insurance.²²⁷

The Congressional Budget Office (CBO) has evaluated the costs of adding a prescription drug benefit based on Clinton's proposal.²²⁸ The Clinton plan is most similar to the Senate Democratic Plan,²²⁹ S. 10, sponsored by Tom Daschle (D-S.D.).²³⁰ This plan would cover at least fifty percent of all beneficiaries' premiums from general revenue funds.²³¹ Further, reimburse-

²²² MARMOR, *supra* note 10, at 189-91.

²²³ CONG. BUDGET OFFICE, *supra* note 219, at 39.

²²⁴ GLUCK, *supra* note 12, at 6-9.

²²⁵ *See id.* at 7 tbl.4

²²⁶ *Id.*

²²⁷ *See id.* at 7 tbl.4 (resulting in a 7.2% increase in Medicare costs).

²²⁸ CONG. BUDGET OFFICE, *supra* note 219, at 49-55.

²²⁹ Iglehart, *supra* note 111, at 1013.

²³⁰ S. 10, 107th Cong. (2001).

²³¹ *Id.* § 3.

ments would be made for large out-of-pocket expenditures.²³² The Congressional Budget Office (CBO) estimated that the proposal for a drug benefit would cost \$149 billion over a decade.²³³ Some of the costs of this program would be defrayed by the collection of the premiums, which would increase over time.²³⁴ The proposal does not include catastrophic coverage protection. The plan covers all beneficiaries to \$5,000. The CBO estimates the Bush proposal to cost \$158 billion over a decade, using vouchers to encourage enrollment in private organizations, his plan would pay for twenty-five percent of premium costs.

Taken together, these cost studies suggest a number of important influences on the cost of a program. The first is that premium contribution is very significant in program cost differences.²³⁵ Clinton's proposal offered fifty percent premium coverage and would have been almost three times as expensive as Bush's plan, which offers to pay twenty-five percent for all enrollees. This was also demonstrated in the NASI study. However the Clinton Plan would attempt to offset program costs by applying premiums directly to prescription drug costs.

The second influence is the inclusion of a stop loss provision—a provision which allows for Medicare to be covered for costs exceeding a certain level, or a maximum benefit. Catastrophic coverage drives costs of a program proposal to nearly double that of a maximum benefit proposal after twenty years.²³⁶ Catastrophic coverage is the coverage for high cost medical care, in this instance high cost prescription drugs. The maximum benefit is more stable while the costs of catastrophic coverage continue to grow.²³⁷ As described above, a lower deductible and a higher co-insurance both reduce expenditures over time.

One suggestion from the CBO analysis is that competition reduces costs. Bush's proposal utilizes private market forces much more than Clinton's proposal. Even though there is a premium differential, the private market influence may lessen costs. A CBO study suggested this might be true when they

²³² *See id.*

²³³ CONG. BUDGET OFFICE, *supra* note 219, at 51.

²³⁴ *Id.*

²³⁵ *See e.g.*, GLUCK, *supra* note 12, at 6-9.

²³⁶ *See id.* at 7 fig.1.

²³⁷ *See id.*

compared Clinton's plan in 1998 with a Democratic House proposal.²³⁸ They were very similar plans, but the House proposal cost less because it relied on competition among providers of coverage.²³⁹

A final structural issue is how a prescription drug plan should be administered. Possible plan administrative measures might include the creation of a separate program outside of Medicare, the creation of a specialized committee or department to oversee the drug benefits, or the creation of committees to oversee specific aspects of a program such as price determinations or drug evaluations. Structural administration of a plan relies on the degree of detail in the running of the plan; how the plan relates to other Medicare components; and whether the administration is more involved and requires greater specialized knowledge. Finally, administration of the plan may increase cost. If the plan requires new agency and support personnel, this may be more expensive than using available resources.

