The Struggle for Rural Pharmacies: Will Medicare's New Privately Insured Prescription Drug Coverage Jeopardize Valuable Pharmacy Services for Rural Seniors?

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INTRODUCTION

A century ago, the concept of government-insured health care in this country was merely an ambitious idea. That idea, inspired by newly established programs in Europe, eventually evolved into a national movement to coordinate medical care for all Americans. It also sparked a lively and continuing debate in our nation’s politics about the role of government in providing health care to its citizens. This

1 J.D. Candidate May 2005, The Catholic University of America, Columbus School of Law, B.S. 1998 University of Arkansas. The author wishes to thank all those who assisted him on this Comment, especially his family and friends for their support, Rev. Raymond C. O’Brien for his edits, and the editorial board and staff of the Journal for their input and hard work.

2 Historians often cite the 1883 inauguration of the German health insurance program by Chancellor Otto von Bismark as the precursor of modern social welfare programs. However, the principle of government involvement in health care dates as far back as the ancient Greek civilizations where city-states were known to have tax-subsidized public physicians. In fact, Bismark’s program was not the first such compulsory health plan in Europe. The state of Prussia enacted a compulsory health insurance law some twenty-nine years earlier, in 1854. It was the success of the German initiative, however, that inspired other European countries, including Great Britain, to follow suit, providing a catalyst for eventual comprehensive worker protections commonly known today as “social insurance.” Peter A. Corning, The Evolution of Medicare . . . from Idea to Law at Introduction (1969), reprinted at http://www.ssa.gov/history/corning.html (last visited Nov. 26, 2004).

2 Id. at Introduction. Discussions of a national health insurance system in the United States first appeared in earnest in the early twentieth century. Encouraged by the passage of the British National Health Insurance program in
discourse regarding the merits of public versus private health insurance is vividly illustrated by the debate surrounding the creation and improvement of the Medicare program.

The national health insurance movement reached a major milestone in 1965 with the historic signing of legislation creating Medicare and Medicaid. In developing these landmark national programs to ensure

1911, a number of American political and intellectual leaders organized a movement to enact health insurance and other social assistance measures on a state-by-state basis. Over the next decade, a debate took shape over the government's role in health care that characterized the attitudes and positions on this issue that continue to this day. *Id.*

3. The Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965). The Social Security Amendments of 1965 created both Medicare and Medicaid as they are known today. *CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE INFORMATION RESOURCE*, at http://cms.hhs.gov/medicare (last visited Nov. 26, 2004). As established by the Act, Medicare was designed as a two-part insurance program to provide coverage for medical expenses of the elderly. Part A, the "basic" program, was to cover inpatient hospital and related expenses, including ninety days of hospital care, one hundred days of nursing home care, one hundred at-home care visits for each illness, and outpatient hospital services. These benefits were financed through social security taxes and subject to "deductibles," "coinsurance," and other conditions. Part B was a voluntary program to provide "supplementary" coverage for physician and outpatient services, additional home health services, diagnostic and laboratory work, certain therapy services, ambulance services, and certain other expenses. Medicare would cover eighty percent of Part B expenses above a deductible amount, which was to be financed through a monthly premium charged to each beneficiary, with a matching amount paid by the federal government through general revenues. *CORNING, supra* note 1, at Ch. 4 n. 39.

In 1972, Congress amended the program to add coverage for disabled adults under age sixty-five and those suffering from permanent kidney failure that requires dialysis or a transplant, known as end-stage renal disease (ERSD). *CTRS. FOR MEDICARE & MEDICAID SERVS., CMS/HCFA HISTORY [hereinafter CMS/HCFA HISTORY], at* http://cms.hhs.gov/about/history/ (last visited Nov. 28, 2004). *See also CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE INFORMATION RESOURCE, at* http://cms.hhs.gov/medicare/ (last visited Nov. 28, 2004). Today, Medicare covers approximately forty million Americans including those age sixty-five or over, those on disability, and those with permanent kidney failure. *CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE INFORMATION RESOURCE, at* http://cms.hhs.gov/medicare/ (last visited Nov. 28, 2004). Medicare continues to cover "inpatient hospital services, skilled nursing facility (SNF) benefits, and hospice care" (under Part A), as well as "physician and outpatient hospital services, annual mammography and other cancer screenings, and services such as laboratory procedures and medical equipment" (under Part B) and certain
access to quality health care for our nation’s most needy citizens, the elderly and the poor, those favoring publicly insured health care prevailed. Supporters of government insurance successfully argued


In addition to the creation of Medicare, the 1965 act also greatly expanded the previous Kerr-Mills program, today known as Medicaid, by extending “medical indigency” benefits to eligible individuals under age sixty-five. CORNING, supra note 1, at Ch. 4 n. 39. The Medicaid program today provides the greatest source of funding for medical insurance for the nation’s poorest individuals and families. CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICAID: A BRIEF SUMMARY [hereinafter MEDICAID: A BRIEF SUMMARY], at http://cms.hhs.gov/publications/overview-medicare-medicaid/default4.asp (last visited Nov. 28, 2004). The program is administered by the states, and the requirements for eligibility and guidelines for services are established by each state. However, the federal government requires that federal Medicaid funds only be extended to persons who fall within the following classes: children, pregnant women, adults in families with dependent children, individuals with disabilities, and individuals age sixty-five and above. CTRS. FOR MEDICARE & MEDICAID SERVS., WELCOME TO MEDICAID: SITE FOR CONSUMER INFORMATION, at http://cms.hhs.gov/medicaid/consumer.asp (last visited Nov. 28, 2004). Only those poor persons whose income and assets fall below specified levels (determined by each state within federal guidelines) may become eligible to receive Medicaid. Generally, persons who qualify fall near or below the federal poverty level. MEDICAID: A BRIEF SUMMARY, supra.

In order to receive federal matching funds, a state’s Medicaid program must also meet mandatory requirements for basic medical services. Among these services are nursing home services, which are not covered under Medicare. Id. The federal government may also provide states with matching funds for certain other optional services. One such service that most state Medicaid programs cover is prescription drugs. Id. Finally, many states also provide “State-only” programs to provide medical coverage for certain low-income individuals who do not qualify for Medicaid. Id.

Currently, over six million Medicare beneficiaries also receive assistance from Medicaid. For these individuals, known as “dual enrollees,” Medicaid pays for their Medicare premiums as well as services not covered under Medicare, such as prescription drugs and long-term care. Expenses for dual enrollees account for thirty-five percent of total Medicaid spending, with an average of $12,318 per elderly enrollee and $11,776 per disabled enrollee, as opposed to $2,334 per regular adult enrollee under age sixty-five. In addition, eighty percent of all Medicaid spending for prescription drugs goes to the elderly and the disabled. KAISER COMM’N ON MEDICAID AND THE UNINSURED, THE MEDICAID PROGRAM AT A GLANCE, at http://www.kff.org/medicaid/200403-index.cfm (last visited Nov. 28, 2004).
that the private sector could not guarantee the quality of care that seniors deserved.

The public versus private debate has continued, particularly with respect to coverage for prescription drugs. The increase of medical treatments involving prescription medications coupled with the dramatic rise in prescription drug prices have caused continued disagreement over how to address outpatient medicines within Medicare. As Congress finally, but narrowly, reached agreement to enact the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, proponents of a privately insured approach prevailed. This approach, however, has created concerns about whether it will truly provide adequate coverage, especially for seniors in rural America. One concern is the potential impact of the privately insured Medicare prescription drug benefit on rural community pharmacies.

More prevalent than primary care physicians in rural America, local pharmacists are on the front line of health care in these communities. However, many independent pharmacies like those typically found in rural areas are struggling as a result of increased third-party discounting, primarily by pharmacy benefit management companies (PBMs), as well as competition from mail order, chains, and mass

4. See CORNING, supra note 1, at Ch. 4.


6. Among these concerns are availability of coverage plans, complexity of the benefit, purchasing power of the risk pool, and access to pharmacy services. See generally MAINE RURAL HEALTH RESEARCH CTR. & RURAL POLICY RESEARCH INST. RURAL HEALTH PANEL, DESIGNING A PRESCRIPTION DRUG BENEFIT FOR RURAL MEDICARE BENEFICIARIES (Aug. 31, 2000) [hereinafter MAINE], available at http://www.rupri.org/ruralHealth/publications/default.asp?flashVersion=6&SubSection=policyPapers&Panel=1 (last visited Nov. 28, 2004).


merchandisers. Meanwhile, the profession itself is struggling to attract young new pharmacists to rural areas as the older pharmacists retire. Because the private entities that will administer the new Medicare prescription drug benefit will likely extract further discounts from these pharmacists, the future of rural family pharmacies is certain. If these rural pharmacies cannot survive, this loss could bring significant costs to rural beneficiaries, their communities, and our health care system as a whole.

This Comment examines the potential impact of the privately insured Medicare prescription drug benefit outlined in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 on the rural pharmacy profession. The Comment first summarizes past legislative efforts to include prescription drug coverage under Medicare. Next, the Comment outlines the prescription drug benefit program and the interim prescription drug discount card program set forth in the Act. The Comment then analyzes the effect of these provisions on rural community pharmacies and comments on the potential costs to seniors, their communities, and the health care system as a whole from the loss of rural pharmacies. Finally, this Comment looks at possible legislative solutions to ensure that seniors in rural areas do not lose the valuable services provided by rural pharmacies.

OF PBMs IN MANAGING DRUG COSTS: IMPLICATIONS FOR A MEDICARE DRUG BENEFIT at Executive Summary (2000), available at http://www.kff.org/medicare/1543-index.cfm (last visited Nov. 28, 2004). PBMs typically negotiate with drug manufacturers to obtain rebates, as well as contract for price concessions from pharmacies in order to reduce pharmaceutical costs. See id. See also further discussion of the role of PBMs infra parts III.A. and B. Additional third-party purchasers of prescription medicines include insurance companies, HMOs, and other government program administrators.


12. This Comment does not discuss Medicare reform provisions relating to traditional Medicare parts A and B that are separate from the prescription drug benefit, including those relating to rural hospitals.
I. MODERNIZING MEDICARE TO INCLUDE PRESCRIPTION MEDICINES

A. Congress Attempts to Create a Medicare Drug Benefit

Policymakers have debated the need to add prescription drug coverage to Medicare since the program's original enactment. The costs of such coverage, along with disagreements over the role of the private sector in administering the coverage, have been the two central issues surrounding the debate and have provided the biggest obstacles to its resolution. The 1967 amendments to the Social Security Act called for the creation of the Task Force on Prescription Drugs to study the possibility of adding a prescription drug benefit to the newly created Medicare program. However, not until two decades later did Congress make the first of three major attempts to pass legislation providing a prescription drug benefit under Medicare.

In 1988, Congress passed the Medicare Catastrophic Coverage Act (MCCA), which would have phased in “catastrophic” prescription drug coverage beginning in 1991. This coverage, however, never materialized. Due to a number of reasons, including a major increase in cost estimates and opposition to a supplemental premium charge to higher income beneficiaries, the MCCA was repealed before it began.

The second major attempt came as part of the Clinton administration's comprehensive health care reform package in 1993.

14. Id. at 25.
18. O'SULLIVAN, supra note 13, at 25. “Catastrophic” coverage is where the provider will typically cover the full costs of medicines once the beneficiary reaches a specified amount in out-of-pocket drug expenses, often referred to as the catastrophic limit or out-of-pocket limit. The benefit under the MCCA was to cover all outpatient medicine expenses above a deductible amount of $600 (in the first year), subject to a 50% coinsurance cost. The deductible for future years was indexed so that 16.8% of Medicare beneficiaries would have prescription drug costs that met the deductible each year. The coinsurance was also scheduled to be progressively lowered to 20% by 1993. Id.
19. Id.
20. Id. at 26.
Introduced in Congress as the Health Security Act, President Clinton's plan called for the addition of a prescription drug benefit to Medicare. Like traditional Medicare, the benefit was to be financed primarily through general federal revenues with some costs covered through beneficiary premiums. However, after months of extensive hearings and negotiations on Capitol Hill, the comprehensive package ultimately fell victim to vast disagreements over the government's role in health care and failed to muster enough support to make it to the floor of either chamber.

The most recent effort to include prescription coverage within Medicare began as a result of the National Bipartisan Commission on the Future of Medicare established by the Balanced Budget Act of 1997. Although the Commission was unsuccessful in agreeing on a Medicare reform proposal, it managed to renew policymakers' interest in addressing the program's lack of comprehensive prescription drug coverage.

Several measures were introduced in the 106th Congress to establish a prescription drug benefit under Medicare. Consistent with previous debates, these proposals reflected contrasting views over whether the government or the private sector should assume a greater portion of the financial risk of administering the program and whether a benefit should be available to all beneficiaries or offered principally to those in lower income brackets. In 1999, the Clinton administration put forth its new plan, which proposed a voluntary drug benefit available to all

22. O'SULLIVAN, supra note 13, at 26. The President's plan would have included a $250 deductible and a 20% coinsurance cost, with Medicare picking up the remaining 80% of beneficiaries' medicine costs above the deductible amount. Id. The proposed benefit also included an out-of-pocket limit of $1,000 and would have helped nearly six of every ten Medicare beneficiaries. Id.
23. Id.
27. Id. at 27.
28. Id. at 26.
Medicare beneficiaries. However, the plan never gained approval from Congress. Instead, in June 2000, the House of Representatives narrowly passed a Republican-sponsored measure, the Medicare Rx 2000 Act, which would have created a Medicare prescription drug benefit relying mostly on private insurance companies to provide coverage. Despite approval of this measure in the House, though, prescription drug benefit legislation stalled in the Senate.

Many similar proposals were reintroduced during the 107th Congress. As with previous proposals, those sponsored by Republican members tended to rely on private entities to bear the financial risk of providing the Medicare prescription drug benefit. The Democratic alternatives tended to favor approaches similar to traditional Medicare in which the federal government assumes most of the coverage risk. In June 2002, the House approved a modified version of the bill it passed during the 106th Congress, entitled the Medicare Modernization and Prescription Drug Act of 2002. The following month, the Senate passed the Greater Access to Affordable Pharmaceuticals Act, which related to the availability of generic

29. Id. at 27. This plan included 50% coverage for a beneficiary's prescription drug costs up to a specified limit ($1,000 in 2002, increasing to $2,500 by 2008), with full catastrophic coverage beginning when the beneficiary reached $4,000 in out-of-pocket costs. The plan carried no deductible and proposed a monthly premium of $25. Id.

30. Id. at 27. H.R. 4680, 106th Cong. (2000).

31. O'SULLIVAN, supra note 13, at 27. Under the bill, the federal government would partially subsidize these private entities for the risk of insuring Medicare beneficiaries' prescription drug costs. Id. Benefit plans had to provide "qualified" or "standard" coverage to be eligible. Id. "Standard" coverage consisted of a $250 deductible (in 2003); 50% cost-sharing for next $2,100 in prescription drug expenses (in 2003); and an out-of-pocket limit at $6,000. Id.


33. See O'SULLIVAN, supra note 13, at 28.


35. H.R. 4954, 107th Cong. (2002). See also O'SULLIVAN, supra note 13, at 28.

drugs. Although this measure became a vehicle for Senate consideration of a number of Medicare prescription drug benefit proposals, none of them managed to capture the votes necessary to be included within the generic drug bill.\textsuperscript{37}

\textbf{B. Controversial Medicare-Endorsed Prescription Drug Discount Card Program Proposed}

While the 107th Congress was debating how to address the need for prescription drug coverage for our nation’s seniors, President Bush made an attempt to reduce the cost of prescription medicines for the elderly. On July 12, 2001, the Bush administration unveiled a Medicare prescription drug discount card program aimed at lowering out-of-pocket medicine costs.\textsuperscript{38} The initiative was designed to be a temporary measure, employing the concept of private discount drug card programs already in existence, to be used until Congress enacted a more comprehensive Medicare prescription drug benefit.\textsuperscript{39} Under the program, Medicare would “endorse and promote a number of privately-administered prescription drug discount card plans which have a one-time maximum enrollment rate of twenty-five dollars per plan.”\textsuperscript{40} Although none of the many card programs then available through private entities or states would have met the administration’s specifications, it was expected that a number of the larger programs would attempt to qualify.\textsuperscript{41}

The prescription drug discount card initiative was met with ambivalence from seniors’ groups\textsuperscript{42} and resistance from pharmacy...

\textsuperscript{37} O’SULLIVAN, supra note 13, at 28.


\textsuperscript{39} VILLARREAL, supra note 38, at Summary. See also THE HENRY J. KAISER FAMILY FOUND., supra note 38, at 7.

\textsuperscript{40} VILLARREAL, supra note 38, at Summary.

\textsuperscript{41} THE HENRY J. KAISER FAMILY FOUND., supra note 38, at v. See further explanation of how prescription drug discount cards work infra part III. A.

organizations and Democratic members of Congress. The opposition centered on concerns that (1) prescription drug discount cards did not provide significant savings to seniors, (2) the proposed program would not improve upon the discount cards already widely available to seniors, (3) it would provide a "boon" to already highly profitable PBMs and drug manufacturers, and (4) such a program might delay action on a more meaningful Medicare prescription drug benefit.