PRESCRIPTION DRUG PROPOSALS

This paper looks at four congressional proposals for a drug benefit addition to the Medicare program. They are Senate Bill 10, House Bill 803, Senate Bill 358 and House Bill 339. These proposals represent the range of different approaches to various structural and theoretical issues but also some areas of similarity among the plans. Each of the proposals offer voluntary enrollment to all beneficiaries, making the plans all consistent with broader coverage of the population. All the plans, except H.R.339 offer subsidies of premiums to low-income beneficiaries. The plans all utilize some form of price controls for drug coverage, with H.R.339 using government payment limits and the other proposals using more competitive methods. Comparisons of certain features of these proposals are presented in Table 3.

A. Senate Bill 10

Thomas Daschle (D-S.D.) sponsored S.10, which is co-sponsored by liberal democrats.²⁴⁰ It is most similar to President

²³⁸ See CONG. BUDGET OFFICE, *supra* note 219.

²³⁹ See *id.*

²⁴⁰ See S. 10, 107th Cong. (2001).

Clinton's prescription drug plan.²⁴¹ Like the Clinton plan, it is a partially capped co-insurance plan. This bill "reflects the Democratic preference for providing partial coverage of routine drug expenditures for most Medicare beneficiaries and providing greater coverage for the large, unexpected drug costs incurred by a small proportion of beneficiaries."²⁴²

The plan creates a Medicare Part D, which is specifically for prescription coverage.²⁴³ However, the premium costs of this Part D coverage are calculated separately from the Part B premium.²⁴⁴ The premium is used to cover almost fifty percent of the drug benefit program.

This proposal best demonstrates the use of competition for regional contracts.²⁴⁵ Eligible providers like PBMs, retail pharmacies, health plans, and States or combinations of these entities can submit bids to the Secretary of Health.²⁴⁶ The use of formularies is encouraged.²⁴⁷ It modifies Medicare+Choice plans to require a prescription drug benefit.²⁴⁸ This bill is presently in the Senate Finance Committee, which is hearing testimony on a prescription drug benefit under Medicare.

B. House Bill 803

H.R.803 is a bill sponsored by Pete Stark (D-Cal.).²⁴⁹ It is part of a larger Medicare reform bill that is not just a prescription drug benefit. The benefit would be offered under Medicare Part B. This proposal uses competition among pharmaceutical providers but would be a closer example of competition for enrollees than the S.10 regional contract competition. The proposal allows for "any willing pharmacy" to participate as long as they meet the requirements.²⁵⁰ It is like S.10 with coverage for extraordinary use, except that it contains greater provisions for catastrophic stop-loss. President Bush has endorsed this

²⁴¹ Iglehart, *supra* note 111, at 1013.

²⁴² *Id.*

²⁴³ S. 10, § 3 (2001).

²⁴⁴ *Id.* at § 5.

²⁴⁵ *See id.* at § 3 (governing enrollment).

²⁴⁶ *Id.* at § 3.

²⁴⁷ *See id.*

²⁴⁸ *See id.*

²⁴⁹ H.R. 803, 107th Cong. (2001).

²⁵⁰ H.R. 803, § 201.

bill.²⁵¹ This is a modified version of the Kennedy-Stark bill from last session, although it has some capped co-insurance provisions. This bill has recently been referred to the House Energy and Commerce Subcommittee on Health.

C. Senate Bill 358

S.358 is also called the Breaux-Frist II, a scaled down proposal of Medicare reforms proposed following the NBCMR, focused on providing a prescription drug coverage benefit.²⁵² Although this represents a bipartisan approach, Breaux (D-La.) is interested in market approaches to Medicare reform. Frist (R-Tenn.) is also a private market proponent.²⁵³

This proposal has many unique features. First, it would establish a new agency, called the Medicare Competition Agency, to run the Medicare Prescription Drug and Supplemental Benefit Program.²⁵⁴ A Commissioner of this program would run the agency but would also be a trustee for the Medicare Supplemental Trust Fund.²⁵⁵

The benefits would be offered to enrollees on a voluntary basis under the Medicare Prescription Plus plan.²⁵⁶ This plan would be available either through Medicare+Choice plans or private insurance.²⁵⁷ There would be competition for enrollees based on the supplemental insurance package for prescription drugs offered.²⁵⁸ While this would utilize Medicare's existing supplemental insurance program, it relies on competition at the level of plan offering, unlike S.10 and H.R.803, which have enrollees in a Medicare plan but introduce competition at the level of drug purchasing and providing. One concern with the Breaux-Frist proposal is the possibility that private plans for a drug benefit will parallel the problems that occurred when pri-

²⁵¹ See Press Release, The White House, Statement by the Press Secretary (Aug. 3, 2001), available at <http://www.whitehouse.gov/news/releases/2001/08/print/20010803-1.html>.