In July 2001, two pharmacy groups filed suit in federal district court against the Centers for Medicare and Medicaid Services (CMS) seeking to enjoin the discount card program. The lawsuit alleged that the administration lacked statutory authority to implement the program and had violated proper procedure in establishing it. After

Discount Drug Card Doesn't Respond to Seniors Lack of Rx Coverage (Mar. 4, 2002).


44. See, e.g. Press Release, Nat'l Comm. to Preserve Social Security and Medicare, supra note 42; Press Release, Pharmacy Benefits All Coalition, supra note 43; Press Release, Senate Democratic Policy Committee, supra note 43.

45. The Centers for Medicare and Medicaid Services, formerly the Health Care Financing Administration (HCFA), is the federal agency charged with administering Medicare and Medicaid. HCFA was created in 1977 to coordinate the two programs, which originally came under the responsibilities of the Social Security Administration (SSA) and the Social and Rehabilitation Service (SRS), respectively. CMS/HCFA HISTORY, supra note 3.


47. The plaintiffs, the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA), specifically alleged that the Department of Health and Human Services (HHS) and CMS:

(1) established the program without legal authority; (2) violated the notice and comment requirements of the Administrative Procedures Act in establishing the program; (3) adopted regulatory standards that were arbitrary, capricious, and an abuse of discretion; (4) failed to comply with the requirements of the Federal Advisory Committee Act; and (5)
issuing a preliminary injunction, the district court stayed the proceedings in November 2001 to allow for public comment on the proposal. The administration subsequently modified its proposal and formally issued a new rule, but five months later the court permanently enjoined the program's establishment and held that the administration lacked statutory authority to proceed. Although legislation was introduced shortly thereafter that would have authorized the Secretary of Health and Human Services (HHS) to implement a discount card program, the administration did not further pursue the program.

C. Medicare 'Part D' Prescription Drug Benefit Becomes Law

Although previous attempts had come up short, the 108th Congress managed to enact a Medicare prescription drug benefit. On June 27, 2003, the Senate passed the Prescription Drug and Medicare Improvement Act of 2003 (S. 1) by a count of 76-21. The House, a few hours later and by a slim one-vote margin, approved the Medicare Prescription Drug and Modernization Act of 2003 (H.R. 1). Both versions established a Medicare prescription drug benefit, set to begin January 1, 2006, within a new Medicare Part D. Both bills also relied on private insurance carriers to provide the coverage while assuming a significant portion of the financial risk. Participating plans would have unlawfully delegated regulatory authority under the care program to a group of private, self-interested card issuers.

THE HENRY J. KAISER FAMILY FOUND., supra note 38, at n.14 (citing Complaint at 4, Nat'l Ass'n of Chain Drug Stores (No. 01-1554)).


49. VILLARREAL, supra note 38, at Summary.


51. VILLARREAL, supra note 38, at Summary.


55. O'SULLIVAN, supra note 53, at Summary.
have to offer "standard coverage" or its actuarial equivalent. Both measures provided greater assistance to lower-income seniors and offered additional federal subsidies where necessary to ensure plan participation in all areas. Finally, both bills authorized the establishment of a temporary Medicare-endorsed prescription drug discount program (essentially equivalent to President Bush's previous proposal) until the Part D program would be fully implemented.

After a conference committee was named, several months of negotiations followed to resolve a number of differences between provisions of S. 1 and H.R. 1. The conferees filed their report on November 21, 2003, outlining the final measure, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The House narrowly approved the bill in a controversially administered vote just before sunrise the next morning. Three days later the measure cleared the Senate with comparative ease (by a vote of 55-45), though a few senators protested the unprecedented procedural nature of the House vote. On December 8, 2003, President Bush signed the bill into law, creating the largest expansion of the Medicare program since its creation.
D. The Medicare Prescription Drug, Improvement, and Modernization Act: A Privatized Approach

Consistent with its two component bills, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 establishes, as of January 1, 2006, a new Medicare prescription drug benefit provided by private insurance carriers. Under the Act, “standard coverage” for the year 2006 is outlined as a $250 deductible, twenty-five percent beneficiary cost sharing for prescription drug expenses between $251 and $2,250, and no coverage beyond the $2,250 initial coverage limit until the beneficiary reaches out-of-pocket costs of $3,600 ($5,100 in total prescription costs). Once the beneficiary reaches the out-of-pocket limit, the beneficiary will be responsible for five percent cost sharing thereafter. The law does not specify a monthly premium amount that beneficiaries will be required to pay, thus allowing individual private carriers the discretion to determine premium amounts for their plans. However, the Congressional Budget Office (CBO) estimates the average monthly premiums will be thirty-five dollars in 2006, rising to fifty-eight dollars in 2013. Beneficiaries will be given the opportunity to enroll through Medicare during a designated time period; those enrolling after the specified initial period could be subject to higher premiums. Seniors with incomes from 100-150 percent of the federal poverty level will be provided with additional subsidies that will pay for most of the beneficiaries' expenses.

68. THE HENRY J. KAISER FAMILY FOUND., supra note 65, at 2.
premium and cost-sharing expenses.\(^71\) Those who also qualify for Medicaid benefits ("dual eligibles") will get their prescription medications through Medicare rather than Medicaid.\(^72\)

Other provisions allow for medication therapy management\(^73\) and subsidies to encourage employers to maintain their retiree health coverage.\(^74\) The required medication therapy management programs must be developed with licensed pharmacists and physicians to target beneficiaries who have multiple chronic conditions, use multiple covered medications, and are likely to have excessive drug expenses.\(^75\) Employers who maintain retiree health plans that offer actuarially

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\(^72\) \textit{Diane Rowland, Kaiser Comm. on Medicaid and the Uninsured, Medicare Prescription Drugs and Low-Income Beneficiaries} at Figure 2 (2003), available at http://www.kff.org/medicaid/kcmu121503pres.cfm (last visited Nov. 28, 2004). Dual eligibles with incomes below 100\% of the federal poverty level will have no premium costs and no initial coverage limit. They will pay copays of $3 for brand name drugs and $1 for generics up to the catastrophic limit ($5100 in total drug spending) and no copays thereafter. \textit{Id.} at Figure 5. \textit{See also} H.R. Conf. Rep. No. 108-391, at 44-45, reprinted in 2003 U.S.C.C.A.N. at 2107-2108. Beneficiaries whose incomes fall below 135\% of poverty and who also meet an assets test ($6,000 per individual/$9,000 per couple) will pay $5 for brand name drugs and $2 for generics, with no deductible, no premium costs, and no cost-sharing beyond the catastrophic limit. \textit{Rowland, supra}, at Figure 6. \textit{See also} H.R. Conf. Rep. No. 108-391, at 44-45, reprinted in 2003 U.S.C.C.A.N. at 2107-2108. Those beneficiaries who have incomes between 135-150\% of the federal poverty level and meet an assets test ($10,000 per individual/$20,000 per couple) will be required to pay a $50 deductible, a sliding scale premium, and a 15\% coinsurance up to the catastrophic limit, with copayments of $5 and $2 thereafter. \textit{Rowland, supra}, at Figure 6. \textit{See also} H.R. Conf. Rep. No. 108-391, at 45-46, reprinted in 2003 U.S.C.C.A.N. at 2108-2109. Finally, all beneficiaries with incomes below 135\% of poverty and not enrolled in Medicaid will be eligible for reduced copays and $600 in transitional assistance in each of 2004 and 2005 for medicine purchases using their Medicare-endorsed prescription drug discount card. \textit{U.S. House of Representatives Comm. on Ways and Means, supra} note 71, at 1. \textit{See also} H.R. Conf. Rep. No. 108-391, at 70-71, 78-79, reprinted in 2003 U.S.C.C.A.N. at 2133, 2140-2141.


equivalent prescription drug coverage will receive a twenty-eight percent subsidy for drug expenses between $250 and $5,000.\textsuperscript{76}

Also included is "fallback" insurance for areas where less than two private carriers bid to offer Medicare prescription drug coverage.\textsuperscript{77} Under the provision, the Secretary of HHS must contract with one carrier in each of these areas to provide coverage.\textsuperscript{78} These entities will be required to provide the standard benefit\textsuperscript{79} and have their premiums set by Medicare.\textsuperscript{80} The Act, however, does not allow for a national fallback plan.\textsuperscript{81}

One of the most controversial provisions of the legislation prohibits the government from negotiating with drug manufacturers for discounts.\textsuperscript{82} This provision was included in order to "promote competition" among providers.\textsuperscript{83} However, many members of Congress and the public have argued that the source of the high prescription prices is the drug manufacturing industry and that, therefore, the Medicare program should use the collective purchasing power of its forty million beneficiaries to obtain lower prices from manufacturers.\textsuperscript{84} A report issued by the Office of the Inspector General for HHS in January 2001 found that the Department of Veterans' Affairs was able to negotiate fifty-two percent lower prices for medicines for its prescription drug coverage plan by purchasing directly from the manufacturers.\textsuperscript{85} At the same time, HMOs and other

\textsuperscript{76} Id. at 63, reprinted in 2003 U.S.C.C.A.N. at 2126.

\textsuperscript{77} Id. at 18, 33-34, reprinted in 2003 U.S.C.C.A.N. at 2081-2082, 2096-2097. See also O'SULLIVAN, supra note 53, at 13.


\textsuperscript{79} See description of "standard coverage," supra part I.D.


\textsuperscript{81} Id. at 33, reprinted in 2003 U.S.C.C.A.N. at 2096-2097.

\textsuperscript{82} Id. at 35, reprinted in 2003 U.S.C.C.A.N. at 2098.

\textsuperscript{83} Id.

\textsuperscript{84} Karin Fischer, Drug Measure Targeted: Democrats Want Agency to Be Able to Get Lower Prices, CHARLESTON DAILY MAIL, Dec. 29, 2003, at 1D.

private purchasers achieved only twelve to forty percent discounts. Under the new drug benefit law, only private coverage providers, not HHS, will be allowed to negotiate for discounts from the manufacturers on behalf of Medicare recipients.

Finally, the bill created a temporary prescription drug discount card program, similar to the Bush administration drug discount card proposal, to provide assistance until the full benefit's January 1, 2006, implementation date. This provision made Medicare-endorsed discount cards available as of June 2004. Beneficiaries have the choice of at least two Medicare-endorsed cards but are only allowed to purchase one card per beneficiary. Card sponsors are required to have three years experience in pharmacy benefit management and are allowed to charge a maximum thirty-dollar enrollment fee to the beneficiary purchasing the card. Sponsors are also required to provide "convenient access" to pharmacies (i.e., card sponsors cannot require the beneficiary to use only mail-order pharmacies to obtain the discounted prescription medicines).

88. Id. at Title I, Subpart 4, reprinted in 2003 U.S.C.C.A.N. at 2131.
89. See U.S. HOUSE OF REPRESENTATIVES COMM. ON WAYS AND MEANS, supra note 71, at 1; Robert D. Hershey, Jr., Discount Drug Cards are Coming: It's Time to Do Your Homework, N.Y. TIMES, Apr. 13, 2004, at G4.
93. Id. at 75-76, reprinted in 2003 U.S.C.C.A.N. at 2138.
II. RURAL SENIORS’ NEED FOR A MEANINGFUL PHARMACY BENEFIT

A. Facing Greater Needs and Obstacles to Affordable Medicines

America’s seniors have borne a significant burden from the recent rise in pharmaceutical prices. While they make up only thirteen percent of the nation’s population, they account for more than one-third of this country’s total drug expenditures.94 Average prescription drug spending per Medicare beneficiary rose from $1,610 in 2000 to $2,322 in 2003. Out-of-pocket costs per beneficiary increased from $644 to $999 during that same three-year period. Concurrently, nearly four in ten Medicare beneficiaries in 2001 had incomes less than 160 percent of the federal poverty level;95 three in ten Medicare beneficiaries were living on incomes under 135 percent of the poverty level.96 In addition, because Medicare does not currently include coverage for outpatient prescription costs, nearly four in ten noninstitutionalized Medicare recipients have no prescription drug coverage.97 These estimated fifteen million seniors who lack any drug coverage spend an average of $350 a year more for prescription medicines than the national average per Medicare beneficiary.98

The remaining two-thirds of the Medicare population that have supplemental insurance covering prescription drugs rely mainly on coverage provided by former employers, Medicare+Choice, Medigap, Medicaid, or other state pharmacy assistance programs.99 About

96. $11,597 for singles, $15,674 for couples. THE HENRY J. KAISER FAMILY FOUND., supra note 95, at 1.
98. See THE HENRY J. KAISER FAMILY FOUND., MEDICARE AND PRESCRIPTION DRUG SPENDING CHARTPACK Figure 2 (2003), available at http://www.kff.org/medicare/6087-index.cfm (last visited Nov. 28, 2004).
twenty-eight percent of all Medicare beneficiaries have prescription drug coverage under plans sponsored by former employers. That number, however, is shrinking; many employers who have not already done so say they plan to eliminate or cut back on retiree health benefits in the near future. With the addition of a prescription drug benefit to Medicare, more employers are expected to drop or reduce their retiree prescription drug coverage. The new Medicare plan will provide subsidies for employers who maintain prescription drug coverage for their retirees. But, this is not necessarily an incentive to maintain or increase current benefits. In fact, the statute may foster reductions in retiree coverage because the employer can collect the subsidy, even while cutting back retiree benefits, so long as its coverage does not drop below the allowed minimum.

For those lacking employer-sponsored plans, another twenty-two percent of Medicare beneficiaries have purchased individual plans through Medicare+Choice or Medigap. However, the coverage provided by these programs is often inadequate to meet the needs of

100. Id.
103. Medicare+Choice (M+C) was created under the Balanced Budget Act of 1997 to give beneficiaries additional options for selecting health plans, primarily through HMOs. CTRS. FOR MEDICARE AND MEDICAID SERVS., supra note 15. See also MARSHA GOLD & LORI ACHMAN, MATHEMATICA POLICY RESEARCH, INC., AVERAGE OUT-OF-POCKET HEALTH CARE COSTS FOR MEDICARE+CHOICE ENROLLEES INCREASE 10 PERCENT IN 2003 at 7 n.1 (2003), available at http://www.cmwf.org/publications/publications_show.htm?doc_id=221566 (last visited Nov. 28, 2004). Concerns have been raised in recent years about the M+C program because M+C plans are not offered in some areas, and the program has seen increased plan withdrawals and a decline in drug coverage. O’SULLIVAN, supra note 13, at 5. Since 1999 drug coverage for M+C enrollees has dropped from 84% to 71%, and four in ten of those still covered are subject to a benefit cap of $750 or less. THE HENRY J. KAISER FAMILY FOUND., supra note 99, at 1.
104. THE HENRY J. KAISER FAMILY FOUND., supra note 99, at 1. Medigap is another type of insurance designed to supplement Medicare by providing coverage for Medicare deductibles and coinsurance as well as some additional items and services not included under Medicare. O’SULLIVAN, supra note 13, at 8. Only three of the ten standard Medigap policies cover prescription drug costs, each to a varying degree. Premiums for these plans also vary widely and have risen sharply in recent years. THE HENRY J. KAISER FAMILY FOUND., supra note 99, at 1.
an elderly beneficiary, especially if that person suffers from chronic illness or multiple conditions requiring several medications. Ten percent of Medicare recipients qualify for prescription drug coverage under Medicaid, and an additional two percent receive coverage under other public initiatives such as state pharmacy assistance programs.

For Medicare beneficiaries in rural areas, there are often further obstacles to obtaining adequate prescription drug coverage. Seniors in rural America tend to have more difficulty being able to afford the medicines they need, over one-half of Medicare beneficiaries that live in rural areas live below 200 percent of the federal poverty level. In 1999, one-half of all rural seniors had no prescription drug coverage compared to only one-third of urban seniors. Only sixteen percent of rural seniors had access to a Medicare+Choice plan in 2000, compared to seventy-nine percent in urban areas. Rural seniors are also less likely to have health insurance from a former employer than their urban counterparts and less than one-half as likely to carry an individually purchased plan that covers prescription drugs.

Adding to the difficulties for rural Medicare beneficiaries is the fact that they often need more prescription medications than urban seniors. Rural seniors, on average, develop more chronic health conditions and in general tend to be in poorer health. They are more likely to suffer from a number of serious conditions, including hypertension, heart disease, stroke, cancer, diabetes and emphysema. Because

105. CONG. RESEARCH SERV., supra note 9, at 1.
106. See GOLD & ACHMAN, supra note 103, at 2.
109. Id.
110. Id.
111. Id.
113. COBURN & ZILLER, supra note 108.
114. Id.
115. Id.
prescription medicines have become essential in the treatment of these chronic conditions, rural elderly on average fill a higher number of prescriptions each year than urban seniors.\textsuperscript{116} More prescriptions and greater lack of adequate drug coverage means rural seniors tend to pay more out-of-pocket for prescription drugs, typically from more limited resources.\textsuperscript{117} These seniors are thus more likely to be faced with the desperate choice of buying groceries or buying their medicines. Those faced with such a dilemma often fail to follow the treatment regimens prescribed by their doctors,\textsuperscript{118} seeking to stretch their medicines as far as possible by skipping or reducing doses. This ultimately puts them at risk for health complications that could result in expensive doctor visits, hospital stays, or even nursing home care. Given these risks, access to reasonably priced prescription drugs and supportive pharmacy services is vital for seniors in rural America.