²⁵² S. 358, 107th Cong. (2001).

²⁵³ BILL FRIST, MEDICARE REFORM AND PRESCRIPTION DRUGS (n.d.) (discussing proposed improvements to the Medicare+Choice program under the Breaux-Frist bill), at http://www.senate.gov/~frist/Health_Agenda_2000/Medicare_Reform (last visited Jan. 24, 2002).

²⁵⁴ S. 358, § 101.

²⁵⁵ *Id.* §§ 101, 102.

²⁵⁶ S. 358, § 201.

²⁵⁷ FRIST, *supra* note 253.

²⁵⁸ *Id.*

vate HMOs were permitted to cover Medicare and Medicaid patients.²⁵⁹ These programs initially enrolled many beneficiaries with the promise of more and better health coverage than the traditional Medicare fee-for-service coverage. However, many of these plans ran into financial difficulties in covering high demand, high cost populations. Many Medicare and Medicaid beneficiaries were left without coverage as these plans went bankrupt or pulled out of the programs. Similarly, private prescription drug programs may initially offer inexpensive good coverage and enroll a number of beneficiaries and then be unable to provide the coverage at competitive prices, leaving the traditional Medicare program to carry these beneficiaries. It is possible, though, that the private market for prescription drug coverage may be able to reduce costs because of strong negotiations with PBMs and pharmacies.

D. House Bill 339

House Bill 339 is sponsored by Eliot Engel (D-N.Y.) and is co-sponsored by other House Democrats.²⁶⁰ This plan is an example of a prescription benefit program that uses price setting for drug payments by the Medicare program. The prices would be set based on regional prices and would use a 90th percentile value of the customary levels for various drugs.²⁶¹ This is the only plan that prohibits the use of formularies.²⁶² It establishes a new committee to set the payment limits for drugs. This system is similar to the manner in which Medicare makes payments under Part B for physician services with their Resource Based Relative Value Scale (RBRVS). A concern in using a 90th percentile value for the customary charges is that it may encourage pharmacies to raise prices in order to recoup the loss. In this, there is an incentive to raise prices because the price paid is based on the amount customarily charged. It is presently in the Committee on Energy and Commerce as well as the Committee on Ways and Means and has recently been referred to the Subcommittee on Health.

²⁵⁹ See Iglehart, *supra* note 111, at 1013 (noting Senator Thomas's recognition that the Medicare+Choice programs have failed many elderly persons).

²⁶⁰ H.R. 339, 107th Cong. (2001).

²⁶¹ *Id.* § 2(c)(3).

²⁶² *Id.* § 2(c)(5).

Table 3. Comparison of Congressional Medicare Prescription Drug Proposals, 2001.

Plan	S.10 (Daschle)	H.R.803 (Stark)	S.358 (Breaux-Frist)	H.R.339 (Engel)
Participation and Enrollment	All Beneficiaries Voluntary Enrollment	All Beneficiaries Voluntary Enrollment	All Beneficiaries Voluntary Enrollment	All Beneficiaries
Inclusion in Medicare Program	Under Medicare Part D	Under Medicare Part B	Medicare+Choice	Under Medicare Part B
Premiums	Monthly Premiums-differ if collected from beneficiary or employer	Monthly Premiums		
Low-income Subsidies	Low income beneficiaries with no premiums or co-insurance	Low income beneficiaries with no premiums or co-insurance	Full coverage for low-income beneficiaries at 150% of poverty level-phasing up	
How Provided	Eligible PBMs, retail pharmacies, health plans, states, combinations Some Catastrophic coverage	Eligible PBMs, retail pharmacies, health plans, states, combinations Catastrophic Coverage Provisions	Eligible entities like PBMs, pharmacies, health plans, may contract with Medicare Committee Some Catastrophic coverage	