\textbf{B. Relying on Rural Community Pharmacies}

In October 1999, \textit{Consumer Reports} published a pharmacy preference survey of 15,000 consumers.\textsuperscript{119} The survey found that consumers preferred independently owned pharmacies over franchises, supermarket drugstores, mass merchandisers, and corporate-run chains.\textsuperscript{120} Reasons cited showed independent pharmacies as (1) more professional, easier to talk to, and more sensitive to families' needs; (2) providing more personal attention to customers; (3) providing more useful information about prescription and nonprescription medicines; and, (4) having prescriptions ready for pickup more often, having shorter wait times for medicines, and getting out-of-stock medicine faster.\textsuperscript{121} The survey illustrates that consumers are often accustomed to the services provided by their local community pharmacist.

Rural seniors rely on their pharmacist not only to get their medicines, but also for other critical health care information and services.\textsuperscript{122} In many small communities where access to a physician or other health care provider is usually limited, the local pharmacist is

\begin{thebibliography}{9}
\bibitem{116} \textit{MAINE}, \textit{supra} note 6.
\bibitem{117} \textit{COBURN \\& ZILLER}, \textit{supra} note 108.
\bibitem{118} \textit{Id.}
\bibitem{120} \textit{Id.} at 43.
\bibitem{121} \textit{Id.}
\bibitem{122} Epstein, \textit{supra} note 7, at 8.
\end{thebibliography}
sometimes the only health care provider in the community. In rural areas, pharmacists collectively outnumber primary care physicians. Thus, where residents may have to wait several days to see the closest doctor or dentist, they can often walk into the local drugstore that day and get over-the-counter recommendations or other medical advice. In fact, customers go to their pharmacists in hopes of avoiding the doctor; some older customers even refer to the pharmacist as "doctor." The ability to ensure that prescription medicines are not only taken, but taken properly is essential for any elderly patient taking multiple medications. In rural communities, because the pharmacist serves a smaller customer base, he or she often knows customers on a personal level, is likely to be more familiar with their medical history, and can more easily monitor their adherence to prescribed therapies. Seniors in these areas are more likely to interact with their pharmacist, allowing the pharmacist to perform critical medication therapy management. Moreover, due to the smaller number of physicians, the pharmacist also knows the area doctors and can work closely with them to develop care systems and manage their patients. All of this allows the pharmacist to effectively counsel the patient regarding potentially harmful drug interactions as well as the consequences of not adhering to his or her medicine regimen.

In addition to the pharmacist's trusted advice regarding prescriptions, over-the-counter medicines, and when to see the doctor, many rural pharmacies offer other value-added services like giving immunizations and delivering medicines to those who are homebound. For an elderly person trying to remain independent, a

123.  Id. at 5.
124.  Id. at 8. See also NAT'L RURAL HEALTH ASS'N, supra note 11, at 2.
125.  See Rowley, supra note 8, at 2.
126.  See Epstein, supra note 7, at 6.
128.  See Epstein, supra note 7, at 8.
130.  See Epstein, supra note 7, at 8.
131.  Id.
132.  See id.
133.  Rowley, supra note 8, at 2. See also RURAL POLICY RESEARCH INST. CTR. FOR RURAL HEALTH POLICY & ANALYSIS, THE RURAL BENEFICIARY NEED FOR A
pharmacy that delivers provides a critical service. Not only is it possible for seniors to fill their prescriptions from home, they also receive the benefit of social interaction with the deliverer. More importantly, it provides an opportunity for a community member to check on the well-being of that elderly individual.134

Lastly, because the local pharmacist is the front line for health care in a small community, he or she is often "on-call" twenty-four hours a day, seven days a week.135 Rural independent pharmacy owners will provide their home phone number to customers in case of emergencies, and regularly they come into the store during off hours, sometimes in the middle of the night, to fill a prescription for a customer when necessary.136

III. THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT’S RELIANCE ON PRIVATE INSURERS LEAVES RURAL COMMUNITY PHARMACIES AT RISK

In the effort to make prescription drugs more affordable for seniors, legislators often overlook the importance of community pharmacies. There are nearly 25,000 independent pharmacies in the United States, which account for forty-four percent of all retail prescription drug sales in the country.137 However, as the number of pharmacy benefit management companies and third-party buyers has increased, community pharmacies are finding it increasingly difficult to stay in

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134. Incidental benefits of pharmacy delivery services can be analogized to the benefits of in-home services provided by Area Agencies on Aging, such as "Meals-on-Wheels" and "Friendly Visiting." See Area Agencies on Aging: A Link to Services for Older Adults and their Caregivers, In-Home Services, at www.n4a.org/aboutaaas.cfm (last visited Nov. 28, 2004).

135. Epstein, supra note 7, at 6.


business. Because both the new Medicare prescription drug benefit and interim discount drug card program rely on PBMs to administer the benefits, pressures that could lead to the demise of rural pharmacies are likely to intensify.

A. The Emergence of Prescription Drug Discount Cards and Concerns over Third-Party Purchasing

Prescription drug discount cards originated as a means to lower the cost of outpatient prescription medicines for those who lack adequate prescription drug coverage. The cards are usually sponsored by PBMs, insurance companies, retail stores, nonprofit organizations, or state agencies. Typically, such cards are marketed directly to the consumer through the use of direct mail, magazines, television, or the Internet. Other cards may be offered through an employer, association, or other group seeking to lower prescription costs for its members. The programs may charge a one-time enrollment fee, though some charge annual or monthly fees. A few others are offered for free. Once enrolled, the consumer receives a card that he or she can use at participating pharmacies (and sometimes through mail order) to obtain discounts on prescription medicines.

Prices available through the discount card are determined based on several variables. Typically, the PBM or other third-party sponsoring organization will negotiate rebates from the drug manufacturers in return for promising increased utilization of their drugs. The sponsor satisfies this promise by having a “formulary” or “preferred medication list” program, whereby the consumer may only be able to obtain discounts on certain medications. However, some sponsors have disclosed that most of the discounts provided by the

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138. See Epstein, supra note 7, at 1; Rowley, supra note 10, at 1; Rowley, supra note 8, at 1.
139. Also sometimes referred to as “consumer cards,” “point of sale cards,” and “100% copay” cards. THE HENRY J. KAISER FAMILY FOUND., supra note 38, at 3.
140. Id.
141. Id. at 4.
142. Id.
143. Id. at 3.
144. Id.
145. Id. at 12.
146. COOK ET AL., supra note 9, at 14.
147. Id. at 13. A “formulary” is defined as a list “of preferred drugs within each therapeutic class, usually combined with financial or other incentives to steer patients toward the listed drugs (e.g., using different levels of copayment).” Id.
cards come from reductions in the dispensing fees and mark-ups normally charged by the pharmacy, rather than as a result of manufacturers’ rebates. In fact, the rebates from manufacturers are typically retained (in full or in part) by the PBM and not passed on to consumers through lower prices.

Discount savings vary among the different card programs because of this and other factors: geography, manner of purchase (at a retail pharmacy, online, or by mail), and type and quantity of the drug being purchased. In addition, discounts for a particular medication may vary from one purchase to the next based on normal price fluctuations. Prescription drug discount card sponsors claim to offer discounts as high as sixty to seventy percent through their programs, while CMS more conservatively estimates that the cards save seniors ten to fifteen percent. Critics charge, however, that the discounts are “minimal savings at best.”

As evidence they point to a recent study by the U.S. General Accounting Office (GAO) that found savings provided by several private discount drug cards in California, North Dakota, and Washington, D.C., to be only three to five dollars on

148. THE HENRY J. KAISER FAMILY FOUND., supra note 38, at 12.
149. Id.
150. Id. at 3.
151. Id.
152. Id. at 6, 13.
153. AM. PHARMACISTS ASS’N, supra note 91, at 8.
155. U.S. GEN. ACCOUNTING OFFICE, REPORT TO CONG. REQUESTERS, PRESCRIPTION DRUG DISCOUNT CARDS: SAVINGS DEPEND ON PHARMACY AND TYPE OF CARD USED, GAO-03-0912 (2003) [hereinafter GAO REPORT]. GAO, today known as the U.S. Government Accountability Office, is the non-partisan “audit, evaluation, and investigative arm of Congress.” Id. at 20. See also GAO Human Capital Reform Act of 2004, Pub. L. 108-271, 118 Stat. 811 (2004) (authorizing the name change and other modifications to GAO). In order to help improve the efficiency and effectiveness of the federal government, GAO “examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions.” Id. at 20.
average. In addition, these savings are reduced by any one-time, annual, or monthly fees required by the cards.

Critics also have concerns over conflicts of interest that exist when drug manufacturers own the PBM administering a discount drug card program. Many pharmacists see discount cards not just as marketing tools for drug manufacturers, but also as unfair competition—such programs force pharmacists to accept lower prices from consumers while typically offering mail-order services that take away from the pharmacists' business. Additionally, a number of states have found the marketing of discount card programs to be deceptive and have enacted laws to prohibit "misleading, deceptive, or fraudulent" advertising of these programs. As of October 2002, sixteen states had laws regulating various aspects of discount card programs.

B. The Profit Squeeze from PBMs

As mentioned above, PBMs obtain most of the discounts beneficiaries receive through price concessions from pharmacists. Though the PBMs characterize these concessions as "negotiated discounts," the contracts offered to pharmacists by PBMs or other third-party purchasers are usually on a "take-it-or-leave-it" basis. In return for providing discounted prices to consumers on pharmaceuticals covered under a particular plan, the pharmacist receives a reimbursement amount plus a dispensing fee from the third-

156. Waxman et al., supra note 154, at 2. See also Villarreal, supra note 38, at Summary.
158. Cook et al., supra note 9, at 35.
162. The Henry J. Kaiser Family Found., supra note 38, at viii, 12. See also Cook et al., supra note 9, at 21.
163. See Cook et al., supra note 9, at 21, 47.
party buyer. In these contracts, however, pharmacists are forced to accept lower reimbursements and dispensing fees. Why is this significant? It means that while pharmacists are still paying more to purchase at wholesale the drugs they dispense, they are receiving less from the customer and less reimbursement from the third-party buyer to make up the discount.

Today, seventy-five percent of all prescriptions filled are paid for by third parties. As a result of the low reimbursement rates, most pharmacies operate on profit margins as low as one to two percent. For smaller rural pharmacies this poses significant difficulties because they cannot offset the small margins through increased sales. Decreased profit margins along with increased competition from chain drugstores and mail-order pharmacies have already driven many small pharmacies to close their doors. A Medicare drug benefit administered by PBMs that promote the use of large chain pharmacy networks or mail-order pharmacies could spell serious trouble for rural pharmacies.

In a statement to the House Small Business Committee, the general counsel of the National Community Pharmacists Association offered testimony from an independent pharmacist regarding the impact of PBMs on her business. Her store, she testified, delivered medications to "an average of 35 residences and approximately 20

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165. See The Henry J. Kaiser Family Found., supra note 38, at 12; Cook et al., supra note 9, at 47.
166. See The Henry J. Kaiser Family Found., supra note 38, at 12; Cook et al., supra note 9, at 21-22; Rowley, supra note 8, at 1-2.
167. Rowley, supra note 10, at 1 (citing information from the National Association of Chain Drug Stores (NACDS)).
170. For example, in Ohio, close to 300 independent pharmacies, many of them in rural areas, closed their doors or sold-out to chains between 1992 and 1996. Other states, such as Kansas, have seen similar results. See Epstein, supra note 7, at 2-3.
long-term care facilities daily.\textsuperscript{173} Working with her husband "for a combined average of 115 hours weekly," they were able to achieve "a higher than average net profit in the neighborhood of 3%.\textsuperscript{174} She concluded that "discounts of 15% or greater are unrealistic, unattainable and [would be] financially devastating to community pharmacies. In fact, discounts of even 5% would have the same disastrous effect."\textsuperscript{175}

Stores like this, even if they can maintain enough profit to stay in business, may not be able to do so without eliminating some relied upon services such as delivery. To offer delivery, the pharmacy must hire someone to run the deliveries or to watch the store while the pharmacist takes the medicine to the customer. In addition, the pharmacy must own or pay for the use of a delivery vehicle. For small pharmacies these costs are significant.\textsuperscript{176} Further, the increasing shortage of pharmacists available in rural areas\textsuperscript{177} makes it difficult for a pharmacy owner to find someone that can fill in while the regular pharmacist--often the storeowner--is out. Many rural pharmacies cannot afford to pay salaries that would attract extra help.\textsuperscript{178} Clearly, just a slight reduction in profits could jeopardize valuable services offered by rural pharmacies.

In recent years members of the pharmacy profession and others have voiced opposition to alleged abuses and conflicts of interest they contend are prevalent in the PBM industry.\textsuperscript{179} They argue that PBMs shift consumers away from community pharmacies to highly profitable mail-order companies owned by PBMs and promote under-utilization of generic medicines by trying to switch patients to more expensive

\begin{footnotes}
\item[173.] Id.  
\item[174.] Id.  
\item[175.] Id.  
\item[176.] Interview with U.S. Rep. Mike Ross, supra note 136.  
\item[177.] See supra Introduction.  
\item[178.] See Rowley, supra note 10, at 6.  
\item[179.] See The Henry J. Kaiser Family Found., supra note 38, at 25; Cook et al., supra note 9, at 35; Doug Smith, Shining light on the PBMs, Ark. Times, Aug. 19, 2004, at 9. According to the Arkansas Times, the Hot Spring County (Ark.) Solid Waste Authority has filed a class action lawsuit against two large PBMs (Caremark, Inc. and Medco Health Prescription Solutions) alleging that PBMs "engage[] in deceptive practices for their own profit and drive up the cost of prescription drugs in the process." Id. A third PBM listed in the article, AdvancePCS, is a part of Caremark.
\end{footnotes}
drugs based on rebates received from drug manufacturers. The National Community Pharmacists Association claims that, according to Wall Street analysts, PBMs make two to four times more profits on mail-order drug sales than traditional pharmacy sales. The Association contends that the PBMs' exclusive focus "on the prescription drug product and [on] eliminating payment for traditional professional community pharmacy services" has reduced patient access to quality pharmacy care and increased significantly the failure of patients to adhere to prescribed drug regimens.

Evidence appears to validate some of these contentions. In September 2003, federal prosecutors filed a complaint seeking to prevent such abuses by one PBM company, Medco Health Solutions, Inc. Allegations included that Medco cancelled and destroyed prescriptions, failed to perform pharmacists' services required by law, switched patients to different prescription medicines without their knowledge, created false records of contact with physicians, solicited and received inducements from drug manufacturers to favor their products, and made false and misleading statements about its conduct. The complaint also stated that Medco's primary reason for switching drugs was to increase revenues, that they ignored patient and physician complaints about switches, and that they favored switching even where other drugs were cheaper, more effective, or had less expensive generic equivalents. According to the Department of Justice, both patients and health care plans incurred increased costs from follow-up doctor visits and tests due to these switches.

180. *Ways and Means Comm. Hearing, supra* note 164, at 4. *See also* Smith, *supra* note 179, at 9. The Hot Spring County Solid Waste Authority lawsuit contends that PBMs keep the rebates they receive from drug companies for their own profits and encourage the use of more expensive medicines. *Id.*


182. *Id.*


In April 2004, federal prosecutors in cooperation with twenty state attorneys general reached an agreement with Medco settling the federal claims for injunctive relief as well as state unfair trade practice claims.\textsuperscript{187} Under the settlement, Medco agreed to pay $29 million in damages, fees, and restitution to the states and patients.\textsuperscript{188} The agreement also requires Medco to make several disclosures to patients when soliciting drug switches, and it prohibits Medco from soliciting switches under certain circumstances.\textsuperscript{189} The settlement, however, did not dismiss federal damages claims against Medco.\textsuperscript{190} As of this writing, the matter is still pending resolution; Medco denies the federal allegations.\textsuperscript{191}

\section*{C. A Closer Look at the Provisions of the New Medicare Prescription Drug Benefit}