Competition	Bidding for regional providing based on drug prices, charges to program- Competition for enrollees	Bidding for regional providing based on drug prices, charges to program- Competition for enrollees	Competition among eligible entities for enrollees	
Price Controls	Permits formularies	Permits formularies	Permits formularies	Payment Limits similar to RBRVS- geographic variations, 90% price <i>Prohibits Formularies</i>
Co-Pays	Co-insurance from 0-50% based on out-of-pocket expenses	Scaled co-insurance	Co-insurance of 50%-limit at 2,100- None at \$6,000 out-of-pocket	Co-insurance- 20%
Deductibles	\$250 (may be waived for generic drugs)	\$250	\$250	\$250

Where is the \$ coming from?	Premiums and Federal Supplemental Medical Insurance Trust Fund	Premiums and Federal Supplemental Medical Insurance Trust Fund	Separate Fund not Supp. Med. Ins. Trust Fund- Premiums Limit to only 40% from General Revenues	Federal Supplemental Medical Insurance Trust Fund
Administration	Medicare Secretary of Health	Medicare Secretary of Health	New committee to oversee Prescription Drug Program- <i>Medicare Competitive and Prescription Drug Program Committee</i> - Committee Head is also on Board of Trustees of Medicare Trust	Secretary of Health- Medicare but new committee for price setting

Estimated Costs (if available)	\$338 billion in new federal costs from 2001-2010. ²⁶³			
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MEDICARE PRESCRIPTION DRUG PROPOSAL AND THE PROSPECTS FOR LEGISLATIVE ACTION

The need for adequate prescription drug coverage among the elderly population is reaching the level of a crisis.²⁶⁴ Seniors are the highest consumers of prescription medications.²⁶⁵ Most seniors receive their health care coverage under Medicare, but because Medicare does not offer prescription coverage, meeting this need requires supplemental insurance.²⁶⁶ Seniors have more limited income and employment and are therefore less likely to be able to afford paying for these medications on their own.²⁶⁷ While some seniors have prescription drug coverage, many do not and the coverage that they have is often inadequate.²⁶⁸ Further, the high cost of coverage is causing fewer employers to offer this coverage and reducing the ability of other programs to meet this need.²⁶⁹

The state assistance programs for drug coverage are not sufficient to meet the demands of this potential crisis for cover-

²⁶³ GLUCK, *supra* note 7, at 10. This proposal is most similar to President Clinton's proposal.

²⁶⁴ See SHEARER, *supra* note 48 (reporting statistics associated with rising costs to seniors).

²⁶⁵ See *id.* at 2 (stating that older Americans, while accounting for just twelve percent of the population, are responsible for one-third of spending on prescription drugs).

²⁶⁶ See GLUCK, *supra* note 12, at 1.

²⁶⁷ See SHEARER, *supra* note 48, at 2 (noting that of those aged sixty-five and older, fifty-seven percent spend more than ten percent of their income on out-of-pocket health care costs).

²⁶⁸ See *id.* at 2-3 (finding that the oldest Medigap policy holders can often have the most expensive policies, since premiums increase with age); Stuart et al., *supra* note 58, at 82 (reporting that fewer than half of all beneficiaries had continuous drug coverage and nearly one-third, gained, lost, or had intermittent coverage); Pourat et al., *supra* note 58, at 186 (finding that those who are more disadvantaged are less likely to have any supplemental coverage).

²⁶⁹ See generally Pear, *supra* note 35 (indicating that employer-provided benefits have increased in cost).

age. Medicaid programs cover low-income seniors with prescription drug coverage but this does not offer assistance to many elderly who are not income-based eligible for Medicaid but still cannot afford the monthly costs of their medication needs.²⁷⁰ State plans to expand coverage are susceptible to challenges. State plans are also not uniform and while the laboratory of state programs may appear at first blush an effective way to address this problem, it is not. A variety of programs operated by the States means that many drug companies and chain pharmacies are faced with the potential of meeting fifty different sets of rules and requirements. The lack of uniformity in State approaches means that at the best, States are offering some seniors more assistance than others, and at the worst, States' assistance ranges from none to full assistance.