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, both the interim drug discount card program and the permanent drug benefit (when implemented) will be provided by private entities, likely PBMs such as Medco.\textsuperscript{192} In fact, discount card program sponsors are required to show "experience" in pharmacy benefit management\textsuperscript{193} as well as "expertise" in administering such a program.\textsuperscript{194} It will be up to these PBMs to

\begin{itemize}
  \item \textsuperscript{187} Press Release, \textit{supra} note 186.
  \item \textsuperscript{188} \textit{Id.} Specifically, Medco agreed to pay $20 million in damages and $6.6 million in fees and costs to the states, as well as $2.5 million to patients who suffered expenses as a result of drug switches involving cholesterol medicines. \textit{Id.}
  \item \textsuperscript{189} \textit{Id.} The circumstances where Medco may not solicit drug switches include when (1) the proposed drug costs more than the prescribed drug, (2) no generic equivalent to the proposed drug is offered where one is available for the prescribed drug, and (3) more than one switch in two years in a therapeutic class is made for any patient. Among the required disclosures by Medco are the "minimum or actual cost savings for health plans," the difference in copayments, financial incentives to Medco to make certain drug switches, and "material differences in side effects between prescribed drugs and proposed drugs." \textit{Id.}
  \item \textsuperscript{190} \textit{Id.}
  \item \textsuperscript{191} \textit{Id.}
  \item \textsuperscript{193} AM. PHARMACISTS ASS'N, \textit{supra} note 91, at 3.
\end{itemize}
determine the discounts and reimbursement rates that pharmacies will receive under a particular Medicare drug plan.\footnote{195. \textit{Id.} at 75, 82, \textit{reprinted in} 2003 U.S.C.C.A.N. at 2138, 2144.}

Undoubtedly, the goal for the Medicare prescription drug benefit program is to lower drug costs. Given that these private carriers will be for-profit entities in the business of insuring high-risk beneficiaries, it is understandable that they will seek to keep pharmacy reimbursements as low as possible.\footnote{196. \textit{See} Rowley, \textit{supra} note 10, at 3.} For rural community pharmacies, the increased use of prescription drugs likely to result from the new Medicare benefit would mean a greater share of prescriptions paid for by third parties and thinner profit margins.\footnote{197. \textit{Id.}}

This result assumes that the pharmacy will be included in a plan's network of participating pharmacies. As evidenced by the shortage of Medicare+Choice plans in rural areas,\footnote{198. \textit{See} Health Policy Alternatives, Inc., Medicare Prescription Drugs Through Private Drug-Only Policies: A Discussion with Actuaries 2 (2003), \textit{available at} http://www.kff.org/medicare/6086-index.cfm (last visited Nov. 28, 2004); Press Release, Public Citizen, Bush Medicare Plan Hurts Seniors by Forcing Them Into HMOs and Private Insurance PPO Plans for Drug Coverage (Feb. 13, 2003), \textit{available at} http://www.citizen.org/pressroom/print_release.cfm?ID=1334 (last visited Nov. 28, 2004).} the possibility of having only one prescription drug benefit plan in a region is not unlikely. This creates the possibility that some willing pharmacies may be excluded from participation in a Medicare plan network. Even those that are included could face competition from mail-order pharmacies.

Providers of the Medicare drug benefit plan must include in their network "any willing pharmacy" meeting the provider's terms and conditions.\footnote{199. \textit{Id.}} Plans will be allowed to reduce copayments for beneficiaries who purchase covered drugs from a participating pharmacy.\footnote{200. \textit{Id.}} Providers will also be required to allow access to any pharmacy outside of the plan's participating network.\footnote{201. \textit{Id.} at 20, \textit{reprinted in} 2003 U.S.C.C.A.N. at 2083.} However, the provider will be permitted to charge beneficiaries for the additional cost of using a nonparticipating pharmacy by requiring a higher coinsurance payment.\footnote{202. \textit{Id.}}
Notably, the measure does require that a plan sponsor’s network must include “a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access . . . ”203 With the combination of this provision and the “any willing pharmacy” stipulation, some rural pharmacies that might not otherwise be included will likely be able to participate in a plan’s pharmacy network. This may save nearby seniors from paying more or looking elsewhere to buy their prescriptions. There are no guarantees, however, that community pharmacies will be able to meet whatever terms and conditions the plan provider requires, or that plans will not charge reduced prices for mail-order purchases to entice beneficiaries to use mail order over traditional pharmacies. Moreover, the current rule set forth by the Medicare Administrator regarding pharmacy network access only requires that seventy percent of beneficiaries be within fifteen miles of a participating pharmacy.204 This could leave close to one-third of rural seniors without “convenient access” to a participating pharmacy. For this group, an increased coinsurance payment for using an outside pharmacy could effectively prevent beneficiaries from using their local pharmacy.

A number of other provisions included in the Medicare drug coverage plan could be beneficial to ensuring access to rural pharmacy services. One such provision gives traditional pharmacies permission to dispense ninety-day supplies of medications, as mail-order pharmacies are currently allowed. This should help level the playing field for community pharmacies.205 The measure also requires plans to include medication therapy management, as discussed above, to be developed in collaboration with practicing doctors and pharmacists. Under this provision benefit providers are required to “take into account” the costs associated with medication therapy management when determining reimbursement amounts to pharmacists.206 This does not ensure, however, that pharmacists will be adequately reimbursed for these services. Because rural pharmacies often tend to provide more extensive monitoring and counseling services, chances are greater that the reimbursement rates will not accurately reflect the value of the services performed.

With the increased use of prescription drugs comes a likelihood of adverse drug interactions, a serious risk for rural seniors who

204. AM. PHARMACISTS ASS’N, supra note 91, at 4.
otherwise have less access to medical information via the Internet or other resources. Thus, the role of the pharmacist in providing pharmaceutical therapy management can be critical. Notwithstanding the beneficial provisions discussed above, the current Medicare drug plan provides neither guarantees that rural pharmacies in isolated communities will be included nor financial incentives to help small pharmacies qualify for participation. Even for those that are included, the law as enacted provides little help for community pharmacies to prevent the increasing financial strain. For many of these pharmacies, the increased business from seniors utilizing their new Medicare prescription drug benefit is unlikely to improve profits as much as the decreased reimbursements are likely to stretch them until the pharmacy can no longer maintain important value-added services such as delivery and immunizations, or simply no longer survive.

IV. IMPACT OF LOSING RURAL DRUGSTORES: WHAT CAN BE DONE TO PREVENT THE ELIMINATION OF THE RURAL PHARMACY?

A. Costs to Beneficiaries

When a rural pharmacy closes, local seniors may be faced with having to drive thirty, fifty, or even one hundred miles to the nearest drugstore.\textsuperscript{207} For these and other seniors, mail order appears to be an easy and reliable option. The use of mail-order pharmacies, however, involves several drawbacks not found with traditional pharmacies. Mail-order pharmacies typically dispense a medicine in a ninety-day supply, the cost of which can be significantly higher than the normal thirty-day supply.\textsuperscript{208} In addition, mail order takes time. In the fall 2002 \textit{Rural Health News}, a small-town pharmacist and former hospital administrator testified that customers would come into his store and ask to be loaned a few pills until their mail order arrived.\textsuperscript{209} More importantly, a postal carrier cannot advise a senior on how to take medicines properly, potential drug interactions, or when to see the doctor; a postal carrier will not know the senior’s medical status and cannot monitor whether that senior is following his or her prescribed drug regimen.\textsuperscript{210} When a rural pharmacy closes, seniors in that area have lost not only potential access to medicine, but also a critical

\textsuperscript{207} NAT’L RURAL HEALTH ASS’N, \textit{supra} note 11, at 3.
\textsuperscript{208} GAO REPORT, \textit{supra} note 155, at 12.
\textsuperscript{209} Rowley, \textit{supra} note, 10 at 5.
\textsuperscript{210} See NAT’L RURAL HEALTH ASS’N, \textit{supra} note 11, at 3.
source for medication management and other health care services--the personal interaction with their pharmacist.

When seniors cannot get to another pharmacy or do not know how to use mail order, they may be forced to go without their medicines. Even when they find alternative sources from which to purchase prescriptions, there is increased likelihood that they may not take those prescriptions appropriately. As noted earlier, according to congressional testimony by the National Community Pharmacists Association, the PBMs' focus on providing prescription drugs but not pharmacist services has caused "a significant increase in non-compliance with the drug regimen prescribed by physicians." When the elderly cannot get the medicines they need or when they fail to take them as prescribed, complications can include doctor visits, hospitalization, and potential long-term care costs. An elderly person that ends up in a hospital or long-term care facility may never return home, and medical bills can quickly erode a senior's life savings. Prescription drugs help seniors avoid these outcomes to live longer, more independent lives, but only when seniors have access to affordable medicines and the guidance to use them properly.

B. Costs to Our Health Care System and Our Rural Communities

Unnecessary doctor visits, hospitalizations, and nursing home stays not only deprive seniors of their livelihood, but also place a significant burden on America's health care system. Adverse medication events cost our nation’s health care system roughly $177 billion and our economy an estimated twenty million workdays annually. With the use of pharmaceuticals surely to rise as a result of the new Medicare drug benefit, one can expect adverse medication events to increase as well.