This disparity is unacceptable in a population whose health care needs are to be protected by an entitlement program. Medicare is health coverage for the elderly. Prescription drugs have become an essential part of health care in this country. The fact that their role was not as prevalent at Medicare's enactment does not decrease their present necessity.

There must be a federal response to this problem. Medicare must make prescription drug coverage available to all seniors. As prescription drug costs increase, more and more seniors will be made vulnerable to the high costs of meeting their health care needs. If coverage is only provided to low income or high-use beneficiaries, many people will be left uncovered over time. Unless all beneficiaries are covered, the legislature will always be forced to grapple with the next group that is left just outside the eligibility for assistance, but without the ability to provide for them.

A drug benefit program under Medicare should be voluntary. Although covering all beneficiaries is one of the leading factors in the cost of this program, it is the most imperative to ensuring basic health care coverage for seniors and meeting this problem directly. One potential way to offset some of this cost is to permit seniors to opt-out if they wish. The voluntary nature of the program also adds an element of competition based on quality of program. If the Medicare program is not adequate, seniors can choose other programs or elect not to participate as a way to voice dissatisfaction. The four congressional proposals

²⁷⁰ See GLUCK *supra* note 12, at 4.

are intended to provide assistance to all beneficiaries; they all provide greater assistance for lower-income elderly, and are all voluntary programs.

A Medicare prescription drug proposal that is made available to all beneficiaries must control costs. There are two overarching ways to control costs for providing benefits to all seniors. The first is to limit the scope of the benefits and the second is to limit the amount paid for the benefit. Benefit limitations may come in the form of restricting covered medications to certain illnesses, or in setting up formularies and tiered formularies, which restrict the brands of drugs covered. Coverage for prescription medications only for certain illnesses is rationing. This presents problems of evaluating the needs of different people with respect to their health and considering the impact on the population as a whole. This is a very difficult way to limit costs because it limits care and it would leave many uncovered for their needs. Formularies limit the choice of drug used to treat a particular illness. Since formularies often reflect a "deal" on the costs of a particular drug, this may be a useful method to control costs. The use of tiered formularies, where beneficiaries have options for higher cost drugs by contributing additional money, offers a method to control costs but also provides choice.

Price controls are essential to controlling the huge expense of a prescription drug program. The question of how best to control these costs relies to some degree on whether government regulation or market competition controls are desired. A more regulatory approach is for the government to set and pay only certain price values. The Medicare program already sets and pays fixed prices for some services.²⁷¹ The limitations of this approach are that it may impact pharmaceutical companies' ability to recoup costs or to continue research and development.²⁷² The government would then be the largest purchaser of goods and would have unprecedented control of ancillary markets to the Medicare program. The only congressional proposal to suggest this is H.R.339, the Engel bill. This method would be very difficult to pass and might lead to pharmaceutical companies being unwilling to participate.

²⁷¹ Under Medicare Part A there are diagnostically related group prospective payments.

²⁷² See generally Pear, *supra* note 35 (discussing the rising costs of pharmaceuticals and its contributing factors).

Increased competition is often cited as the health care market's cost control answer. There are various levels where competition can be introduced into a prescription drug plan, but the two models most often discussed are competition for contracts and competition for enrollees.²⁷³ Although there is some overlap, generally competition for contracts is competition at the product level (prescription drugs) and competition for enrollees is competition at the provider level (prescription drug plans). The Daschle plan in the Senate and the Stark plan in the House both use competition for contracts.²⁷⁴ The Breaux-Frist II plan is competition for enrollees.²⁷⁵ All three of these plans permit the use of formularies.²⁷⁶ There is an advantage for price controls with the competition at the level of product or for contracts. Medicare has greater negotiation power and information in deciding particular contracts to accept. Further, there is more competition among product competitors, in this case the PBMs, manufacturers, wholesalers, distributors and pharmacies. Under the competition for enrollees, there would be competition between private coverage groups and Medicare+Choice plans.²⁷⁷

Another key issue in designing a benefit is the amount of responsibility that beneficiaries should have for their coverage. This includes the amounts of premiums, co-insurance and deductibles to be paid by beneficiaries. Premiums, as demonstrated by the cost analysis by the CBO of the Clinton plan, can significantly contribute to paying for the program.²⁷⁸ This contribution is important to controlling the cost of the program. Both deductibles and co-insurance can be used to reduce the costs over time to the program as well.²⁷⁹ A lower deductible and a higher co-insurance combine to be the most effective at slowing costs. Although catastrophic coverage should be considered eventually for a prescription drug benefit, it is highly expensive. Initial enactment of a benefit should focus on cover-

²⁷³ See McClellan et al., *supra* note 7, at 35-36.

²⁷⁴ S. 10, 107th Cong. § 3 (2001); H.R. 803, 107th Cong. § 201 (2001).

²⁷⁵ See S. 358, 107th Cong. § 201 (2001) (indicating that eligible beneficiaries will make an election to enroll in the program).

²⁷⁶ See S. 10, 107th Cong. § 3 (2001); S. 358, 107th Cong. § 201 (2001); H.R. 803, 107th Cong. § 201 (2001).

²⁷⁷ See S. 358, 107th Cong. § 201 (2001) (indicating enrollees has choice between entities).

²⁷⁸ See Iglehart, *supra* note 111, at 1013 (stating that \$152 billion of the \$442 billion Clinton drug plan would be paid by premiums).

²⁷⁹ See GLUCK, *supra* note 12, at 6-9.

ing all beneficiaries for most of their needs with some protections for catastrophic coverage (capped co-insurance).

Finally, if a prescription drug plan covers all beneficiaries and is run based on competing contracts to control prices, the administration of this program may be quite time-consuming and complicated. Since prescription drug coverage will be an addition to the Medicare program, it seems necessary to have a specialized section for this benefit integrated into the Medicare administration as a whole. Further, the financial demands of this program may require that the finances be separated some from the other Medicare program finances. The Breaux-Frist II proposal is the only proposal to address these administrative demands of initiating such a large program. None of the proposals before Congress offer all of the described elements for a strong prescription drug benefit, although S.10, H.R.803 and S.358 each have certain of the attributes.

Politics will have a large impact on whether a prescription drug benefit gets passed and in what form it gets passed. The political climate at the initial passage of Medicare was unique. At that time, there was a newly elected Democratic president, President Johnson, and a Democratically controlled Congress.²⁸⁰ There was also overwhelming public support for the passage of a health care program for the aging.²⁸¹ Presently, there is a newly elected Republican President from a very close election. The Congress is very evenly split, although Democrats have a slight majority. There is large public support for prescription drug coverage but also public recognition of the cost of the Medicare program, the future financial problems of the program, and the imminent future growth of the Medicare population.²⁸² Another voice in the political discussion is that of the pharmaceutical industry. Although there is less challenge of a Medicare prescription drug benefit, they will be an interested party aiming to preserve their revenues and limit government intervention.

President Bush's two-part strategy for creating a Medicare drug benefit is based largely on the Federal Employees Health Benefit Program and the previous recommendations of the NBCFM. Recent changes in Congressional committee leader-

²⁸⁰ MARMOR, *supra* note 10, at 45.

²⁸¹ *Id.*

²⁸² See Iglehart, *supra*, note 111.

ship, however, may make passage of his programs difficult. The new chair of the Senate Finance Committee, Chuck Grassley (R-Iowa), has experience with Medicare policy. He was on the Senate Special Committee for the Aging. He initially announced that the Senate would not consider Bush's Medicare reform programs this session in order to try to pass a drug benefit for Medicare. He also announced his opposition to expanding state programs.²⁸³ The new chairman of the House Ways and Means Committee is Representative Bill Thomas (R-Cal.). Thomas was also the co-chair of NBCFM, and although he has worked with Breaux, he does not support creating a drug benefit around Medicare+Choice.²⁸⁴ He also announced his opposition to President Bush's state expansion plans.²⁸⁵ Finally, the new chairman of the House Energy and Commerce Committee is W.J. Tauzin (R-La.).