When a rural pharmacy closes, the costs to the health care system as a whole add up quickly. What would have been a $100 prescription expense may increase exponentially due to additional physician, hospital, or nursing home expenses. While the private Medicare insurance carriers will pay most of the prescription costs, the taxpayers will likely pick up a much higher tab for doctor visits and hospital stays through Medicare Parts A and B. If the beneficiary ends up in a nursing home and qualifies for Medicaid, which often is the case in

rural areas, again the taxpayers, via both the state and federal
governments, will have to pay costs that the senior cannot. As many
states have been forced to cut funding for Medicaid programs in recent
years to balance their budgets, any additional costs or even lost savings
could be difficult for those states to absorb. These many thousands of
dollars can be saved simply by ensuring that seniors know how to take
their medicines properly.

To see how devastating the loss of rural pharmacies could be to the
communities they serve one need only look at the impact that changes
in 1983 to Medicare's hospital payment system had on rural health care
facilities. As a result of these changes, 438 rural hospitals over a
fifteen-year period were driven out of business. Rural clinics and
hospitals provide not only critical medical services for small
communities and their surrounding areas, but also good paying jobs
that help support struggling rural economies. These closures left many
small communities reeling from the loss of jobs from their local
economy and cost even more rural Americans access to vital hospice
care services.

Twenty-one percent of all Medicare beneficiaries live in rural
regions of the country, whereas only fifteen percent of pharmacies and
only twelve percent of pharmacists are located in such areas. Those
numbers are shrinking as more rural pharmacies are shutting
their doors and older pharmacists are retiring with no one to take their
places. When these entities close, it not only leaves the community
with a health care void, but also strips from the area jobs, economic
revenues, and community involvement. Small town pharmacists are
often among the most educated and active civic leaders in their
communities. Rural experts estimate that every job at a small-town
pharmacy creates 1.2 to 1.6 more jobs and generates $1.20 to $1.60
more for the local economy for every dollar paid in salaries at the

214. Nat'l Rural Health Ass'n, supra note 11, at 1.
215. Id.
216. See id. This provides a partial explanation of why, in some areas, the
pharmacist is the only health care provider left.
217. Carol Ukens, Will Medicare Rx Benefit Threaten Rural Pharmacy? 147
Drug Topics 29 (June 16, 2003), available at http://www.drugtopics.com/
drugtopics/issue/issueDetail.jsp?id=3838 (last visited Nov. 28, 2004).
218. Nat'l Rural Health Ass'n, supra note 11, at 2.
220. Id.
pharmacy. These communities and the seniors that live nearby simply cannot afford to lose more health care providers.

C. Steps to Prevent the Loss of Rural Pharmacies

Medicare was created to provide our nation's elderly with adequate, affordable health care. Adding coverage for prescription drugs under Medicare should give seniors the ability to obtain and utilize the medicines they need to get well or stay healthy. The full benefits of this coverage, however, will not be realized if care is not taken to prevent the loss of pharmacies on which seniors often rely. The closing of many rural hospitals over the last two decades has shown that poorly structured Medicare payments can deal a severe blow to the rural health care systems. The Medicare prescription drug benefit legislation, as passed, appears likely to produce similar effects on another one of those critical rural health care providers: the community pharmacy.

To ameliorate such effects a number of changes to the new Medicare drug program should be considered. First, Congress should give the program the ability to use the collective purchasing power of its forty million beneficiaries to negotiate price concessions from pharmaceutical manufacturers. If the goal of the prescription drug benefit is to make prescription medicines more affordable and accessible for seniors, the most logical way to do so is to address high drug prices at the source the drug manufacturers. Dividing the purchase power of our seniors into many groups as the new program will do if it takes effect as currently written diminishes the negotiating muscle of the providers and ultimately reduces the amount of savings that could be realized. Squeezing price concessions out of pharmacies does not provide meaningful savings to seniors. Moreover, it harms many vital pharmacies already struggling to make a profit.

Proponents of the current plan argue that allowing the federal government to negotiate price concessions on behalf of its Medicare beneficiaries would constitute price-fixing. Regardless of the label, many countries, including Canada and several European nations, engage in such practices, thereby allowing seniors in those countries to benefit from significantly lower drug prices. Pharmaceutical

221. Id. See also NAT'L RURAL HEALTH ASS'N, supra note 11, at 3.
222. Fischer, supra note 84. See also CONG. RESEARCH SERV., supra note 9, at 16.
manufacturers argue that such price-fixing would greatly restrict their ability to produce new life-saving medicines.\textsuperscript{224} In 2000, however, the top ten drug manufacturers, while collectively achieving the highest profits of any industry,\textsuperscript{225} spent more than twice as much on advertising and administrative costs as on research and development.\textsuperscript{226}

The Department of Veterans' Affairs has already shown the benefits of federal government negotiations with drug manufacturers through the large savings achieved through wholesale purchases of prescription medicines.\textsuperscript{227} Allowing the Medicare program to negotiate price discounts on behalf of all Medicare beneficiaries would bring more meaningful savings to our seniors. Moreover, it could help eliminate concerns of collusion between drug manufacturers and PBMs that may be affiliates of the manufacturers. More importantly, it will reduce the profit squeeze on small pharmacies by eliminating the need for Medicare drug benefit providers to force them to accept price concessions. Legislation has already been introduced to amend the current law by allowing the federal government to use its collective bargaining power.\textsuperscript{228} Congress should take the initiative to enact such a measure.

A second option that should be considered would be to allow pharmacists to negotiate collectively with Medicare benefit providers. Again, although PBMs characterize price concessions from pharmacies as "negotiated," pharmacists are in reality forced to accept whatever


\textsuperscript{226} \textit{Id.} at 44.

\textsuperscript{227} \textit{See supra} note 85 and accompanying text.

reimbursement third-party purchasers offer, "take-it-or-leave-it." Further, it is forbidden under antitrust laws for independently owned pharmacies to join together to contract with third-party purchasers.

In the 106th Congress, the House passed bipartisan legislation to allow such negotiations, but the measure was not enacted. This legislation would have allowed health care professionals to collectively bargain with health care plans regarding services contracts. However, this measure and similar bills subsequently introduced would have excluded any negotiations pertaining to benefits provided under Medicare, Medicaid, and other government health insurance programs. Such legislation, provided that it did not except negotiations relating to the new Medicare benefit, would allow pharmacies to demand that discounts be passed through directly from the drug manufacturer to the consumer rather than at the expense of pharmacies by providing pharmacists the ability to collectively negotiate with health insurance providers. This negotiating authority would protect the viability of the rural pharmacies, allowing them to provide valuable services that rural seniors need. Congress should continue to consider such modifications.

Lastly, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 should be amended to ensure appropriate payments to pharmacists for the medication management services they provide. Commendably, the Act specifies that providing plans must take this into account when determining reimbursement fees to be paid to pharmacies. Although the Act offers general guidelines for medication therapy management programs, it is ultimately up to each plan to determine what an appropriate program is and what

229. CONG. RESEARCH SERV., supra note 9, at 9. See also Small Business Comm. Hearing, supra note 168; Rowley, supra note 10, at 3; Rowley, supra note 8, at 2.
234. H.R. 1304 § 2(g); H.R. 3897 § 7; H.R. 1120 § 7; H.R. 1247 § 3(e).
appropriate fees are. There are no guarantees that the fees decided upon by an individual plan will adequately compensate the pharmacists for the services they provide. Rural pharmacies, which generally offer more personal interaction and more extensive patient counseling, will likely be reimbursed at the same rate as other pharmacies that offer fewer services.

Congress should consider amending the medication therapy management provision to specifically mandate that rural pharmacists be consulted by providers when making their pharmacy reimbursement determinations. Such a measure, for example, could require that fees be determined in consultation with licensed and practicing pharmacists from different regions, with at least one of them being from a rural pharmacy. This requirement would provide assurance of a voice for rural pharmacies in each plan's decision making process, helping to insure seniors from losing the valuable pharmacy services that are critical to quality health care in rural America.

CONCLUSION

Making prescription drug coverage a part of Medicare is crucial to bringing this critical government health insurance program up to speed with today's medical care. All seniors deserve access to affordable health care that includes prescription medicines. To ensure quality care for our seniors, especially those in rural areas, a Medicare prescription drug benefit must protect access to all the vital services provided by their local pharmacist. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 fails to adequately safeguard rural pharmacies. Its reliance on private entities, namely PBMs, leaves these pharmacies in jeopardy of eliminating needed services, like delivery, or simply closing their doors for good. Unless Congress acts to alleviate some of the strains on rural pharmacies, our nation's rural health care system, our small towns and communities, and especially our rural seniors may pay a high price.