The present political climate means that the key to passage of a prescription drug benefit is "bipartisanship." The influence of the NBCFM is meaningful here. President Bush's general support for the recommendations of the NBCFM suggests some shared views with the Breaux-Frist proposal. However, Breaux is a Democrat and although, his bill is co-sponsored by a Republican, some key Republican leaders oppose the Breaux-Frist II plan. Similarly, large Democratic support for either S.10 or H.R.803 suggests that Democrat support for the Breaux-Frist proposal will be limited. Democratic proposals are more expensive and will be hard to bring to the table following passage of Bush's 1.6 trillion-dollar tax cut.²⁸⁶ This tax cut is expected to make passage of any Medicare prescription drug plan this year unlikely. Votes on the tax cut reflected much partisanship and it is likely that bipartisanship will be difficult to achieve when even party agreement is difficult to reach. A Medicare prescription drug benefit discussion will continue to be a prominent and divisive issue for Congress.

²⁸³ Iglehart, *supra* note 111, at 1013.

²⁸⁴ *See id.*

²⁸⁵ *See id.*

²⁸⁶ *See Bush Tax Cut, supra* note 186.

LESSONS FOR LARGE-SCALE MEDICARE REFORM?

At the beginning of the 107th Congressional session, the prospects for passage of a prescription drug benefit appeared more likely than they do presently. Since the passage of the original Medicare program, there has not been such single party control and coordination of the legislative and executive branches on Medicare proposals.²⁸⁷ In large part this is due to the dramatic expansion of this program and fundamental differences on how to run Medicare. However, there are still promising points of agreement between the parties on prescription drug coverage under this program.

Both parties recognize the need for coverage among the elderly population. They also appear to agree that Medicare should be involved in eventually providing some of this coverage. There is agreement that a benefit should be available to all beneficiaries with additional assistance to lower-income elderly and some protection for high-use beneficiaries. For the most part, based somewhat on the influence of President Clinton's health plan of 1993 and the work of NBCFM, most major proposals are considering the use of competition to achieve price controls.

These similarities however mask certain trends in the substantive development of Medicare policy and regulation. According to Jon Oberlander, a political scientist, there are three substantive features to Medicare's politics.²⁸⁸ These are struggles over benefits, struggles over financing, and struggles over federal payments.²⁸⁹ The struggle over benefits has been characterized as "non-distributive." This means that there has not been expansion of Medicare's benefits even when demand for these is strong. The struggle over finances has been characterized as the struggle of crises. This reflects the trend of addressing financial concerns, premium levels and funding, when bankruptcy or financial security of the program is in question. Finally the struggles of federal payment have been concerned with

²⁸⁷ See MARMOR, *supra* note 10, at 45; Iglehart, *supra* note 111, at 1012 (discussing the political players involved).

²⁸⁸ MARMOR, *supra* note 10, at 182 (citing Oberlander, J.B., Medicare and the American State, dissertation, Yale University, 1995).

²⁸⁹ *Id.*

the regulatory politics of paying providers. Often these reforms have been coordinated with financing struggles.

The trends suggest that expansion of the Medicare program is usually hampered by financing and payment concerns. However, the prescription drug benefit may have the advantage of being considered during a time of, and in the context of, both financial and regulatory reforms for payments. The trends of the benefit proposals suggest that both parties are viewing Medicare as a social entitlement program and that coverage of a benefit must be for all beneficiaries. Further, the emphasis, even among Democrats, of market principles and managed competition suggest a continued approach to controlling costs through a mixed government/market approach. A prescription drug benefit may be viewed as the trial case, testing these approaches with the intention of implementing them in larger scale reform plans. In sum, the struggles over providing a benefit may become a crisis political issue, as the lack of coverage for medications among the elderly continues to increase health care costs impacting the States and the Medicare Program.

